



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Medication safety monitoring programme in public acute hospitals - An overview of findings

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About the Health Information and Quality Authority

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.

HIQA aims to safeguard people and improve the safety and quality of health and social care services across its full range of functions.

HIQA's mandate to date extends across a specified range of public, private and voluntary sector services.

Reporting to the Minister for Health and 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.

Note on terms used in this document

A full range of terms used in this document is contained in a glossary at the end of this report.

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Executive summary

As modern medicine continues to advance, increasing medication treatment options are available for patients with proven benefit for treating illness and preventing disease. This advancement has brought with it an increase in the risks, errors and adverse events associated with medication use. While most medication errors do not result in patient harm, medication errors have the potential to result in catastrophic harm or death to patients in some instances.¹

Medication safety has been identified internationally as a key area for improvement in all healthcare settings.² In March 2017 the World Health Organization (WHO) identified *Medication Safety* as the theme of the third Global Patient Safety Challenge. This global safety initiative aims to address the weaknesses in health systems that lead to medication errors and the severe harm that may result. The WHO sets out its specific aim to 'reduce the level of severe avoidable harm related to medications by 50% over 5 years globally'.³ This global safety initiative is also a key area for improvement in an Irish context.^{4,5}

HIQA's medication safety monitoring programme, which commenced in 2016 aims to examine and positively influence the adoption and implementation of evidence-based practice in public acute hospitals around medication safety. HIQA monitors medication safety against the *National Standards for Safer Better Healthcare*, to determine if public acute hospitals in Ireland have:

- the required governance arrangements at a foundation level in place to drive improvement in medication safety
- recognised medication safety as a priority at a senior management level with a medication safety strategy and appropriate support
- effective arrangements in place to protect patients from harm related to medication use, in line with international best practice and research
- the essential elements of a medication safety programme in place.

From November 2016 to October 2017, 34 public acute hospitals were inspected as part of HIQA's medication safety monitoring programme. HIQA identified that many Irish hospitals have performed very well in implementing medication safety programmes. Effective medication safety programmes were evident where there was leadership from chief pharmacists, supported by senior management, and effective reporting to clinical governance and patient safety structures. Inspectors also found examples of hospitals that had made considerable progress in medication safety in a short period of time. This involved collaboration and learning from the work and

efforts of other hospitals within hospital groups, but also in the wider context, for example specialist paediatric hospitals collaborated with regional general hospitals that provided paediatric services.

However, HIQA found that several hospitals require further investment and or sharing of resources across their respective hospital groups to implement effective medication safety programmes. There was clear evidence that where appropriate resources have been provided, progress in implementing medication safety programmes had generally advanced.

Of the 34 hospitals inspected, HIQA found that 30 had a Drugs and Therapeutics Committee in place, three hospitals had established links with another hospital's Drugs and Therapeutics Committee and one hospital had no Drugs and Therapeutics Committee at the time of the inspection.

HIQA found that 13 hospital's Drugs and Therapeutics Committees were not functioning effectively and were required to strengthen their governance structures and processes to support medication safety.

Six hospitals had medication safety strategies, outlining the future vision and direction in relation to improving safety with medicines. Other hospitals inspected had a medication programme or plan, but one in three hospitals had no formal strategy or plan to direct medication safety improvement activities.

Formularies* and systems for evaluating new medicines using written criteria and multidisciplinary oversight was in place in 13 hospitals, with all new medicines approved by the Drugs and Therapeutics Committee. The other 21 hospitals did not have a formulary in place, but had a stock list or inventory of medicines. These hospitals were advised by HIQA at the time of inspection that they should consider the development of a defined formulary, or collaborate with other hospitals to facilitate the use of a shared medicines formulary.

There is currently no national strategy or standards outlining requirements for the provision of clinical pharmacy services in Irish hospitals as recommended by a multi-agency review of hospital pharmacy services in Ireland in 2011.⁶ HIQA found disparities in clinical pharmacy services, both in how they were provided and in the resources allocated to them. The clinical pharmacy service in five of the hospitals

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

inspected was almost entirely confined to dispensing,[†] one of these five hospitals was reliant on a nearby hospital to provide clinical pharmacy services.

Clinical pharmacy provision to paediatric and maternity services in some regional hospitals was generally offered as reactive rather than as a continuous service. The limited and incomplete clinical pharmacy cover in paediatric and maternity services, including Paediatric and Special Care Baby Units, in a number of regional public acute hospitals was of concern to HIQA. International evidence on medication errors indicates that a small error in dose of medication given to children has a greater risk of harm compared with the adult population.⁷

Practice related to medicines reconciliation[‡] in hospitals during transitions of care was also found to be varied. Three of the 34 hospitals inspected conducted medication reconciliation on admission and discharge. Thirteen hospitals had implemented medication reconciliation on admission. Eight hospitals had a clinical pharmacist in their emergency department to support medication reconciliation on admission.

Some developments had been made to introduce smart technology and eHealth to the medication management process such as electronic prescribing, electronic medication reconciliation, automated dispensing as well as information communication technology (ICT) solutions to stock control and ordering of medicines at ward level. Many of these projects were only at pilot phase at the time of inspection, but the future potential for efficiency and improved safety through innovative use of technology is supported by HIQA in line with international research and best practice.

HIQA found that all hospitals inspected had some systems in place to support the provision of patient information and education in relation to medication use. Clinical pharmacists were usually available to provide information to patients on request from clinical staff and some hospitals demonstrated good examples of patient information and education, in particular specialist and paediatric hospitals. However, the processes in place for providing patients with information about their medicines varied between hospitals. Some patients received structured education by an appropriate clinician, clinical pharmacist or other healthcare professional, supported by individualised written information, while other patients reported that they did not receive information about new medicines they were prescribed.

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

[‡] Medication reconciliation is a systematic process to obtain an accurate and complete list of all medications taken prior to admission, discharge and other transitions in care.

HIQA conducted an anonymous patient questionnaire with 444 patients who had been inpatients in hospital within the past year and were discharged on regular medicines. Over half (58%) of patients reported that a member of staff explained newly prescribed medicines in a way they could completely understand, with an additional 16% reporting new medicines were explained to some extent. One in 10 patients reported that the purpose of their new medication was not explained. The remaining sixteen percent responded that they hadn't started new medicines or didn't require an explanation. These findings broadly reflected findings from the recent National Patient Experience Survey^{5, 8}.

Most hospitals had policies, procedures, protocols, guidelines and access to information at the point of care to support medication safety. This had been enhanced in some hospitals through sharing and collaboration between hospitals and the use of mobile technology for access to medicines information at the point of prescribing and administration. However, inspectors found in a small number of cases, medicines information sources were not designed for use in that hospital and were not overseen and approved for use by the hospitals Drugs and Therapeutics Committee. This could pose a risk if a medicine, although used correctly, was used in the wrong clinical setting.

Hospitals with well-established medication safety programmes had systems of assurance in place regarding medication safety including; proactive risk assessment, monitoring against international standards and best practice, and quality improvement monitoring. Two hospitals had planned medication safety audits that were aligned to their overall medication safety strategy.

It is estimated that at least one medication error occurs per hospital patient each day.⁹ Internationally, hospitals face challenges with underreporting of medication errors as part of incident reporting systems.¹⁰ All hospitals inspected had incident reporting systems in place, but inspectors found that many hospitals had significant under-reporting of medication safety incidents. Incident reporting systems were mainly supported in hospitals by clinical pharmacists and nurses.

HIQA found that five hospitals had a comprehensive, ongoing medication safety training programme for clinical staff. Almost all hospitals had medication management education sessions for nurses and doctors on induction, with some hospitals providing structured, ongoing medication safety training programmes. However, there was a lack of planned and structured ongoing training for clinical

⁵ The National Patient Experience Survey was a nationwide survey which asked people for feedback about their stay in hospital. The survey was a partnership between the Health Service Executive (HSE), HIQA and the Department of Health. All adult patients discharged during May 2017 who spent 24 hours or more in a public acute hospital, and have a postal address in the Republic of Ireland were asked to complete the survey.

staff in relation to medication safety in many hospitals, with potential scope for improvement consistently identified throughout this monitoring programme.

HIQA identified areas of high risk in six hospitals, four were in relation to the governance of medication safety, one was in relation to intravenous monographs and one was in relation to accommodating paediatric patients in a room with unsecured access to medications. These risks were brought to the attention of hospital managers at the time of the inspection in line with HIQA's escalation process. HIQA sought assurance that improvements would be made in a timely manner to mitigate the risks identified to ensure patient safety. Improvements in these hospitals governance structures and processes around medication safety need to be prioritised to bring medication safety up to the level necessary to ensure patient safety.

A variety of medication safety quality improvement initiatives were demonstrated during this programme and some examples are highlighted throughout this report. Many of these were based on risk reduction strategies and learning from medication incidents. In addition, some quality improvement initiatives were as a result of collaboration with other hospitals. While collaboration between hospitals is happening, a greater focus on collaboration at a hospital group and national level would reduce duplicated effort, and lead to faster progression in driving collective improvement. This is essential to ensure that errors with the use of medicines are not repeated, and above all so that patients do not suffer harm from known and potentially avoidable errors.

Furthermore, this should be supported by strategic planning for medication safety at a hospital group and national level. In addition, a national coordinated response is required to progress innovations with technology and information systems in order for significant improvement to occur in medication safety

Key recommendations

Key recommendations from HIQA medication management monitoring programme are listed below. They are separated into recommendations with a national focus and those focused on improving medication safety in hospitals.

Recommendations focused on improving medication safety at a national level

1. At a national level, efforts to enhance learning from medication incidents and quality improvement initiatives should be put in place. This should include reviewing research in relation to medication safety, both nationally and internationally, to proactively address medication related risk.
2. Centralised arrangements should be put in place to ensure good practices that HIQA has reported through these series of inspection are shared.
3. A national plan for the development of comprehensive clinical pharmacy services that sets out the desired model of care, and the appropriate resources to ensure consistency across hospitals should be developed.
4. Develop a national approach to advance medication reconciliation to include defining responsibility for medication reconciliation and using electronic solutions to reduce time spent by clinical staff on medication reconciliation.
5. Utilise information technologies such as ePrescribing, smart pump technology and decision support tools to reduce medication incidents and risks. At a national level hospital groups should work together to commence the implementation of electronic solutions to improve medication safety.

Recommendations focused on improving medication safety in hospitals

6. Hospitals must have formalised governance structures with clear accountability and responsibility arrangements to support medication safety. This includes a functioning Drugs and Therapeutic Committee with clear terms of reference and membership to provide assurance that medication management systems are safe.
7. The Drugs and Therapeutics Committee should have a clear strategic plan for improving medication safety outlining short, medium and long-term goals, with a supporting time bound medication safety programme or plan.

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

Role of the Health Information and Quality Authority

HIQA was established in 2007 to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

Under section 8(1) (b) of the Health Act 2007,¹¹ HIQA has, among other functions, the role of setting standards on safety and quality in relation to services provided by the Health Service Executive (HSE) or a service provider in accordance with the Health Acts 1947 to 2007.

Under section 8(1) (c) of the Health Act 2007,¹¹ HIQA also has the function to monitor compliance with standards and to advise the Minister for Health and the HSE as to the level of compliance of service providers with the standards.

The role of standards and continuous monitoring in improving quality and safety in healthcare

The *National Standards for Safer Better Healthcare*¹² (referred to in this guide as the National Standards), which are available to view on HIQA's website www.hiqa.ie, took effect from June 2012. The National Standards aim to help promote improvements in the quality and safety of healthcare services in Ireland. Their purpose is to help the public, people who use healthcare services and the people who provide them to understand what a high-quality safe healthcare service should look like.

The National Standards contain 45 standards presented under eight themes as shown in Figure 1. Collectively, these standards describe how a service provides high-quality, safe and reliable healthcare which is centred on the patient. To deliver high-quality, safe and person-centred care that promotes the individual's health and wellbeing, there needs to be certain capacity and capability factors in place to ensure the sustainability of the service.



Figure 1. Diagrammatic representation of the themes in the National Standards for Safer Better Healthcare

Themes one to four of the National Standards describe the dimensions of quality and safety in the delivery of a person-centred healthcare service.

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

Themes five to eight of the National Standards describe the capacity and capability factors necessary to deliver high-quality, safe care.

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

International experience shows that implementing evidence-based standards in healthcare settings, together with continuous monitoring of compliance with these standards, is a crucial quality and safety improvement measure.^{13,14} It is the role of each hospital to assure itself, its patients and the public that it is providing safe, high-quality care by demonstrating that it is meeting the National Standards at all times.

HIQA, through its monitoring programmes, aims to assure the public that hospitals are implementing and meeting the National Standards¹² and are making any necessary quality and safety improvements that are required to safeguard patients.

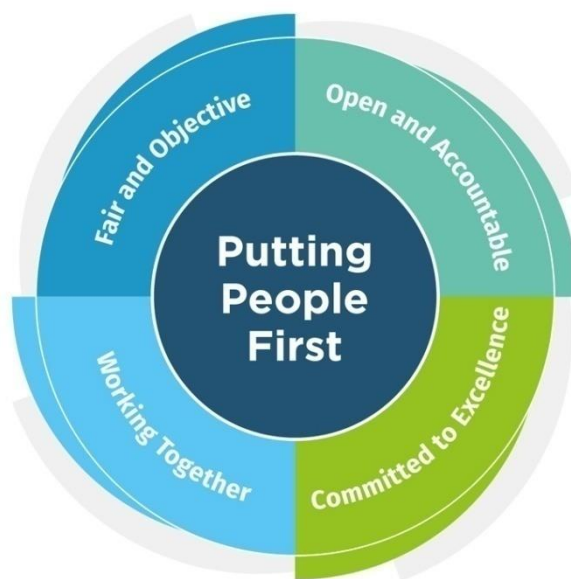
To achieve this, HIQA designed an evidence-based monitoring programme targeted at medication safety and underpinned by the National Standards¹² to examine if public acute hospitals have the essential capacity and capability factors in place to improve patient safety related to medication use.

This medication safety monitoring programme is aligned to HIQA's mission to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public and operates within HIQA's core values.

Our mission

The mission of HIQA is derived from the statutory functions described in the Health Act 2007¹¹ and can be summarised as:

"Drive high-quality and safe care for people using our health and social services."



Our values

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

1. Background

Medicines play an essential role in the treatment of illness, managing chronic conditions and maintaining health and wellbeing. Many of the advances in life expectancy and improved patient quality of life that have been experienced over the past few decades are attributed to advancements in the availability and use of medicines. Increased choice of treatments, including the use of high-risk medicines adds complexity, and medication safety needs to be understood in relation to increasingly complex health systems as new treatments can involve multiple medicines and higher risk of medication errors.¹⁵

Extensive international research has identified medication use as the leading cause of unintended harm for patients availing of hospital care.^{3,16,17,18} The Institute of Medicine estimated that on average at least one medication error per hospital patient occurs each day.⁹ This figure would potentially equate to over three million medication errors in Irish public hospitals per year.¹⁹ Medication incidents, errors, and adverse drug events are terms that have been used to refer generally to describe harm caused by medicines occurring during the medication management process^{** 16}.

It is estimated that the majority of medication errors could be potentially preventable. However, the true number of medication errors is difficult to determine, as many errors are never discovered, acknowledged or reported.²⁰ Most medication errors cause little to no actual harm to patients, and some are unavoidable through unforeseen circumstances.²¹ Nonetheless, medication errors have in some instances the potential to result in catastrophic harm or death to patients.²²

Medication safety has been identified by a number of bodies in Ireland as a key focus for improvement to prevent or reduce medications incidents.^{23,24,25,26,27,28} A national clinical incident five-year review from 2010 to 2014 in Ireland found that medication incidents accounted for 14.7% of the ten most common reported incidents. These medication incidents related to incorrect dosage, missed medication and incorrect or not reconciled medication.⁵

Medication errors occur when weak medication safety systems are in place and or human factors such as fatigue, poor environmental conditions or staff shortages impacts on any stage of the medication management process.¹⁶

While those with responsibility for prescribing medicines need to balance the benefits of using a chosen medicine against the risks for patients, in some instances

** The medication management process includes selection, procuring, storing, ordering, prescribing, transcribing, distributing, preparing, dispensing, administration documentation, reconciliation, monitoring and disposal of medicines.

patients may experience adverse effects from medication use due to expected or unexpected side-effects.¹⁶ In addition, where medicines are used, the potential for error in use also exists, for example in prescribing, administering, monitoring, or using in combination with other incompatible medicines.

Medication safety programmes have been introduced in many hospitals to try to minimise the likelihood of harm associated with the use of medicine, and in doing so maximise the benefits for patients. These programmes aim to drive best practice in medication safety by working to encourage a culture of patient safety at all levels in the organisation, and through the introduction of systems and processes that prevent and or reduce the impact of medication-related risk.^{29,30}

Traditional medication safety programmes have focused on changing individual behaviour using education, policies and procedures, and disciplinary action to improve compliance with policies and procedures.³¹ However, it is now generally accepted that medication safety programmes must take a systems-oriented approach rather than the traditional person-centred approach that focuses only on increasing the vigilance of those working in healthcare.³² Medication safety programmes should be directed towards standardising practices and systems to reduce unnecessary variation, along with effective use of resources to enhance knowledge and skills. In addition, medication safety programmes should strive to develop a patient safety culture with senior leadership support, continuous operational training for front-line staff and high-level organisational learning from incidents.¹⁶

Medication safety programmes, as with all patient safety programmes, should be underpinned by accountability and governance arrangements to ensure effective oversight of medication use and safety within hospitals. Furthermore, hospitals should have a clear strategic plan for medication safety to support a medication safety programme. Medicines-related policies and procedures must be in place to ensure patients are not unduly exposed to clinical risk or harm from medication use.³³

2. Introduction to findings from on-site inspections

An evidence-based monitoring programme, which involved announced inspections of public acute hospitals in Ireland, was developed by HIQA to examine and analyse systems in place to support safe medication practice in line with international best practice and research. HIQA carried out 34 announced on-site inspections to evaluate the structures and systems in place to support medication safety.

HIQA's monitoring programme aims to establish if hospitals have the essential elements of a medication safety programme in place, with a particular focus on:

- governance of medication safety,
- medication safety support structures and processes,
- person-centred care,
- policies, procedures and guidelines and information to support medication safety,
- risk management and incident reporting,
- evaluation and audit of medication safety,
- training and education.

Inspections were carried out to determine if hospitals had effective and safe medication management systems in place to ensure patient safety in line with international best practice and research.

This report sets out the findings from 34 hospital inspections as part of HIQA's medication safety monitoring programme from October 2016 to November 2017. The purpose of this overview report is to collate the findings, both to highlight good practice seen on inspections and to elicit where improvements should be made to improve safety with the use of medicines in public acute hospitals in Ireland.

All 34 hospitals inspected are listed in Appendix 1 and individual hospital reports, previously published, are available on the HIQA website www.hiqa.ie. The methodology, lines of enquiry and process for onsite inspections used by HIQA in this medication safety monitoring programme, are set out in detail in Appendix 2.

The findings outlined in this report focus on the essential elements of a medication safety programme. Areas of good practice observed in hospitals inspected are highlighted throughout the report to support learning and collaboration, and recommendations for improvement across the wider healthcare system supporting medication safety are included at the end of each section.

During the course of the 34 inspections, HIQA identified specific high risks in six hospitals as listed below:

- Bantry General Hospital,
- Letterkenny University Hospital,
- Midland Regional Hospital Mullingar,
- St Luke's General Hospital Kilkenny,
- University Hospital Limerick,
- University Hospital Waterford.

Risks were primarily identified in relation to the governance of medication safety and were brought to the attention of the Senior Management Team in the hospitals at the time of inspection. Subsequently, formal written notification of the identified risks was issued to the accountable person^{††} in each hospital within two working days of the inspections. Hospitals were required to formally report back to HIQA with an action plan to reduce and effectively manage the risks identified within five working days of receipt of the written notification.

A summary of the risks identified during inspections, as well as the process for risk escalation and identification are outlined in Appendices 3, 4 and 5. Details of the risks identified were included in the hospitals published medication safety inspection reports, along with copies of correspondence between HIQA and the hospitals.

As part of its assessment, HIQA included an opportunity for patients to provide insight into their experience of the medicines information given to them. During the course of the inspections, hospitals were requested to distribute a short, anonymous paper questionnaire to a number of patients in their outpatient department.

The purpose of the questionnaires was to gather key information about the advice and information patients received in relation to their medication, while in hospital and at the point of discharge. Questionnaires were distributed to patients who had been inpatients in the hospitals within the past year and who were prescribed regular medications. A total of 444 patients completed the questionnaires throughout the 34 hospitals inspected. The patient questionnaire and results are outlined in more detail later in this report.

HIQA would like to thank the patients who took the time to complete questionnaires and would like to acknowledge the cooperation and assistance of hospital staff who participated in the on-site inspections.

^{††} Accountable person: is the identified individual or individuals with overall executive accountability, responsibility and authority for the delivery of high-quality, safe and reliable services.

2.1 Governance of medication safety

Line of enquiry:

- Patient safety is enhanced through an effective medication safety programme underpinned by formalised governance structures and clear accountability arrangements.

The National Standards state that a well-governed service is clear about what it does, how it does it, and is accountable to its stakeholders, including the people who use the services.¹² To comply with the National Standards in relation to medication safety, health service providers are responsible for ensuring that effective governance structures are in place in relation to all stages of the medication management process. Therefore, the first phase of HIQA's medication safety monitoring programme focused on how management structures and accountability arrangements were configured in public acute hospitals to promote governance and oversight of medication safety including risks relating to medicines.

Governance structures and Drugs and Therapeutics Committees

International evidence outlines that the medicines management system of each hospital should be under the governance of a committee such as a Drugs and Therapeutics Committee.³⁴ This Committee should be multidisciplinary^{**} with responsibility for the overall governance and oversight of the medicines management system. The Drugs and Therapeutics should have clear terms of reference outlining its role and function with formalised reporting structures to the organisation's executive and clinical governance committees. In addition, hospitals should have a medication safety strategy with an operational medication safety plan aligned to the hospital's overall strategic goals.¹²

The scope and function of a Drugs and Therapeutics Committee may vary depending on local requirements and structures.³³ The Drugs and Therapeutics Committee is the advisory Committee on medication management for the hospital and its functions include:

- evaluating and selecting medicines for use within the hospital (formulary),
- monitoring and evaluating medicine use to identify problems through medication incidents reports, audit and evaluation,

^{**}Multidisciplinary: an approach to the planning of treatment and the delivery of care for a service user by a team of healthcare professionals who work together to provide integrated care.

- monitoring of medication incidents and adverse drug reactions,
- quality improvement interventions to improve medicine use,
- providing oversight of devices and technologies used in medicines management,
- reviewing and approval of medication policies, procedures and guidelines and all information sources in use,
- educating and sharing information,
- involvement in monitoring and evaluating the risks of clinical trials.

Organisational charts which outlined how Drugs and Therapeutics Committees fitted into the overall accountability arrangements of hospitals were requested and provided to HIQA in advance of inspections. Typically inspection teams found that Drugs and Therapeutics Committees were part of the hospital's overall clinical governance structure and reported to the Quality, Safety and Risk Committee (or equivalent), which in turn reported to hospital's Executive Committees.

Overall, HIQA found that hospitals that had well-established governance structures (such as a Drugs and Therapeutic Committee), with support from senior hospital management and effective clinical pharmacy leadership, were more likely to have identified medication safety as a key priority area and have an effective medication safety programme in place (Figure 2). Inspectors also found that senior management and clinical leaders in higher performing hospitals had invested dedicated resources to medication safety and clinical pharmacy services over a number of years. In hospitals where this had not occurred approaches to improve medication safety were more fragmented.

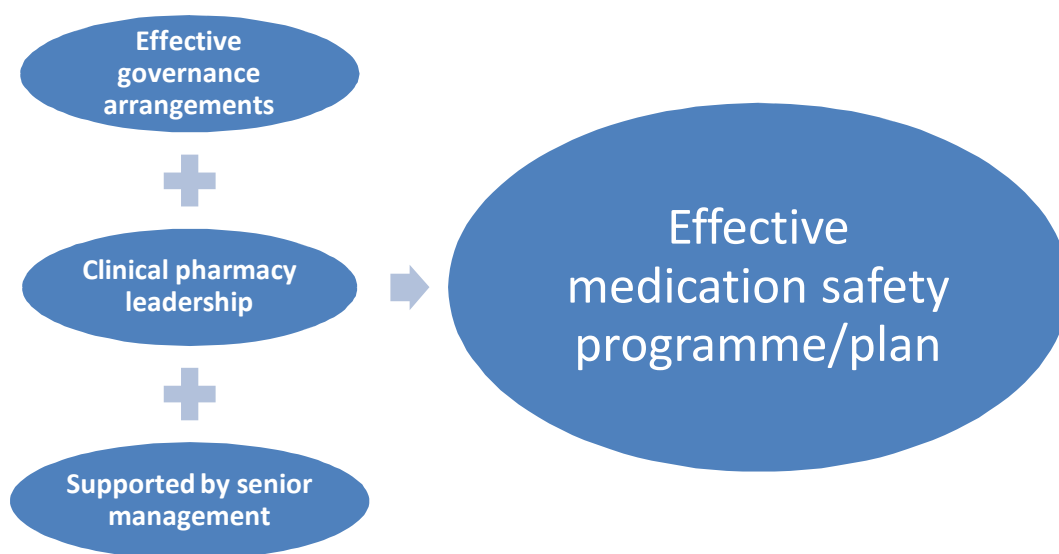


Figure 2: Effective medication safety programmes

Many hospitals' Drugs and Therapeutics Committees had additional subcommittees or working groups reporting to them that were set up to dedicate more time and expertise on specific areas of medication safety. Subcommittees covered aspects of medication safety including medication safety, antimicrobial stewardship, nurse prescribing and drug evaluation and formulary management.

Medication Safety Committees were set up to oversee medication safety programmes in 19 out of the 34 hospitals inspected. Some hospitals had only recently set these up at the time of the inspection, so they were at the early stages of development. HIQA concluded that while some hospitals had established Medication Safety Committees, it is not an essential requirement to support medication safety. The strong focus placed on medication safety is commendable but hospitals need to ensure that each committee is an effective and efficient use of staff resources to avoid over burdening staff and duplication of effort. Hospitals, depending on their model^{§§}, size and structure, can support medication safety through other committees or systems as appropriate.³⁵

Almost one in four hospitals with well-established medication safety committees and programmes had employed specialist pharmacy staff in the role of dedicated medication safety officer. The vast majority of these were based in large Dublin teaching hospitals.

HIQA identified variation in the presence and effectiveness of governance structures, such as Drugs and Therapeutics Committees. While some hospitals had strong and clear accountability arrangements for managing and improving medication safety, other hospitals had a lack of or fragmented governance structures in place to oversee medication safety.

Of the 34 hospitals inspected, 21 had a functioning Drugs and Therapeutics Committee that was responsible for the overall governance and strategic leadership of medication management systems within these hospitals.³³ Of the remaining 13 hospitals:

^{§§} The National Acute Medicine Programme model of hospitals involves four levels of acute hospitals in relation to acute medicine patients;

Model-1 hospitals: are community and or district hospitals and do not have surgery, emergency care, acute medicine (other than a select group of low-risk patients) or critical care.

Model-2 hospitals: can provide the majority of hospital activity including extended day surgery, selected acute medicine, local injuries, a large range of diagnostic services, including endoscopy, laboratory medicine, point-of-care testing, and radiology – computed tomography (CT), ultrasound and plain-film X-ray – specialist rehabilitation medicine and palliative care.

Model-3 hospitals: admit undifferentiated acute medical patients, provide 24-seven acute surgery, acute medicine, and critical care.

Model-4 hospitals: are tertiary hospitals and are similar to model 3 hospitals but also provide tertiary care and, in certain locations, supra-regional care.

- one hospital had no Drugs and Therapeutics Committee,
- three model 2 hospitals had no Drugs and Therapeutics Committee, but had links with a Drugs and Therapeutics Committee within their hospital group^{***},
- nine hospitals had a Drugs and Therapeutics Committee, however these committees required strengthening of their governance and oversight arrangements with regard to medication safety.

The hospital which had no Drugs and Therapeutics Committee on the day of inspection subsequently informed HIQA that it was planning to link into a Drugs and Therapeutics Committee in the model 4 hospital within their group.

Three model 2 hospitals had links with a Drugs and Therapeutics Committees in a nearby tertiary hospital within their hospital group. Despite this link, there remained a lack of integration between these hospitals, resulting in a disjointed approach to leadership, governance, oversight and support for medication safety. For example, the governance arrangements in one of these hospitals were further complicated by ambiguity in relation to responsibility for medication safety at a corporate level. This was due to a legacy agreement, whereby the hospital was corporately and clinically managed by a large regional university hospital that was responsible for medication safety, while pharmacy services were provided by another local general hospital.

Inspectors noted that two hospital groups had established a group wide Drugs and Therapeutics Committee at the time of the announced inspections to support collaboration about medication management at hospital group level.³⁶

Of the nine hospitals that needed to strengthen governance, four hospitals were found to have governance arrangements that were fragmented and underdeveloped due to a lack of leadership, resources and effective systems in place at the time of inspection to ensure the minimum standards of medication safety and quality were met. HIQA identified that these hospitals in particular needed to make significant improvements to the functioning of their Drugs and Therapeutics Committees.

It was of concern that these four hospitals, some providing significantly complex clinical care, did not have adequate governance structures and clear accountability arrangements in place for medication safety. Therefore HIQA wrote to these four hospitals immediately after the inspection as part of HIQA's risk escalation process seeking assurances that the hospitals were mitigating the composite of medication

^{***} Hospital groups: The hospitals in Ireland are organised into seven hospital groups. 1. Ireland East Hospital Group. 2. Dublin Midlands Hospital Group. 3. South/South West Hospital Group. 4. Saolta Hospital Group. 5. University Limerick Hospitals Group. 6. RCSI Hospitals Group. 7. National Children's Hospital Group.

safety related risks identified by inspectors. Risks identified included a combination of some or all of the following risks:

- a lack of strategic and operational plans detailing the development, implementation and maintenance of hospital-wide medication safety systems,
- inadequate arrangements in place to identify, report and manage risks associated with medication use,
- no medication formulary to ensure that there were clear and transparent criteria for adopting, removing or updating the medicines in use in the hospital,
- a relative lack of current policies, protocols, and guidelines to support relevant clinical staff in safe prescribing and administration of medications at ward level,
- a Drugs and Therapeutics Committee that had only met once within the previous year and one which had only re-convened two days preceding HIQA's inspection.

Of the nine hospitals that needed to strengthen governance, inspectors found moderate issues of concern relating to medication safety and governance in five of these hospitals which included the following:

- Drugs and Therapeutics Committees which were not operating according to their terms of reference, and governance arrangements which needed to be strengthened and developed to progress improvements in relation to medication safety.
- the frequency of Drugs and Therapeutics Committee meetings was not in line with their terms of reference.
- a lack of clarity regarding who was responsible for medication safety.
- a Drugs and Therapeutics Committee that was primarily focused on financial management rather than patient safety.
- a lack of oversight of medication safety incidents by a hospital's Drugs and Therapeutics Committee.

Drugs and Therapeutics Committee scope and functions

The terms of reference for Drugs and Therapeutics Committees should clearly define its role, functions and objectives to avoid ambiguity and clearly articulate its position and reporting structures within a hospital.^{17,33,34}

Positive findings from the monitoring programme highlighted that all Committees had terms of reference, with a small number in draft format. These terms of reference outlined the objectives, membership, frequency of meetings and reporting

relationships. However, inspectors found a lack of consistency in the scope, role and function of terms of reference in different hospitals, even between similar types of hospitals. For example, medication safety, clinical trials or formulary oversight was not included on all hospital's terms of reference.

While the functions of many Drugs and Therapeutics Committees have not necessarily changed in recent years, the scope has expanded from the approval of medications towards ensuring patient safety and promoting evidence-based practice. HIQA found that Drugs and Therapeutics Committee terms of reference in the hospitals inspected had numerous different functions including:

- formulary management,
- ensuring rational use of medications, including antimicrobials,
- dealing with product shortages,
- policies and procedures regarding medication use,
- quality assurance activities,
- audit and evaluation,
- risk management,
- oversight of nurse prescribing.

There was poor compliance with the functions and objectives outlined in the terms of reference in many hospitals, for example:

- frequency of meetings and attendance was not in keeping with terms of reference,
- medication incidents were not reported to the Committee as outlined in the terms of reference,
- audit reports were not formally submitted to the Drugs and Therapeutics Committees for review,
- management of hospital formulary was not as described in terms of reference.

HIQA found that very few hospitals inspected (with some exceptions) had measured the effectiveness of their Drugs and Therapeutics Committees in an objective way. Only four Committees had produced a Drugs and Therapeutics Committees annual report on the Committee's activities.

HIQA concluded that these findings highlighted variance in the scope, role and function of Drugs and Therapeutics Committees across Irish hospitals. In the absence of national guidance on terms of reference for these committees, hospitals should refer to international evidence to guide the role, function and scope of Drugs and Therapeutics Committees.^{33, 34}

Chairperson and membership

Previous HIQA publications have identified the requirement for integration of clinical and corporate governance structures in hospitals with clear accountability arrangements.^{37,38,39} Best practice recommends that Drugs and Therapeutics Committees are chaired by an individual with the necessary expertise, interest and time to devote to the position. Membership should reflect the size of the hospital and services provided with representatives from all the major specialities; medical, nursing, pharmacy, hospital management and other relevant stakeholders including community partners.¹⁷ Membership may also include front-line clinical staff that experience operational issues with medication management. Strong commitment and regular attendance are essential requirements from all members.

HIQA found that Drugs and Therapeutics Committees were chaired by a consultant physician with one exception which was chaired by the Hospital Manager. Drugs and Therapeutics Committees in the hospitals inspected were multidisciplinary to reflect the fact that medicines management was the responsibility of a number of clinical professional groupings and composition was generally representative and commonly included doctors, pharmacists, nurses, and representatives from hospital management and quality and risk departments.

Many hospitals reported that regular attendance of members at the Drugs and Therapeutics Committee meetings was a requirement to remain on the committee, in line with its terms of reference. Despite this requirement, inspectors found that overall there was poor representation on the Drugs and Therapeutics Committee from surgeons, general practitioners (GPs) and community pharmacists. Inspectors were informed by some hospitals that while GP representation was difficult due to the timing of meetings, medicines-related issues were raised as required at separate GP liaison committee meetings or other similar forums.

Medication safety strategy

Hospitals should have a clear corporate strategy that sets out the organisation's mission, values, role, functions and actions to be taken to meet organisational goals.^{40,41} A medication safety strategy should be aligned to the hospital's strategic goals to send out a clear message from clinical leaders and management that medication safety is an important goal that all healthcare staff should strive to attain.

A hospital's medication safety strategy needs to clearly articulate the long-term strategic and short-term operational goals, be consistent with national and international standards and policy,⁴⁰ and may include:

- focusing on driving evidence-based practice and standardisation of medication management systems
- ensuring collaboration with multidisciplinary teams so that evidence-based practices are implemented through continuous quality improvement in medication management
- focusing on high-risk medicines, high-risk processes and medicines use systems, continuity of care, medication management workforce, evaluation and research.

Inspectors found widespread variance in the planning and delivery of medication safety programmes. HIQA found that the majority of hospitals inspected lacked an up-to-date medication safety strategy, and associated operational plan, to guide the overall approach to medication safety.

Six hospitals had a formal medication safety strategy in place guided by national and international guidance on strategic planning in medication safety.^{30,40,41, 42} One specialist maternity hospital had a detailed medication safety strategy developed following a multidisciplinary medication safety self-assessment carried out in 2015.⁴³ Fourteen hospitals had a documented medication safety programme or plan to guide the overall approach to medication safety. The remaining 14 hospitals inspected had no written plan for improving medication safety, but had some medication safety interventions in place.

More established medication safety programmes, particularly in larger Dublin-based hospitals were generally managed by designated full-time or part-time medication safety officers, whereas in smaller hospitals this function was mostly managed by the Chief Pharmacist.

HIQA concluded that while the majority of hospitals had a medication safety programme, the absence of formalised medication safety strategies, programmes or plans had resulted in a lack of direction within some hospitals in the collective approach to dealing with medication safety.

Hospitals without formal medication safety strategies, programmes and plans could learn from the experience of hospitals with more advanced medication safety programmes. In doing so, hospitals can rapidly progress improvement by adopting research-based and proven approaches to medication safety in an Irish context.

In the absence of national guidance in this area, international research^{40,41} that outlines best practice in relation to medication safety strategic planning and quality improvement should be used.

Formulary management

Medications are one of the largest areas of potential risk as well as health expenditure, and hospitals must have explicit medication selection systems that are transparent and evidence-based to ensure safe and cost-effective prescribing.³³

For a Drugs and Therapeutics Committee to be effective, there must be a structured drug selection system that is explicit in its methodology, transparent and evidence-based. A formulary⁺⁺⁺ includes the hospital's locally approved medications which staff can use as a reference document to ensure safe and cost-effective prescribing. The purpose of maintaining a hospital formulary is to ensure that appropriate governance exists with the Drugs and Therapeutics Committee around what is approved for use and that in doing so, a proper safety evaluation occurs before medications are introduced into practice at the hospital.⁴⁴ In addition, the Drugs and Therapeutics Committees should provide oversight in the selection of appropriate new medicines for addition to the formulary and promote safe, rational and cost-effective use of medications.

A carefully considered formulary guides clinicians in choosing the safest, most effective medications for treating specific medical problems.

HIQA found that 13 hospitals had developed and managed hospital formularies of medications over a number of years. Many of these hospitals had dedicated pharmacy resources allocated to formulary management outlined in Figure 3.

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

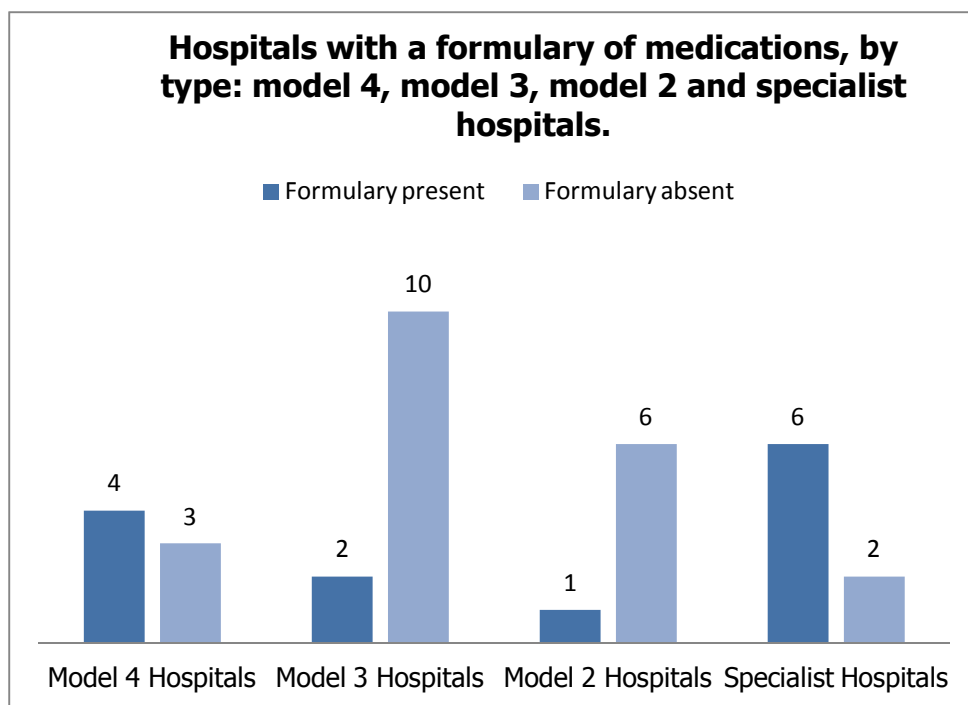


Figure 3: Number of hospitals inspected with a formulary of medications

In contrast, 21 of the 34 hospitals inspected had no documented formulary, but had a pharmacy inventory stock list. Inspectors found that considerable variation existed in the interpretation of what constituted a hospital formulary. This was particularly evident in regional model 2 and 3 hospitals, as they had significantly less resources such as formulary pharmacists or formulary subcommittees in comparison to larger hospitals to develop a formulary.

However, HIQA found that although resources were far more limited in smaller model 2 and 3 hospitals, two hospitals had overcome this challenge by sharing a formulary developed in a model 4 hospital. Collaboration and sharing of information, such as this, could enable wider establishment of medication formularies across all public acute hospitals and there is considerable potential to share the experience of those hospitals that have more advanced hospital formularies.

A good example of formulary management from St Vincent's University Hospital, Dublin and collaboration and sharing this with St Columcille's Hospital's Drugs and Therapeutics Committee is detailed below.

Formulary Management at St Vincent's University Hospital, Dublin

At St. Vincent's University Hospital, the Drugs and Therapeutics Committee was responsible for administering an evidence-based formulary of medications accepted for use in the hospital. Decisions to add or remove medications from the formulary were guided by written criteria. New medicines were evaluated on the basis of efficacy, safety, quality and cost. Decisions with significant budgetary impact were additionally overseen by senior hospital management. Mechanisms were in place to communicate with healthcare professionals about all aspects of the formulary system. In addition, there was a process in place for an annual review of the formulary.

The Pharmacy Department had established and maintained a medicines guide⁺⁺⁺ containing the hospital medication formulary. The medicines guide was accessible via all computer desktops in the hospital and as an application which could be downloaded to mobile phones or tablets. This use of mobile technology gave prescribers easy access to the guidelines at the point of prescribing.

St Columcille's Hospital's Drugs and Therapeutics Committee formally adopted the St Vincent's University Hospital formulary and adapted it for use within the hospital.

Hospitals should work to develop local formularies that are more than an inventory of medications stocked in the hospital. Inspectors were given examples of where, in the absence of established formularies, hospitals had taken steps to minimise unnecessary duplication of the same basic drug type, drug entity, or drug product. Optimising the number of medications and products available from the pharmacy can promote patient safety and produce financial benefits. It also minimises the number of medications with which practitioners must be familiar.

Inspectors were informed by some hospitals that in the absence of a local formulary, the adult or children's British National Formulary (BNF)^{§§§} was used in the hospital. However, this document is too comprehensive to substitute as a local formulary as it includes every medication licensed for use in the United Kingdom. A consequence of using the BNF in place of a local formulary is that staff prescribing and administering

⁺⁺⁺ Prescribers' Guide: a guide that contains the agreed policies involving medications as well as the hospital medication formulary.

^{§§§} British National Formulary :a reference book that contains authoritative information and advice on prescribing medicines including indications, contraindications, side effects, and recommended doses.

medications may not be familiar with the medications prescribed or the local policies governing the use of the medication.

HIQA found that a formal application process for evaluating requests for new medications to be added to the hospital's formulary, or for use in the hospital, had been introduced in 24 of the 34 hospitals inspected, but not all of these hospitals reported that error potential was included in the discussion and evaluation process.

The quality of the formulary submissions were not reviewed in this monitoring programme.

Recommendations

1. Hospitals must have formalised governance structures with clear accountability and responsibility arrangements to support medication safety. This includes a functioning Drugs and Therapeutic Committee with clear terms of reference and membership to provide assurance that medication management systems are safe.
2. The Drugs and Therapeutics Committee should have a clear strategic plan for improving medication safety outlining short, medium and long-term goals, with a supporting time bound medication safety programme or plan.
3. Hospitals should have a defined formulary process to outline medicines that are approved for use in the hospital and provide information and standard guidance on the use of these medicines.

2.2 Medication safety support structures and processes

Lines of enquiry:

- Patient safety is enhanced through an effective medication safety programme underpinned by formalised governance structures and clear accountability arrangements.
- Hospitals develop effective processes to promote medication safety that are implemented and supported by clear and up-to-date policies, procedures and or protocols.

Clinical pharmacy services

In the past, clinical pharmacy services were limited to the dispensing^{****} of medications. However, modern high-quality healthcare requires greater clinical involvement by clinical pharmacists in patient care to ensure the safe and effective use of medicines.^{5,45,46,47,48,49,50,57} Clinical pharmacy services are described as a team of pharmacists who, with the support of pharmacy technicians, are involved in the delivery of a combination of activities to individual patients.⁵¹

The role of the clinical pharmacist can vary from a ward-based clinical pharmacy service to a team-based clinical pharmacy service. Ward-based clinical pharmacy activities include reviewing medication prescriptions to prevent prescribing-related incidents, providing a counselling service to patients in relation to their medicines (particularly high-risk medications), providing advice, education and training to staff to support safe medication management, performing medication reconciliation, participating in audit, conducting research, and implementing quality improvement initiatives in relation to medication management.⁵¹

A more comprehensive team-based model of clinical pharmacy service performs the duties as detailed above, but also provides a collaborative approach to service delivery. This means clinical pharmacists are deployed to clinical teams rather than wards, and may have certain direct intervention powers agreed with medical consultants.⁵²

International and national studies have highlighted that hospitals face challenges in providing clinical pharmacy services due to insufficient resources.^{6,52,53,54,55,56,57} A United Kingdom report titled 'operation productivity and performance' in 2016⁵⁵ identified significant variation in total pharmacy and medicines cost across acute

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

healthcare trusts⁺⁺⁺⁺ (or regions), while allowing for some variation due to trusts providing teaching or specialist services.⁵⁵ This report found that over 55% of pharmacy staff time was spent on infrastructure services like buying and supplying medicines. The report recommends that more than 80% of trusts' pharmacist resources should be utilised for direct medicines optimisation activities,⁺⁺⁺⁺ medicines governance and safety remits, while at the same time reviewing the provision of local infrastructure services, which could be delivered collaboratively. Medicines optimisation is critical for patient safety and to reduce overall medicine costs. Therefore, deploying more clinical pharmacists to work closer with patients, doctors and nursing staff is required to deliver the best possible use of medicines.

A 2016 report produced by the Pharmaceutical Society of Ireland highlighted significant variation in the level of clinical pharmacist review of patients in hospitals, especially in many smaller hospitals.⁵⁷ A HIQA report on the review of antimicrobial stewardship in public acute hospitals in Ireland in 2016 also found considerable variation among the levels of clinical pharmacists engaging in ward-based clinical work; most clinical pharmacy posts were located in the major Dublin hospitals and staffing of clinical pharmacy roles was least resourced in model 3 hospitals, particularly in rural areas.⁵³

There is currently no national strategy or standards outlining the requirements for providing clinical pharmacy services in Irish hospitals, as recommended by a report on the review of hospital pharmacy services in Ireland in 2011.⁶ The lack of national clinical pharmacy standards creates variability in how pharmacy services are delivered and resourced.^{6,56,57,58}

The Society of Hospital Pharmacists in Australia (SHPA) developed standards in 2016 for the practice of clinical pharmacy services to include maximising clinical pharmacist services activities and managing workload.⁵¹ The European Association of Hospital Pharmacists (EAHP) published commonly agreed statements on what every European health system should aim for in the delivery of hospital pharmacy services. The EAHP plan to work with national member states to fully implement these statements.⁵⁹ In Ireland, these agreed statements could form the basis for the development of national clinical pharmacy standards. In addition, the Pharmaceutical Society of Ireland's 2016 report made 24 recommendations to support the future of pharmacy practice in Ireland.⁵⁷ These recommendations could also support the development of standards in clinical pharmacy services in Ireland.^{52,57}

⁺⁺⁺⁺ A National Health Service trust is an organisation within the English NHS generally serving either a geographical area or a specialised function (such as an ambulance service). In any particular location there may be several trusts involved in the different aspects of healthcare for a resident.

⁺⁺⁺⁺ Medicines optimisation: a person-centred approach to safe and effective use of medications, to ensure people obtain the best possible outcomes from their medications.

Clinical pharmacy service provision

Pharmacy leaders and hospital managers are responsible for ensuring that pharmacists provide the best care within a given budget and use their resources effectively.⁶⁰ HIQA found that medication programmes were actively progressed throughout the hospitals as a result of initiative and leadership from chief pharmacists in collaboration with multidisciplinary teams and with support from senior management.⁶¹ This was found particularly in large Dublin hospitals, but also in some regional hospitals.

Consistent with HIQA findings on the antimicrobial stewardship programme in 2015,⁵³ inspectors found that there was a very uneven distribution of clinical pharmacy staff resources across public acute hospitals. Almost half of the clinical pharmacist resources were located in Dublin model 4 hospitals and staffing levels were more inadequately spread in model 3 and model 2 hospitals, particularly those in non-urban settings.

In the 34 public acute hospitals inspected in year one of this programme, HIQA found that 25 hospitals had provided a ward-based clinical pharmacy service to the inpatient ward areas; however this service was limited in some hospitals to medical wards only. Three hospitals provided a team-based model of clinical pharmacy with the aim of better interdisciplinary collaboration with patient care.

The pharmacy service in five of the 34 hospitals inspected was almost entirely involved in the dispensing of medications in the pharmacy department with one hospital supported by a clinical pharmacy service from a nearby local hospital. This meant that these five hospitals had either no or limited clinical pharmacy service available for review of patient's medications in clinical areas. Therefore, they could not sufficiently support the implementation of an effective medication safety strategy and medication plan.

In addition, activities by clinical pharmacists that support medication safety were inadequate due to the relative lack of clinical pharmacy management and resources. These activities included: reviewing medication prescriptions to prevent medication prescribing-related incidents, involvement in tracking and trending of medication incidents, medication reconciliation, participating in audit and implementing quality improvement initiatives in relation to medication management.

HIQA found that of the seven model 4 hospitals inspected, six hospitals provided a ward-based clinical pharmacy service to all inpatient ward areas with the exception of one or two ward areas. Four specialist hospitals provided a ward-based clinical pharmacy service. One of the seven model 4 hospitals inspected provided a team-based pharmacy service where clinical pharmacists were deployed to a number of

medical teams rather than wards, and had certain direct intervention powers agreed with consultants as detailed below.

Team-based Collaborative Pharmaceutical Care in Tallaght Hospital model (PACT)

Configuration of the clinical pharmacy service at Tallaght Hospital was changed from a ward base model to a team-based Collaborative Pharmaceutical Care in Tallaght Hospital model (PACT) following a study in 2014 to improve care and reduce the rate of serious adverse medication events.⁵²

This model which has as a first step been prioritised towards adult medical and vascular surgical patients on the basis of risk facilitates medication reconciliation by clinical pharmacists and physicians at admission, during inpatient care and at discharge. The hospital planned to expand this service to inpatient services by the end of 2018.

HIQA found that two model 3 hospitals had also adopted a team-based approach and provided a team-based model of clinical pharmacy service throughout the hospital. However, in contrast to model 4 and specialist hospitals, almost all of the model 3 hospitals inspected had not provided a pharmacy service provision to all of the wards due to a lack of clinical pharmacy resources. HIQA found that:

- nine model 3 hospitals had provided a ward-based clinical pharmacy service to a limited number of inpatient ward areas
- one model 3 hospital's pharmacy service was mostly involved with dispensing of medicines, this meant that the clinical pharmacy service available to the ward was very limited.

Similarly, HIQA found that in the seven model 2 hospitals inspected, three had a clinical pharmacy service in most ward areas and four had a pharmacy service that was almost entirely dispensing. One hospital, that had no clinical pharmacist on site, was instead supported by a clinical pharmacy service from a nearby model 3 local hospital (see Figure 4).

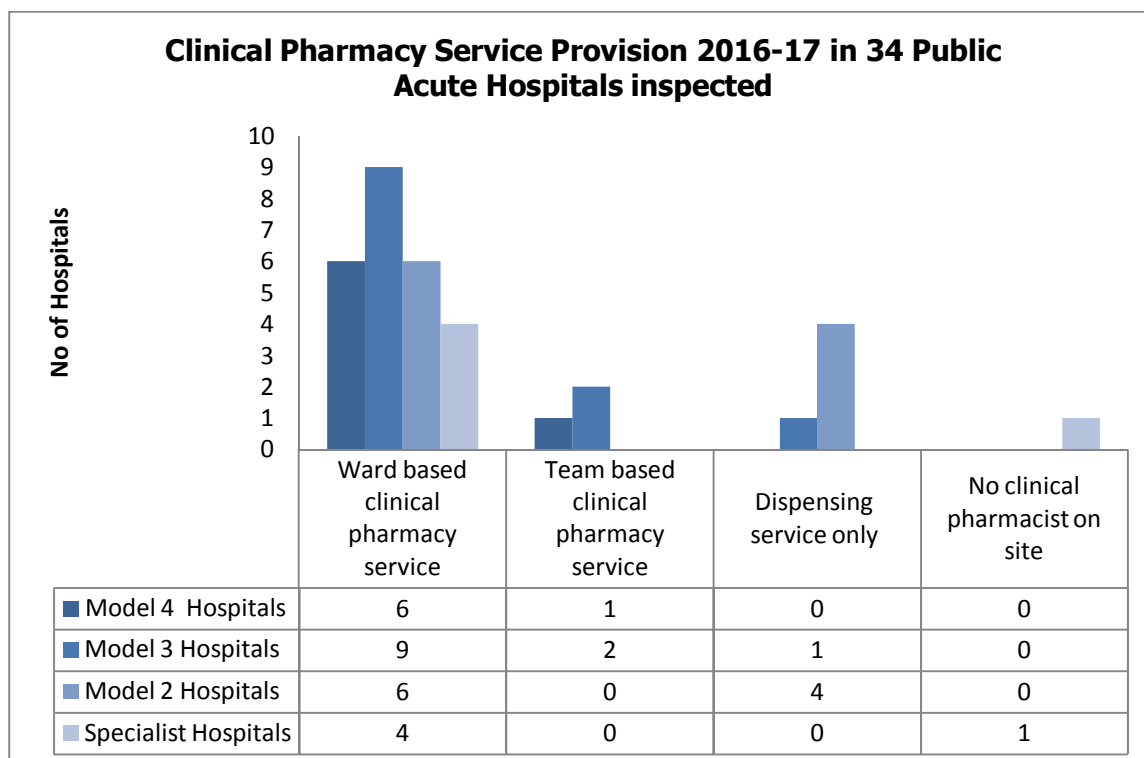


Figure 4: Clinical pharmacy provision in hospitals inspected

Paediatric intensive care units and neonatal units in large teaching hospitals had a clinical pharmacy service. In contrast, HIQA found that in most regional paediatric and maternity units, within a public acute hospital, there was limited access to a clinical pharmacist. Paediatric and maternity services were generally offered a reactive clinical pharmacy service. This meant that a clinical pharmacist would respond to medication-related queries and incidents only on request. HIQA was informed that while management in these hospitals were aware of this risk, they reported that limited clinical pharmacy resources meant that other adult clinical areas, where high-risk medicines were administered, were prioritised over paediatric and maternity services.

The limited and incomplete clinical pharmacy cover in paediatric and maternity services including paediatric and special care baby units in a number of the regional public acute hospitals areas was of concern to HIQA. International evidence on medication errors indicates that a small error in dose of medication given to children has a greater risk of harm compared with in the adult population.⁶² Furthermore, paediatric prescribing requires weight-related dose adjustment and other dose calculations, which are less common in adult prescribing. Published studies also indicate babies in the special care baby units are more likely to experience a medication error than other hospitalised patients and to experience more harm when a medication error does occur.^{63,64}

HIQA found much progress had been made by committed front-line pharmacy staff in advancing medication safety. However, there was major variation in clinical pharmacy resources from hospital to hospital. HIQA found evidence that a number of hospitals were better resourced with clinical pharmacists in comparison to others and, in general, larger voluntary hospitals had prioritised resourcing of clinical pharmacy services more than smaller statutory hospitals.

Medication reconciliation

Medication reconciliation is a process of creating and maintaining the most accurate list possible of all medications a person is taking including drug name, dosage, frequency and route. This process identifies any discrepancies and ensures any changes are documented and communicated to complete an accurate medication list.⁶⁵ There are three steps in the medication reconciliation process:

1. **Collecting:** This involves the collection of the medication history and other relevant information.
2. **Checking:** This is the process of ensuring that the medicines, doses, frequency and routes, etc. that are prescribed for a patient or service user are correct.
3. **Communicating:** This is the final step in the process where any changes that have been made to a patient or service user's prescription are documented, dated and communicated to the person to whom the patient's or service user's care is being transferred.^{65, 66,67}

Medication reconciliation should be carried out in a structured manner by trained and competent health professionals with the necessary knowledge, skills and expertise.^{65,68,69} Therefore, using a multidisciplinary approach that involves nurses, pharmacists, doctors and other appropriately trained healthcare professionals from acute, ambulatory and community services is essential to drive and sustain medication reconciliation.⁷⁰ Equally, defining how patients, families or caregivers should be involved in the whole process of knowing and maintaining an up-to-date real time medicines list is imperative.⁷⁰

International studies support the implementation of medication reconciliation as an effective strategy to lower rates of medication errors throughout patients' hospital stays and subsequently across transition to community care or other care facilities.^{3,68,70,71,72,73} In addition, published studies indicate that children in paediatric hospitals are more likely to experience a medication error than other hospitalised patients and the implementation of medication reconciliation systems have the

potential to reduce non-intercepted medication errors on admission or unintentional changes to repeat prescribed medication.^{74,75}

A number of studies completed in Ireland support the implementation of medication reconciliation.^{52, 65, 76} One study, in a large Irish teaching hospital where medication reconciliation had been completed by clinical pharmacists, showed that medication errors were identified in approximately one in four patients' admission prescriptions.⁵² A second study relating to the medication details documented on discharge found that a lack of reconciliation on discharge from public acute hospitals in Ireland was frequent and can contribute to patient harm or unplanned readmission.⁷⁶

In 2008, the Report of the Commission on Patient Safety and Quality Assurance in Ireland identified that, as a key part of their safety and quality governance framework, hospitals must prioritise the implementation of formal medication reconciliation. This report identified that hospitals should include regular audits and the deployment of resources for this purpose.²³

However, studies have also highlighted the barriers to implementing medication reconciliation for hospitals^{70,71,76}, including the following:

- the difficulty patients have in accurately recording their medications
- polypharmacy^{§§§§}
- multimorbidity^λ
- pharmacy staff time and work constraints
- a lack of resources, most notably clinical pharmacy staff to perform medication reconciliation.

A number of studies confirmed that the clinical pharmacist contributed positively to medication reconciliation on admission.^{45,46,47,48,49,50} However, as medication reconciliation is a labour-intensive process, the high cost of clinician time (pharmacists, doctors, nurses) spent sourcing patients' real-time medicines list cannot be ignored. It is essential for hospitals to identify situations most likely to benefit from medication reconciliation, such as patients on high-risk medications, and determine the most appropriate and efficient way to do this.^{70,71,72,77,78} The use of pharmacy technicians could also be a useful strategy for developing and expanding medication reconciliation with appropriate supervision and education.^{79,80}

While multidisciplinary collaboration can improve medication reconciliation, the reconciliation process without technological aids remains costly and time-consuming

^γ Polypharmacy: the concurrent use of multiple medications by a patient.

^λ Multimorbidity: commonly defined as the presence of two or more chronic medical conditions in an individual.

for healthcare providers.^{76,81} Medication reconciliation supported by information technology has been shown to minimise medication-related incidents.⁷⁰

Medication reconciliation practice and the required discussion among healthcare professions and hospitals to reduce medication errors on admission and discharge are not widely standardised.^{77,82} Key to implementing medication reconciliation is establishing who should be ultimately accountable for obtaining the patients' medication information, and performing the various steps in the reconciliation process. Studies indicate that while different professional groups such as doctors, pharmacists and nurses recognise the importance of medication reconciliation, there remains a lack of clarity regarding the roles and responsibilities for medication reconciliation. Therefore, policies and training are required to provide clarity for roles and responsibilities when medication reconciliation is introduced to a healthcare setting.^{77,82}

Through the medication monitoring programme HIQA found that there were various systems implemented to support medication reconciliation. While some hospitals had more comprehensive systems in place, other hospitals had a significant amount of work to do in implementing medication reconciliation.

HIQA found that where there was leadership from chief pharmacists, supported by a functional Drugs and Therapeutics Committee and Hospital Management, medication reconciliation was more likely to be implemented and pharmacy-led.

Of the 34 hospitals inspected:

- Three hospitals were completing medication reconciliation on admission and discharge. These hospitals had a policy, audit and training in relation to medication reconciliation.
- Thirteen hospitals were completing medication reconciliation on admission in most of the clinical areas of the hospital, through a process that was pharmacy-led.
- Fourteen hospitals had implemented aspects of medication reconciliation on admission in a small number of wards with limited clinical pharmacy resources supported by multidisciplinary teams.
- Four hospitals reported to inspectors that patients' medications were checked by nurses and or doctors on admission.

In the 29 hospitals inspected that had an Emergency Department, eight had implemented medication reconciliation for admitted patients in their Emergency Department.

Of the 34 hospitals inspected, HIQA found that eleven hospitals had supported medication reconciliation with the implementation of a policy. Seventeen hospitals had completed audits. Six hospitals had provided training on medication reconciliation. Ten hospitals used an electronic system to support medication reconciliation (this will be discussed in more detail in the next section).

HIQA found that a number of hospitals had implemented areas of good practice with medication reconciliation. An example at Naas General Hospital is detailed below.

Medication reconciliation at Naas General Hospital

Naas General Hospital's medication reconciliation service was underpinned by a policy which specified that all patients should have medication reconciliation completed within 24 hours of admission, or on the next working day. A clinical pharmacist collected a gold standard pre-admission medication list using a designated admission medication reconciliation form.

Patients' pre-admission medications were verified by a clinical pharmacist using two information sources, one of which was always the patient or their carer, and these were then compared to the patient's hospital medication prescription chart.

This hospital had evaluated its medication reconciliation service in line with the World Health Organization's guidelines for medication reconciliation. A series of audits conducted in 2009, 2011 and 2016 in this hospital indicated that medication reconciliation practices had, over this timeframe, significantly decreased the number of unintentional unresolved medication discrepancies at 48 hours.

Technology and medication safety

eHealth is defined by the World Health Organization as the adoption of information and communication technologies in delivering health services.⁸³ Regardless of worldwide advances in the use of health information technology, the implementation of electronic prescribing is delayed in many countries.^{84,85,86} A study relating to e-medication in European countries identified that the implementation of nationwide e-medication systems and cross-border harmonisation was slow due to the development of privacy and security requirements.⁸⁷

Internationally, the US government and the European Commission have made progress with the requirement for healthcare to move from one that was primarily paper based to one that uses electronic technology.^{88,89, 90} The government policy in

the UK has also driven the use of technology in healthcare with a plan for the National Health Service (NHS) to be paperless by 2020^{91,92} and Scotland is regarded to be well advanced with adopting eHealth by that date.⁹³

In Ireland, HIQA completed a review of ePrescribing and electronic transfer of prescriptions in 2012.⁹⁴ This review identified that six jurisdictions^{*****} throughout the world had commenced or had already implemented ePrescribing solutions focusing mainly on the prescribing and dispensing of medication in the community. This international review provided information and evidence to aid the development of an electronic transfer prescription solution for Ireland. Likewise, the Department of Health in Ireland has developed an eHealth strategy (2013) to provide a roadmap on eHealth with proposals for governance and delivery structures.⁸⁵

Numerous international and national studies support the introduction of ePrescribing to improve inpatient medicines management systems and reduce medication errors.^{73,74,87} While these studies highlight that there are patient safety benefits to introducing ePrescribing, these benefits are dependent on successful implementation of the system, as various unintended consequences relating to the introduction of ePrescribing have also been identified in the literature. For example, new medication errors can occur when a prescriber picks from a drop down menu drug list, or while filling in free text fields electronically, or as a consequence of overriding medication alerts.^{95,96} Despite these findings, the widespread use of ePrescribing offers opportunities to improve patient safety with regard to medication use. These opportunities include access to shared medication-related information by healthcare professionals including clinical information at the point of care.⁸⁴ In addition, the benefits of ePrescribing also relate to generating legible and complete medication orders and sharing this information with multiple professionals within the hospital and the wider community.⁹⁷

A number of technologies have been developed to reduce medication errors and to support ePrescribing.⁸⁴ These technologies include the following:

- pharmacy-based systems to manage stock control
- clinical speciality-based systems including cancer and intensive care systems
- components of large hospital information systems such as electronic health record
- hospital software systems developed locally by hospital informatics teams.

***** The six jurisdictions: New Zealand, Australia, the Netherlands, England, Scotland and Northern Ireland.

The Department of Health's 2013 eHealth strategy aims to deliver a more personalised patient-centred healthcare system to reduce errors. This involves the integration of all information involved in the delivery of healthcare through information technology-based systems.⁸⁵ Potential priority projects that fall under the eHealth strategy include:

- Electronic Health Record (EHR)
- National health identifier infrastructure
- ePrescribing systems
- Telehealthcare⁺⁺⁺⁺ – relating to chronic diseases
- development of Patient Summary Records
- online access to Health Information
- National Patient Portal.⁺⁺⁺⁺

A national Electronic Health Record (EHR) has been identified by the Health Service Executive (HSE), national directors and clinical leaders as a key requirement for the future delivery of healthcare.⁹⁸ The EHR is the cornerstone of the eHealth Strategy as it supports the creation and sharing of key patient information. Key to implementing the EHR is the need for an Individual Health Identifier^{§§§§} on which the electronic health record system is centred.⁹⁸ The national EHR will consist of core operational functions including ePrescribing.

The national technology project for 2018, as part of the eHealth strategy, will initially focus on the shared care and discharge summary data from the Maternity Newborn Clinical Management system.⁹⁹

ePrescribing aims to reduce errors due to manual prescribing. The eHealth strategy describes ePrescribing as the transmission of prescription or prescription-related information between prescriber, dispenser, pharmacy, and health plan using electronic media through an ePrescribing network.⁸⁵

During this monitoring programme HIQA found that a number of hospitals had implemented quality improvement initiatives using technology to assist. These included ePrescribing, smart pump technology, technology-assisted medication reconciliation, standardised concentration infusions and innovative uses of smart phone technology.

⁺⁺⁺⁺ Telehealth: involves the distribution of health-related services and information via electronic information and telecommunication technologies.

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

^{§§§§} An Individual Health Identifier (IHI): a number that safely identifies a person using a health or social care service. This number will be used to safely identify the individual and link their health records from different health systems to generate a complete medical history.

Four hospitals reported that they had implemented some elements of electronic prescribing in critical care areas, and eight hospitals had implemented electronic discharge summaries to support medication reconciliation and communication with community pharmacists and GPs.

An example of electronic prescribing demonstrated to inspectors during an inspection is detailed below.

Electronic prescribing and medicines administration record at St. James' Hospital, Dublin

St James' Hospital had commenced work in early 2017 on a project to introduce an electronic prescribing and medicines administration record (ePMA)^o. One of the deliverables of this project was that electronic prescribing would be launched in clinical areas in April or May 2018. Access to such information could potentially support prescribers in better decision-making, prescribing and improve patient safety. This project is considered a positive step in progressing medication safety in a hospital setting.

Inspectors viewed this system, which had been established in an outpatient area for a number of years, and observed that this computerised decision support system provided integration of patient clinical history, clinical review, laboratory results, diagnostics and medication history.

Smart pump technology

Another use of technology to support medication safety is 'smart-pump' technology which is computerised infusion devices with multiple safety features that include customised drug libraries and drug calculations.^{100,101} The benefits of using technology can provide high-level risk-reduction strategies, including forcing functions^{*****} and constraints, automation⁺⁺⁺⁺⁺ and standardisation (Appendix 7).

***** Forcing functions: are design processes so errors are virtually impossible to make, for example removal of a product from use such as concentrated potassium in ward areas.

+++++ Automation: the method of making a machine, a process, or a system work without being directly controlled by a person.

HIQA found during the medication monitoring programme that three specialised hospitals had implemented smart pump technology^{*****} with customised drug libraries. Two of these three hospitals had collaborated on the development of a customised drug library for smart pumps and shared access to drug libraries with other regional paediatric units in public acute hospitals. This was a good example of effective collaboration, facilitating wide-scale standardisation of medication practices, sharing expertise and experience with efficient use of resources. One paediatric hospital that implemented a drug library for use with smart pump technology was Our Lady's Children's Hospital, Crumlin as detailed below.

Smart pump technology at Our Lady's Children's Hospital, Crumlin

Critically ill, paediatric patients are at high risk of medication error. Our Lady's Children's Hospital had enhanced medication safety in this vulnerable cohort of patients through the introduction of smart pump technology and the development of a drug library containing an agreed list of standardised concentration infusions.

A cross-site collaborative multidisciplinary working group was convened and the hospital's drug library was further developed to enable its use across the Irish Paediatric Acute Transport Service and in the paediatric intensive care unit at the Temple Street Children's University Hospital.

Standardisation was achieved for paediatric patients requiring intensive care management with continuous intravenous infusions. The safety benefits of this cross-site standardisation of the smart pump infusion drug library containing a list of standardised drug concentrations facilitated a reduction in the risk of medication error when critically ill children were transferred from one facility to another.

Medication reconciliation on discharge using information technology

Medication reconciliation supported by an electronic tool has been shown to minimise medication incidents.^{94,102} In addition, working with community pharmacists and GPs to support medication reconciliation is essential to reduce the risk of medication incidents occurring.⁷⁰

^{*****} Smart pump technology: computerised infusion devices with multiple safety features that include customised drug libraries, dose calculations based on programmed patient weights and the setting of dose limits.

The use of handwritten discharge summaries and prescriptions remains routine practice in the majority of Irish hospitals.⁷⁶ This ongoing practice is more likely to result in one or more medication errors than if this system was computerised.⁸¹ Therefore, the process of electronic reconciliation of medication records between hospitals, GPs and community pharmacists would ensure an accurate, up-to-date electronic medication list, common to all healthcare providers.^{70,81}

Three hospitals inspected used technology to assist with medication reconciliation. One of these hospitals had implemented a specific system to support medication reconciliation and reported that over 80% of patients had an electronic discharge prescription completed on discharge that had been reconciled with their pre-admission medication list. This was then transmitted to the patient's GP via Healthlink.^{§§§§§§}

Similarly, two other hospitals were involved in trialling a pharmacy-led discharge medication reconciliation as described below.

Naas General Hospital and St Luke's General Hospital, Kilkenny: Medication reconciliation using technology

Naas General Hospital and St Luke's General Hospital, Kilkenny collaborated on a joint initiative using medication computer software in collaboration with e-Health Ireland, the School of Pharmacy at University College Cork, and an industry sponsor.

This was described as a computer software programme used by pharmacists to generate a record of medication reconciliation on admission and to generate a discharge prescription.

Discharge prescriptions were then printed and signed by the patient's doctor and sent to the patient's GP, community pharmacy and nursing homes where applicable.

An evaluation of this initiative found it improved efficiency and patient safety.

^{§§§§§§} Healthlink: provides a web-based messaging service which allows the secure transmission of clinical patient information between hospitals, healthcare agencies and GPs.

Other uses of electronic technology

HIQA found other examples of electronic technology systems which were implemented to support medication safety. These included:

- computer technology, tablet and applications at point of care to support drug prescribing and administration
- drug libraries with standardised medication infusion concentrations in intensive care units
- standardised protocols and dosing regimens, for example insulin and chemotherapy
- piloting the use of mobile technology to record medication incidents
- ePrescribing in a small number of critical care units.

Four of the 34 hospitals reported to inspectors that they had implemented automated dispensing systems in some areas.[‡] Inspectors observed an automated dispensing system in one hospital's pharmacy department which had been recently introduced. Inspectors were informed that this was a positive addition to the dispensary, helping to increase efficiencies of the service and improve tracking or monitoring of medication stock levels. However, electronic ordering was not directly linked to the automated system at the time of this inspection.

One hospital had implemented an electronic medication prescribing, compounding and administration system used in the oncology/ haematology service to support cancer treatment planning, therapy monitoring and the preparation of cytotoxic medications. This system was designed to minimise errors in intravenous medication preparation and administration, through bar code verification of prescribed medications, in this complex speciality.

Three specialist maternity hospitals inspected were in the process of implementing an electronic healthcare record. This was part of a national Maternal and Newborn Clinical Management System⁹⁹ which will include functionality and allow clinicians by the bedside to have each patient's current and complete list of medications. Inspectors were informed that this project was being implemented nationally in maternity units on a phased basis.

Utilising automation and intelligent systems has the potential to improve dispensing and prescribing medication management systems, support the effective use of clinical pharmacist resources and free up pharmacy resources to enable clinical pharmacists and other staff to provide an increased patient focused service.⁵⁷

[‡] An automated dispensing system: a system controlled by a computer that stores, dispenses and tracks medications with the aim of improving efficiency and patient safety.

Recommendations

1. A national plan for the development of comprehensive clinical pharmacy services that sets out the desired model of care, and the appropriate resources to ensure consistency across hospitals should be developed.
2. Develop a national approach to advance medication reconciliation to include defining responsibility for medication reconciliation and using electronic solutions to reduce time spent by clinical staff on medication reconciliation.
3. Utilise information technologies such as ePrescribing, smart pump technology and decision support tools to reduce medication incidents and risks. At a national level hospital groups should work together to commence the implementation of electronic solutions to improve medication safety.

2.3 Person-centred care

Lines of enquiry:

- Patients and or carers are informed about the benefits and associated risks of prescribed medicines in a way that is accessible and understandable.

Patients should be supported to take responsibility, where possible, for maintaining and improving their own health through the provision of clear and relevant information in an accessible format.¹² One in five patients has an adverse event after discharge from hospital, with the majority of these relating to medicines.¹⁰³ Patient 'transitions'***** such as discharge from hospital to home is a complex process which should include patient education.^{104,105} Patients should be informed about any new medication they are prescribed or any changes to their medicines; this is especially relevant for patients who are taking multiple or high-risk medicines.^{106,107,108}

Appropriate education and the provision of written information to patients or carers is the responsibility of the multidisciplinary team that supports patients to make informed choices about their medicines and to achieve best outcomes with treatment plans.^{17,106} When patients are better informed about their medicines, compliance with taking medicines improves, and medication errors and visits to GPs and hospitals reduces.^{109,110} A well-informed patient and or family is less likely to make medication errors at home and can help prevent hospital staff from making medication errors.¹¹⁰

All hospitals inspected reported that they had systems in place to support the provision of patient information and education in relation to medication use. However, the process for giving patients information and education about their medicines varied between hospitals from informal education to more structured education provided by an appropriate clinician and supported by individualised written information.

HIQA survey

Hospitalisation and subsequent discharge can involve multiple changes in medication regimes. Good communication between healthcare professionals and patients is needed to involve patients in decisions about their health and medicines.¹⁰⁶ As part

***** Transition of care: the movement of a patient from one setting of care to another. Settings of care may include hospitals, primary care, long-term care facilities, home health, and rehabilitation facilities. Transitions increase the risk of error due to the potential for miscommunication.

of the HIQA inspections, a small sample of recently discharged hospital patients attending the outpatient department were asked to complete an anonymised questionnaire in relation to prescribed medications. The questionnaire was designed to ascertain whether patients received appropriate information in relation to the purpose of, side effects of and instructions for taking their medicines. Three questions were asked with four or five possible responses (as outlined in Figure 5, 6 and 7 below). The questions were:

1. While in hospital did a member of staff explain the purpose of new medicines in a way you could understand? (Figure 5)
2. Prior to discharge from hospital, did a member of staff tell you about the possible side effects of medicine to watch for when you went home? (Figure 6)
3. Were you told how to take your newly prescribed medicines in a way you could understand? (Figure 7)

A total of 444 patients who had been inpatients in hospitals within the past six months, and who were prescribed regular medications, completed the questionnaire.

Over half (58%) of patients reported that a member of staff explained newly prescribed medicines in a way they could completely understand. An additional 16% reported that new medicines were explained to some extent. One in 10 patients reported that the purpose of their new medication was not explained.

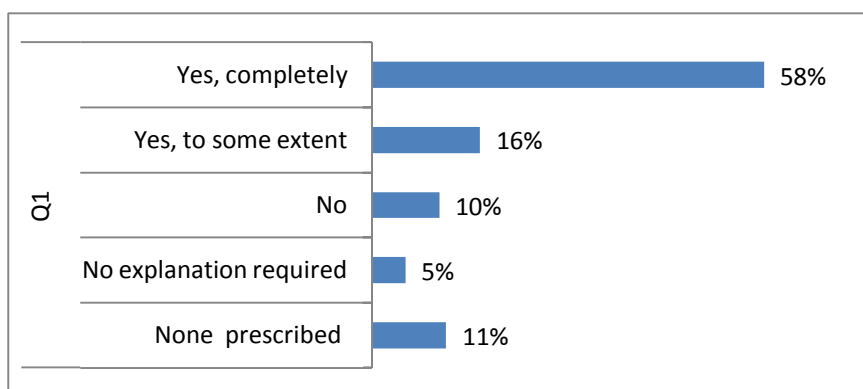


Figure 5: Question 1. While in hospital, did a member of staff explain the purpose of new medicines prescribed in a way you could understand?

One in four (25%) patients reported that they were not told about possible side effects, 17% stated they were told to some extent, and 43% reported they were given complete information as detailed in Figure 6 below.

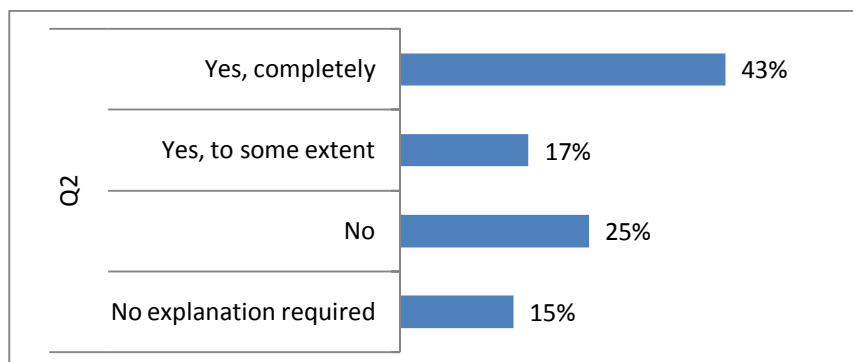


Figure 6: Question 2. Prior to discharge from hospital, did a member of staff tell you about possible side effects of medicine to watch for when you went home?

Over six out of 10 patients were told how to take their medicines in a way they could understand. Nearly one in ten were told 'to some extent' and 11% were not told how to take their medicines in a way that they could understand.

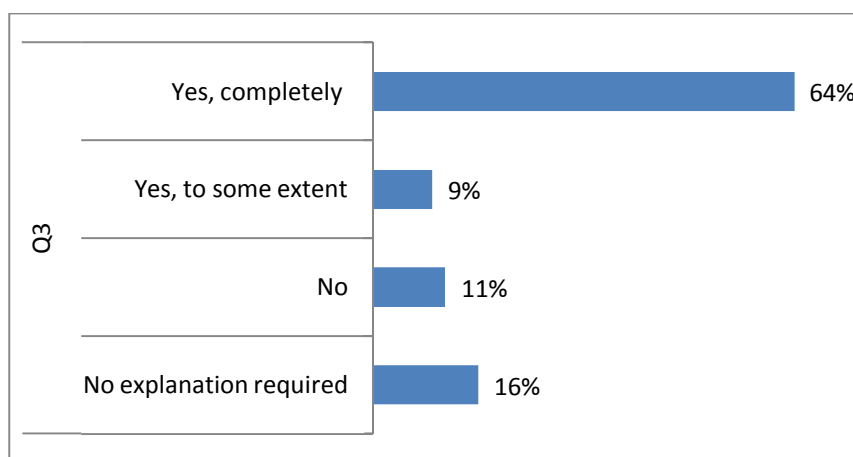


Figure 7: Question 3. Were you told how to take your newly prescribed medicines in a way you could understand?

It is acknowledged that the sample size of patients who completed the anonymised questionnaire was small and therefore was not representative of all recently discharged patients taking prescribed medications from each hospital. However, this patient questionnaire did provide some baseline information about outpatients' understanding of medications in the hospitals inspected.

The results found during this monitoring programme broadly reflected findings from the recent National Patient Experience Survey⁺⁺⁺⁺⁺⁺¹¹¹ which are outlined below.

It must be noted that the questions differed slightly as the focus for this phase of the medication safety monitoring programme was on new medicines, whereas the questions in the National Patient Experience Survey asked about all medicines a patient was taking.

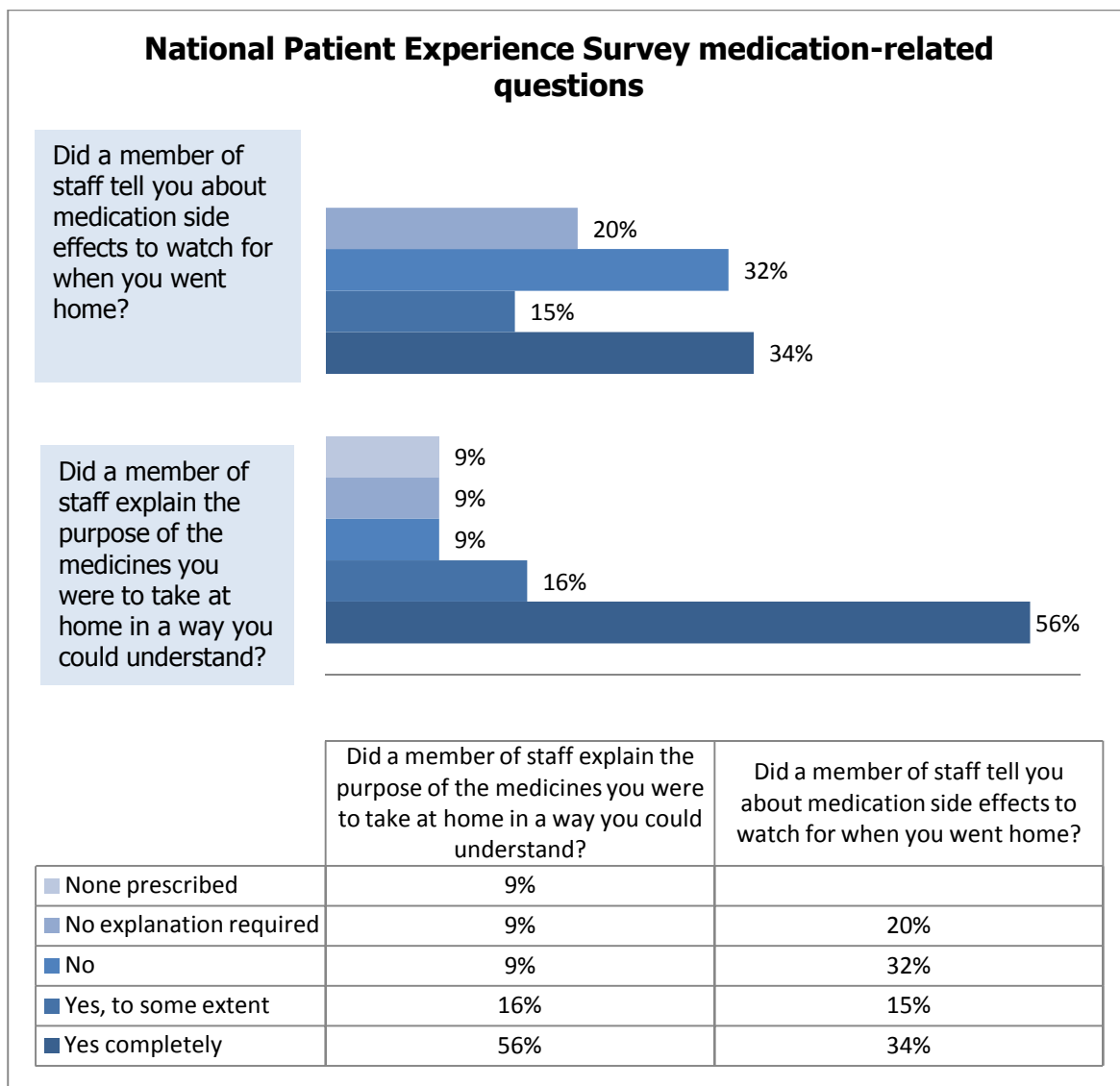


Figure 8: Results of the National Patient Experience Survey medication-related questions (12,940 responses to these questions)

++++++ The National Patient Experience Survey: was a nationwide survey which asked people for feedback about their stay in hospital. The survey was a partnership between the Health Service Executive (HSE), HIQA and the Department of Health. All adult patients discharged during May 2017 who spent 24 hours or more in a public acute hospital, and have a postal address in the Republic of Ireland were asked to complete the survey.

These results highlight a significant requirement to improve the information given to patients at a national level in relation to the purpose and side effects of medicines.

Patient information and education in relation to medicines

A number of hospitals, particularly specialist and paediatric hospitals demonstrated good examples of formalised patient information and education processes in place, provided by staff such as pharmacists, clinical nurse specialists or midwife specialists.

Other hospitals inspected outlined a multidisciplinary team approach to patient information and education in relation to medication use with doctors, nurses and pharmacists providing patient information and education. The multidisciplinary approach described to inspectors was in some cases informal, and was dependant on the expertise and time available for staff to provide patient education. Appropriate policies, procedures, protocols and guidelines should be in place to support patient education and to define each team member's role and responsibilities in relation to providing medicines information for patients.¹¹²

Clinical pharmacists were available to counsel patients in relation to medication issues on request from a patient, nurse or doctor in most hospitals inspected.

Most hospitals informed inspectors that clinical nurse and midwife specialists provided education and support to patients on medication management, most often in relation to medicines for diabetes, respiratory conditions, cardiac failure and after having a stroke.

Patient information leaflets were available at the point of care in many hospitals. However, the quality and quantity of the patient information leaflets available varied across hospitals. Information leaflets on oral anticoagulants were the most commonly available information leaflets. Patients in one hospital were provided with an anticoagulant alert card which they could show to their healthcare provider to alert them to the fact that they were taking oral anticoagulation medication.

A number of hospitals had introduced quality improvement initiatives to improve patients' knowledge of their medicines as detailed below.

Quality improvement initiatives to improve patients' knowledge of their medicines

Cappagh National Orthopaedic hospital

Clinical pharmacists offered counselling to all patients in the orthopaedic ward on newly prescribed oral anticoagulant. Clinical pharmacist also provided counselling on medications to patients in the acute rehabilitation unit and provided a medication planner for patients and or carers, prior to planned discharge.

Coombe Women & Infants University Hospital

The Coombe Women & Infants University hospital identified that parents of babies discharged on complex medications required additional education and support and were provided with this support by neonatal nurses, pharmacists and the discharge nurse. The pharmacist often linked with external community pharmacists or external hospitals to ensure a continuous supply of medications for the baby follow transfer or discharge.

Education for parents was undertaken throughout the hospital stay to prepare the parents and the baby for discharge. In addition, the hospital held monthly support groups for parents of these babies post discharge, to provide an additional source of support and educational opportunity if required.

Know your medication initiatives

Campaigns were in progress in the National Maternity Hospital, Tallaght Hospital and Mayo University Hospital with the aim of increasing patient awareness of their medications, through the use of medication leaflets that were carried by patients that included a record of their medicines.

Quality improvement initiatives to improve patients' knowledge of their medicines

Patient education on anticoagulant medications:

Oral anticoagulants⁺⁺⁺⁺⁺ and more recently direct oral anticoagulants^{§§§§§§§§} (DOAC) have been widely identified as high-risk medications which continue to be a key medication safety priority in many hospitals inspected.

To reduce this risk, clinical pharmacy counselling can be provided to patients who are commenced on anticoagulant medication. In other hospitals where clinical pharmacy were only assigned to certain ward areas, patients were provided with anticoagulation counselling on their assigned wards and in other areas of the hospital if requested by nurses or doctors.

For example, Tallaght Hospital had set up an atrial fibrillation clinic with the support of the pharmacy service to manage atrial fibrillation and supervise the use of direct oral anticoagulants (DOACs).

Naas Hospital pharmacy departments had also established outpatient education clinics for patients who had commenced on direct oral anticoagulant medication. This was an example of how hospitals optimised their available clinical pharmacy resources to provide standardised care to patients prescribed high-risk medications.

Giving patients the opportunity to provide feedback about medicines information they receive provides hospitals with the opportunity to implement improvements where deficiencies are identified.¹⁰⁷

Some hospitals sought patients' opinions and used the information to improve care; such as in St James' Hospital as detailed in the following table.

⁺⁺⁺⁺⁺ Anticoagulants: are commonly referred to as blood thinners that prevent or treat blood clots, but these medicines also carry an increased risk of bleeding or clots, so patient education and regular monitoring of blood levels are essential to maintain patient safety and ensure good patient outcomes.
^{§§§§§§§§} Direct oral anticoagulants: are medications used to treat or prevent blood clots. However, there is a potential for bleeding with their use or clotting leading to stroke with missed doses. Options for anticoagulation have been expanded recently with the introduction of new anticoagulants called direct oral anticoagulants.

St James' Hospital medication safety focus groups

While developing a medication strategy, St James' Hospital identified that the views and experiences of patients and their carers on medication safety issues should form an essential component of the medication strategy. A patient safety focus group was held in March 2016 with the hospital's Patient Representative Group which was formed at the beginning of 2016. Three themes emerged relating to medication management from the focus group and action plans to address these issues were incorporated into the hospital's medication strategy. The themes identified were:

- patient control over self administration of their own medication
- communication between patients and healthcare professionals on medication issues
- unsecured medications left by patient bedside following medication administration.

Hospitals must develop strategies to ensure patient engagement in relation to the safe use of medicines so that patients receive appropriate, individualised information in relation to their medicines, in particular with new medicines and high-risk medicines.

Recommendation

1. Hospitals should build patient education requirements into the medication management process, based on services provided and their patient population, to ensure patients and or care givers are given the appropriate medicines-related information.

2.4 Policies, procedures, protocols and guidelines and information to support medication safety

Lines of enquiry:

- Hospitals develop effective processes for medication management that are implemented and supported by clear and up-to-date policies, procedures protocols and guidelines.
- Essential information supporting the safe use of medicines is readily available in a user friendly format and is adhered to when prescribing, dispensing and administering medications.

The National Standards outline that healthcare should be delivered according to policies, procedures, protocols and guidelines based on national and international research to achieve best outcomes for patients.¹² Clinical policies, procedures, protocols and guidelines based on best available evidence reduce variation in practice, improve patient outcomes and ensure the efficient use of healthcare resources.^{113,114}

Medications have proven to be very beneficial in treating illness and preventing disease, but advances in medication have also resulted in added complexity and potential risk for patients.¹ Therefore, organisations need policies, procedures, protocols and guidelines, used in conjunction with higher level risk-reduction strategies to effectively guide medication safety and reduce risk.¹¹⁵

It is important that policies, procedure, protocols and guidelines are developed using a standardised approach, involve end-users, are easy-to-read and officially introduced with training and wide distribution to front-line staff.^{17,116} Oversight of medication policies, procedures, protocols and guidelines should include the expertise of the hospital's medication safety governance group, such as the Drugs and Therapeutics Committee, to ensure they are appropriately developed, implemented and have effective assurance mechanisms in place to monitor their effectiveness.¹⁷

Policies, procedures, protocols and guidelines must be readily available at the point of use^{*****} to ensure the information is followed in practice.¹⁷ In addition, clinical staff should have access to medicines information resources at the point of prescribing and preparation, and should have access to clinical expertise such as clinical pharmacists.

***** Point of use: includes when prescribing, preparing or administering medicines.

Types of policies, procedures, protocols and guidelines could include, but are not limited to: guidelines for healthcare staff on safe procurement, dispensing, storing, compounding, prescribing, administration and monitoring the effects of medicines.¹⁷ Additional policies, procedure, protocols and guidelines to support safe medication management system may also include:

- criteria for inclusion of medicines on the hospital medicines formulary
- medication reconciliation
- high-risk medicines
- generic substitution
- provision of medicines information on discharge
- related guidance to support the medicines management system such as:
 - patient identification
 - use of abbreviations
 - reporting of incidents and adverse drug reactions.¹⁷

Policies, procedures, protocols and guidelines should be controlled documents using appropriate systems.^{17,116} This process involves defining controls needed to develop, approve, review, identify changes and revision status, and provide access at point of use.

On inspection HIQA found that most hospitals had medication management policies, procedures, protocols and guidelines in place. The majority of hospitals inspected had procedures in place for the approval of these documents, most of which were up to date and document controlled. Hospitals had processes in place for communicating new policies, procedures, protocols and guidelines to staff, but limited evidence of auditing compliance with these was found.

The majority of hospitals reported that the hospital's Drugs and Therapeutics Committee approved policies, procedures, protocols and guidelines to support safe medication management systems. In a small minority of hospitals, medication-related policies, procedures, protocols and guidelines were reviewed by the Drugs and Therapeutics Committee before final sign off by other committees (such as the Clinical Governance Committees) or senior hospital management.

The majority of hospitals inspected had an electronic document control system which supported the document control process and provided staff access to the most current version of the documents at point of use. These systems also sent email alerts to identified personnel when the documents were due for review. The hospitals which did not have electronic document control systems stored their documents on hospital computer systems where staff could access them, but document control depended on manual systems.

Although some hospitals were challenged with keeping documents up to date, almost all hospitals' documents viewed by inspectors were version controlled with review dates clearly stated.

Inspectors found that some hospitals had externally developed policies, procedures, protocols and guidelines and or medicines information sources which were not reviewed and or not approved for use within the organisation. This could result in staff accessing information which is not appropriate to the local setting.

Inspectors found some good examples of sharing of policies, procedures, protocols and guidelines and collaboration within hospital groups with efficient use of staff expertise and resources.

Access to medicines information and decision support tools

Access to relevant up-to-date and accurate medicines reference information and decision support tools⁺⁺⁺⁺⁺⁺⁺ is essential at all stages of the medication management pathway.¹⁷ A range of medicines information and decision support tools were available to guide staff involved in providing safe and effective medication management within the clinical areas of all hospitals inspected. However, the quantity and quality of the tools available varied between hospitals.

The clinical pharmacist was identified by staff as a key source of medicines information in clinical areas inspected. Computerised decision support tools, including electronic tablet devices and smartphone applications, in place in some hospitals, had provided easy access to accurate, up-to-date information at the point of prescribing, preparation and administration of medicines. Given the diversity of medical applications available to support decision-making and future technology developments, quality control of all information sources to guide staff is vital, and should be under the governance of the Drugs and Therapeutics Committee.¹¹⁷

Intravenous medication monographs

In the majority of hospitals inspected, locally developed or adapted intravenous medication monographs⁺⁺⁺⁺⁺⁺⁺ were available to provide staff with a quick reference guide to support the safe and effective prescribing and administration of intravenous

⁺⁺⁺⁺⁺⁺⁺ Decision support tools: are resources that provide guidance or incorporate knowledge to help clinicians make the most appropriate clinical decision for patient care.

⁺⁺⁺⁺⁺⁺⁺ Intravenous medication monographs: an approved set of standardised and approved instructions for the correct preparation and administration of intravenous medication, that have been designed to reduce the risk of error, and that are specifically tailored to the intravenous medicines stocked within the hospital.

medications. The intravenous medication monographs observed were in bound, hard copy versions which could only be updated in totality or in unbound hard copy versions where individual monographs could be updated as required and in electronic format.

However, a number of hospitals did not have appropriate information in place. One hospital had intravenous medication monographs specifically designed for use in another hospital, and two other hospitals had commercially available intravenous medication guidance which had not been formally reviewed as suitable for the hospitals. Inspectors identified this as a risk, as instructions for administration of intravenous medications could be inappropriate for use in that particular clinical area or hospital with potential for patient harm. For example, medications designed for use in a critical care area being administered in a general ward area.

Other hospitals that did not have intravenous medication monographs used instruction leaflets from manufacturers as a reference guide for staff. This could pose a risk if a medicine is used in the wrong way or in the wrong setting. Although manufacturers' information is up to date and accurate, it cannot ensure that medicines are being used in an appropriate setting. For example using procedural sedation in general ward areas^{§§§§§§§§} which carries additional risk if these agents are used without the requisite patient monitoring.¹¹⁸

Intravenous medication monographs were available in electronic format at the point of medication preparation in three of the hospitals inspected. The use of technology to deliver resources at the point of care can enhance clinical practice, provide work practice efficiencies and improve safety of medicines use by increasing guideline update and adherence.¹⁷ However, in embracing technology for medicines information resources hospitals need to ensure that the required information is still accessible to staff at point of use, such as, the clinical room where medications are prepared.

An example of intravenous medication monographs in electronic format at the point of medication preparation is described in the following example.

^{§§§§§§§§} Procedural sedation: a technique of administering sedatives or dissociative agents with or without analgesics to induce a state that allows the patient to tolerate unpleasant procedures while maintaining cardiac and respiratory function.

Tablet devices in clinical rooms at Our Lady's Children's Hospital Crumlin

Our Lady's Children's Hospital Crumlin had electronic tablet devices in clinical rooms which contained an electronic version of up-to-date intravenous monographs, the hospital formulary and medication safety alerts. This information was standardised across the hospital, updated and controlled by the pharmacy department and approved through the Drugs and Therapeutics Committee.

The use of electronic tablet devices was supported by an up-to-date standard operating procedure. A survey of front-line staff carried out after implementation found that their experience in using the electronic tablets had been positive with 100% of staff using the tablet as the main means of checking medication information.

Antimicrobial prescriber's guidance

Antimicrobial prescribers' guidance was available to guide prescribers in all hospitals inspected. The antimicrobial prescriber's guidance had been developed by some hospitals and shared with other hospitals within the hospital groups. For example, Galway University Hospital had developed an antimicrobial prescribing guideline, which was also available in mobile application format for smartphone devices. These guidelines had been shared and formally adopted by a number of hospitals within the Saolta Hospital Group. Also five hospitals in the south east had collaborated in the development of a Guide for Empiric Use of Antibiotics which reduced variance in prescribing practice and provided prescribers in each organisation with evidence-based, up-to-date information at the point of prescribing.

The antimicrobial prescriber's guidance was available to staff as a smartphone application in 19 of 34 hospitals, providing prescribers with up-to-date guidance at the point of prescribing.

Prescriber's guide

Seven model 4 and specialist hospitals that were inspected had developed comprehensive medicine prescriber's guides which were available in book and electronic format or as an application which could be downloaded. These guides also contained the hospital's antimicrobial guidelines. Again, HIQA found good examples

of sharing between hospitals, for example, national maternity and paediatric hospitals shared their guidance with regional maternity and paediatrics units.

Medicines reference information and decision support tools

A number of medicines reference information and decision support tools were available to staff in hospitals inspected and are included in Figure 9.

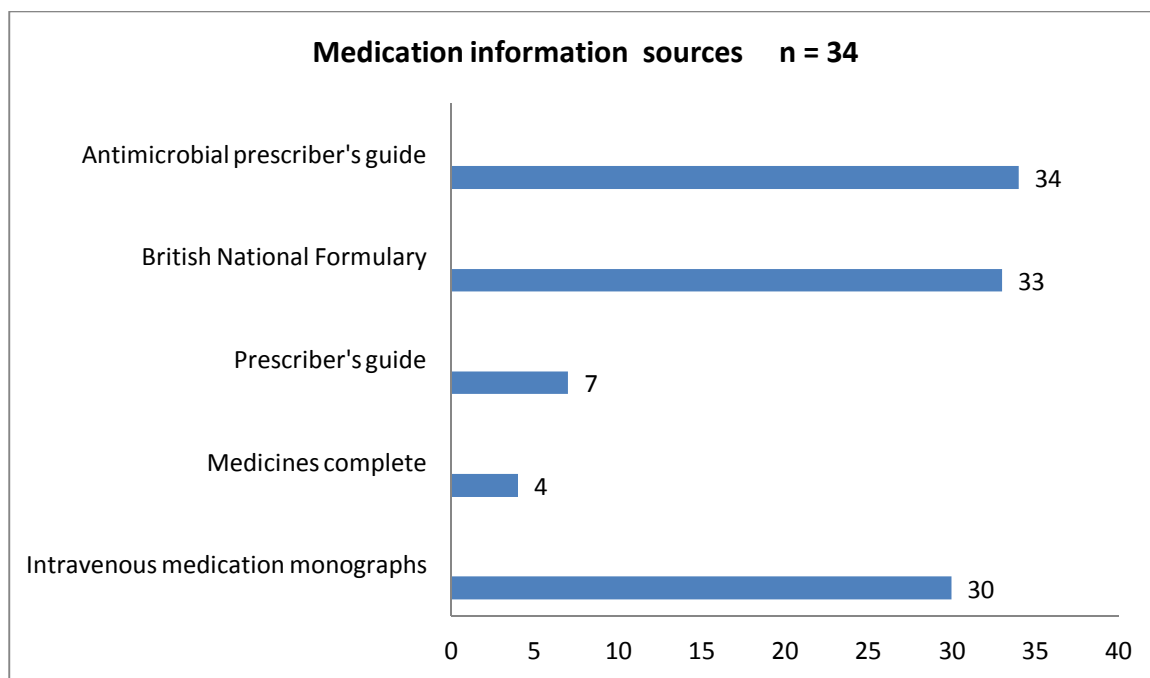


Figure 9: Medication information sources

Advice and support from the clinical pharmacy service

The nursing and medical staff in most of the hospitals inspected cited the clinical pharmacist as a key source of medicines information. In addition, six pharmacy departments from model 4 and specialist hospitals had a formal medicine information service ***** with ready access for all staff to expert advice in the management of medication-related queries. For example one Hospital that provided this service reported over 1,300 enquiries answered from staff on medication annually.

***** Medicines information service: Pharmacists give over the phone information and advice regarding all aspects of medicine use to doctors, nurses, pharmacists and other appropriate healthcare professionals.

Medicines information services support medication safety by providing accurate, up-to-date, unbiased information on medication use. This information was provided to healthcare professionals for specific patient care or for general information on the safe use of medicines.

Access to laboratory results to support safe use of medications

Healthcare staff required access to complete and accurate patient information, relevant to the safe use of medications, at the point of clinical decision-making to ensure patient safety.¹⁷ All hospitals inspected reported that staff could electronically access laboratory results in all clinical areas. This was verified by inspectors on clinical areas visited during inspections.

Informing staff of the hospital's medicines management supports

Relevant staff should be informed of policies, procedures, protocols and guidelines, medicines reference information and decision support tools developed, adapted or adopted by the Drugs and Therapeutics Committees.³³

HIQA found that medicines management information was provided to staff using a variety of methods such as:

- education sessions,
- meetings,
- safety huddles,⁺⁺⁺⁺⁺⁺⁺
- emails,
- safety alerts,
- pharmacy department memos,
- and medications safety bulletins.

One hospital held a medication safety week at which they launched their medication management policy. Two hospitals developed a 'one minute' slide outlining medicines information on a slide presentation, which staff could read in one minute. This 'one minute' slide was circulated to staff via email, a group text message and the hospitals' internal communication system.

⁺⁺⁺⁺⁺⁺⁺ Safety huddles are brief and routine meetings for sharing information about potential or existing safety problems facing patients or workers. They aim to increase safety awareness among front-line staff, allow for teams to develop action plans to address identified safety issues, and foster a culture of safety.

Sharing and collaboration of medicines information

Inspectors observed some good examples of collaboration and sharing of policies, procedures, protocols and guidelines between hospitals in eight model 4 and specialist hospitals to reduce variation and improve outcomes and efficiency. One hospital shared their prescriber's guide with two other hospitals within their hospital group. This was a good example of collaboration through the sharing of expertise and avoiding duplication of effort to support medication safety.

Recommendations

1. Hospitals should provide clinical staff with easily accessible information and or policies, procedures, guidelines and or protocols to guide the safe use of medicines at the point of prescribing, preparation and administration.

2.5 Risk management and incident reporting

Lines of enquiry

- There are arrangements in place to identify report and manage risk related to medication safety throughout the hospital.

The National Standards require that hospitals protect patients from the risk of harm associated with the design and delivery of healthcare. All hospitals should have effective and comprehensive processes in place to identify, understand, monitor and address risks associated with the use of medicines.¹²

Effective prevention of medication incidents is dependent on:

- a well-organised incident reporting system
- a culture of openness with reporting and awareness among staff of the systemic nature of many of these errors
- analysing, tracking and trending medication incidents to identify emerging medication safety concerns
- an open disclosure process where hospital staff communicate with patients in an open and honest manner when things go wrong.¹¹⁹

Measuring medication safety is a challenge and efforts to date have focused on voluntary reporting systems. Voluntary reporting systems are reactive by nature in that they analyse information after an incident^{*****} or near miss has occurred. There can be significant underreporting where staff do not, or are hesitant to report an incident.¹²⁰ Medication incident reporting systems should operate in a 'just culture',^{§§§§§§§§} be confidential, independent, timely and systems-oriented.

***** Medication Incident: any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labelling/ packaging/ nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

§§§§§§§§ Just culture: an environment which seeks to balance the need to learn from mistakes and the need to take disciplinary action.

Studies have found a positive association between increased incident reporting rates and a patient safety culture.^{5,10} This means that increased incident reporting is a good indicator of a positive patient safety culture within a hospital.¹⁰ In contrast, low numbers of incidents reported does not necessarily mean a low number of incidents occurring.

Proactive risk assessments identify and systematically analyse risks and hazards embedded in a process to prevent an adverse incident or harm from actually reaching a patient. Proactive risk assessments can include:

- self-assessments against standards
- failure modes effects analysis^{*****}
- chart reviews
- trigger tools⁺⁺⁺⁺⁺
- audit.

A risk register is another way to proactively manage risk. The creation and maintenance of risk registers (at all levels within an organisation) ensures that risks relevant to a particular area of healthcare are identified and rated, and that appropriate controls and precautions are put in place to eliminate or reduce the risks. Where corrective actions are outside the control of the department or hospital, the risk is escalated through the appropriate governance structures.^{12,121}

In Ireland all public hospitals covered by the Clinical Indemnity Scheme have a statutory requirement to report all adverse clinical incidents and 'near misses'⁺⁺⁺⁺⁺ via the National Incident Management System (NIMS).^{§§§§§§§§§§} Adverse incidents involving medication^{*****} is one of the most common categories of adverse incidents in Ireland and internationally.^{2,4,16}

^{*****} Failure Modes and Effects Analysis (FMEA): a systematic, proactive method for evaluating a process to identify where and how it might fail and to assess the relative impact of different failures, in order to identify the parts of the process that are most in need of change.

⁺⁺⁺⁺⁺ Trigger tools: are ways of identifying and documenting patient harm using a systematic record review process on a randomly selected set of medical records using triggers as flags for patient harm.

⁺⁺⁺⁺⁺ A near-miss incident: an incident which could have resulted in harm, but did not either by chance or timely intervention.

^{§§§§§§§§§§} National Incident Management System (NIMS): a risk management system that enables hospitals to report incidents in accordance with their statutory reporting obligation to the Clinical Indemnity Scheme (Section 11 of the National Treasury Management Agency (Amendment) Act, 2000).

HIQA found that there was a disjointed approach to the oversight and management of medication-related incidents reported at some hospitals. All hospitals inspected had systems and protocols for reporting incidents, but the level of incidents reported in the majority of hospitals was not in line with internationally accepted norms and most hospitals were aware of the need for improvement.² As a result of underreporting, key medication-related risks could not be understood, recorded, escalated or mitigated effectively by hospitals.

Inspectors found that where hospitals had established medication safety programmes with strong leadership supporting a safer patient culture related to medication use, incident reporting rates had increased significantly in recent years. This reflected the emphasis placed on patient safety by clinical leaders, hospital management and, in particular, pharmacy departments in these hospitals. Increased incident reporting rates also reflect the willingness of front-line staff to provide information that ultimately could reduce the risk of harm to patients.

In general, clinical staff reported medication incidents on a standardised form or on an electronic system which was sent to the hospital's risk management department and entered onto the NIMS system. Although hospitals have a statutory requirement⁺⁺⁺⁺⁺ to report all adverse clinical incidents and near misses via the NIMS, inspectors found variations in what medication-related incidents were actually inputted into the NIMS. The time it took to complete an incident report form was identified by front-line staff as a key barrier to reporting medication incidents.

In general, hospitals inspected had increased reporting rates of incidents in the last five years and Figure 10 illustrates the hospitals with the best reporting rates (hospital F was inspected in 2016 so no data was available for 2016 at this time). It should be noted that the hospitals detailed in the graph differ in size and services so comparisons cannot be made between them. Figure 10 serves to illustrate the improvement in the reporting of incidents.

⁺⁺⁺⁺⁺ Under the National Treasury Management Agency (Amendment) Act 2000 there is a statutory requirement for all State authorities including the HSE and its funded agencies to report adverse incidents promptly to the Clinical Indemnity Scheme of the State Claims Agency (SCA) and to facilitate any subsequent investigation. This allows the SCA in conjunction with the HSE to identify and analyse developing trends and patterns, and to develop and implement risk mitigation strategies which is also important in the investigation of any subsequent claim.

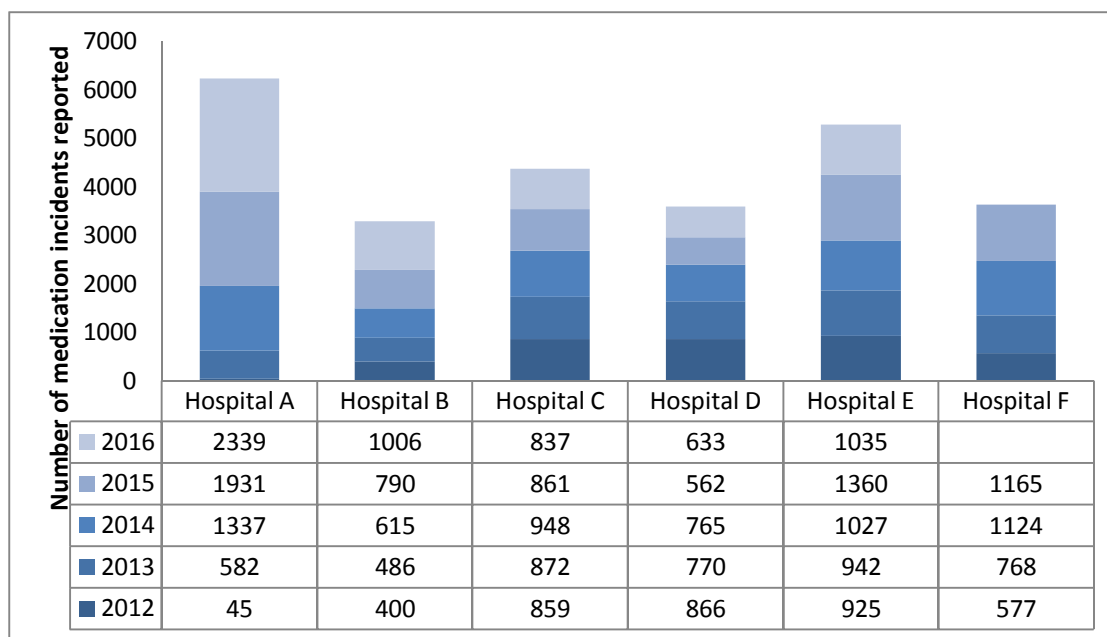


Figure 10: Reporting rates of medication incidents reported in hospitals with established medication safety programmes over years

In Hospital A, there was over 50 times more incidents reported in 2016 when compared with 2012. This reflected the emphasis placed on patient safety by the Pharmacy Department in particular, and the willingness of front-line staff to provide information that was ultimately intended to reduce the risks associated with medication use. However, a number of hospitals reported extremely low levels of medication incidents that were significantly below what would be expected (in the context of the likely presence of, on average, one medication incident per patient per day). For example, two smaller hospitals inspected reported three medication incidents over a period of 10 months, and another hospital reported four in total in 2016.

HIQA noted that despite the recent positive trend in reporting in some hospitals, the majority of reports were submitted by clinical pharmacists and nursing staff with limited evidence available to suggest that medical staff were reporting medication incidents. The culture of reporting medication incidents needs to be significantly improved to ensure that all healthcare staff feel safe to report incidents and near misses. Increased reporting will ensure safety surveillance is improved, learning is shared, and a safety culture is promoted and enhanced across the organisation. For example, one Hospital improved the culture of reporting medication incidents by providing feedback to each ward area and to medical and nursing staff with key points for learning and consideration. This information was stored in a ward folder for all staff to access. Following this initiative there was an improvement in medication incident reporting; with an increase from 25 to 60 per month reported by

clinical pharmacists, nursing and some medical staff. Ward staff confirmed to inspectors that the regular feedback on medication incidents encouraged more reporting of incidents.

Effective governance ensures the establishment of learning systems so that all experience within an organisation is shared and used to improve the system.¹²² During the onsite inspections, hospital managers gave examples of how they provided feedback to front-line staff regarding lessons learned, for example via a staff newsletter.

Staff in the majority of hospitals informed inspectors that they routinely received updates on medication errors that had occurred. However, inconsistencies were reported in the level and timeliness of feedback to staff once an incident had been reported.

Feedback and learning methods should be improved to ensure that appropriate systems improvements are implemented as a result of these reports. Inspectors found limited evidence of sharing the learning from incidents and near misses across the hospital groups.

Inspectors were informed that staff involved in a medication administration incident were required to complete additional training in five of the hospitals inspected. While HIQA acknowledges the importance of promoting a culture of professional responsibility it is important that following an incident or near miss a systems approach is used to identify causes of error. This ensures that systems are designed to reduce or eliminate errors and do not solely rely on staff vigilance.^{123,124}

Inspectors were informed that all hospitals had implemented the national open disclosure policy or had a local open disclosure policy in place to promptly inform patients when medication-related incidents occurred. Staff who spoke with inspectors were familiar with their hospital's open disclosure policy.

Analysis of medication incidents

Hospitals should analyse or 'track and trend' medication incidents and near misses to identify trends and patterns so that action can be taken to prevent injury to patients and ensure that mistakes are not repeated.²

All hospitals, with a small number of exceptions, categorised medication incidents in terms of patient harm, the impact of the incident for the patient and the likelihood of the risk reoccurring. The National Co-ordinating Council Medication Error Reporting and Prevention (NCC MERP) classification system was the most commonly used system (see Appendix 6). The index considered factors such as whether the error

reached the patient and, if the patient was harmed, to what degree. Other hospitals used NIMS and or the HSE Risk Assessment Tool and Risk Impact Table.¹²⁵ One hospital used a locally developed tool to grade medication incidents; however this was not an evidence-based methodology for analysing patient safety incidents.

The lack of standardisation in how medication incidents were graded and risk rated between hospitals in Ireland makes analysis and comparisons difficult. Due to this variation, data cannot be benchmarked between hospitals.

HIQA found that sub-categorisation of medication incidents to aid analysis was evident in a number of hospitals and included; patient outcome, stage of the medication process^{*****}, type of error and or therapeutic group or medicine. For example, one hospital had good tracking and trending of medication safety events including:

- overall trends
- location of events
- category of staff reporting events
- type of event
- severity grading of events
- types of medication errors causing patient harm.

A number of hospitals with established systems for reporting and analysing medication incidents and near misses used analysed or trended data to identify emergent medication safety concerns and prioritise medication safety activities.¹²⁶

Direct acting oral anticoagulant medications featured frequently in reports from hospitals analysis of medication incidents. This highlights the importance of analysing and synthesising medication incidents reports in greater detail to reveal trends in incident reports. Such information is key to the implementation of proactive medication safety initiatives, and inspectors were shown examples of measures introduced by hospitals to address the risks identified in relation DOACS that included:

- Direct oral anticoagulant medications were not stocked at ward level and were supplied on a “named-patient basis” to the wards. High impact risk-reduction strategies¹²⁷ such as dispensing high-risk medicines on a named patient basis can catch and correct errors before they reach patients (Appendix 7).

***** Stage of the medication process: during dispensing, prescribing or administration.

- Clinical pharmacists offered counselling to all patients newly prescribed oral anticoagulant medication
- The introduction of an anticoagulant sticker on the healthcare record to highlight anticoagulant use
- A dedicated medical intern lecture on prescribing of anti-coagulants was delivered as part of the intern education programme
- The publication of pharmacy newsletter to outline practice points with oral anticoagulant medications
- The distribution of a staff quiz which aimed to raise staff awareness of the risks associated with oral anticoagulant medications.

Senior clinicians and pharmacists in Ireland East Hospital Group had collaborated to develop a direct oral anticoagulant therapy record. This booklet contained an anticoagulant therapy record and practical guidelines for the management of direct oral anticoagulant medications for both patients and healthcare professionals (written information has also been shown to augment patients' knowledge about prescription drugs, even when oral communication does occur).

Risk-reduction strategies

Hospitals can develop risk-reduction strategies using the hierarchy of effectiveness framework to inform medication quality initiatives (Appendix 7). This framework¹²⁷ divides strategies in person or system-based and rates the level of risk-reduction strategies into:

- low leverage and least effective strategies
- medium leverage and moderately effective strategies
- high leverage and most effective strategies.

Key elements that influence medication use such as the patient's name, medicines information, labelling, packaging, drug standardisation and storage. These key elements can identify contributing factors that lead to medication errors and subsequently lead to the development of risk-reduction strategies. Inspectors found that all hospitals inspected had introduced some risk-reduction quality improvement initiatives to improve medication patient safety. The most common low level risk-reduction strategies included policies and education.

Recognising that a small number of higher-leverage risk-reduction strategies were more effective to improve patient safety than a larger number of least effective strategies, inspectors found that 10 of the 34 hospitals inspected had implemented high level risk-reduction strategies.

For example, as high-risk medications that bear a heightened risk of causing significant patient harm when not used correctly, many hospitals had implemented a number of high impact risk-reduction strategies to promote the safety of prescribing and administration of high-risk medicines. These included, but were not limited to the introduction of:

- standardised concentrations and dosing regimens for high-risk medicine infusions
- prescribing and administering restrictions
- reducing the number of strengths available for certain medications to reduce selection errors
- use of prefilled syringes in operating theatres where available
- availability of pre-mixed potassium available at ward level and the restriction of concentrated potassium to a limited number of identified areas in the hospital
- designated storage areas for high-risk medications in pharmacy and clinical areas.

In addition, simple redundancies, such as removal of stocks of non essential high-risk medications from patient care areas, had reduced the risk of serious incidents associated with these agents before they reached patients.

High impact risk-reduction strategies such as dispensing high-risk medicines on a named patient basis can catch and correct errors before they reach patients. It was reported at interview that this had reduced the numbers of medication incidents associated with these agents.

High-risk medications

High-risk medication lists are maintained to determine which medications require special safeguards to reduce the risk of errors. The majority of hospitals maintained a list of high-risk medications at the time of the onsite inspection. A small number of hospitals had developed their own local list following an analysis of medication

incidents and near misses while other hospitals had adopted the Institute for Safe Medication Practices (ISMP) list of high-risk medications.¹²⁸

Inspectors found that of the 34 hospitals inspected, 31 had a list of high-risk medicines and three hospitals had neither a rationalised list of high-risk medications nor embedded processes to ensure that high-risk medications were stored, prescribed, dispensed and administered safely.

Six hospitals used the acronym 'A-PINCH' which grouped medications into categories to facilitate education and to raise awareness of high-risk medications.¹²⁹ The medications on the list included:

- A**nticoagulants and anti-thrombotic medicines
- P**otassium and intravenous Paracetamol
- I**nsulin's and intrathecal or epidural administration
- N**arcotics and neuromuscular blocking agents
- C**ytotoxic medicines
- H**ypertonic and hypotonic intravenous fluids.

Hospitals promoted medication safety awareness of high-risk medications through posters displaying the list of high-risk medications.

High-risk medications lists are ineffective unless risk-reduction strategies are in place and underpinned by policies, procedures and guidelines.¹²⁷ Many hospitals had implemented a number of high impact risk-reduction strategies which reduced unwarranted variation and promoted the safety of prescribing and administration of high-risk medicines. However HIQA found that other hospitals relied solely on low-leverage risk-reduction strategies to prevent errors, such as staff education and appeals for staff awareness.

Hospital policies reviewed by HIQA relating to the use of high-risk medicines detailed a requirement for independent double-checks of high-risk medications. Independent double checks can be a useful mid-range strategy when applied correctly and used in combination with other error reduction strategies. However, it is important that this strategy is not assigned in isolation as a management strategy for all high-risk medications and result in an over reliance on staff vigilance to keep patients safe when receiving high-risk medications.

Some hospitals put in place measures such as removal of stocks of non essential high-risk medications from patient care areas and or dispensing high-risk medicines on a named patient basis only.

Other medication safety initiatives

Medication safety has been identified by a number of bodies in Ireland as a key focus for improvement.^{23,24,25,26,27} International research highlights a number of successful strategies that have been implemented to reduce medication incidents^{29,127,128,130,131} These strategies include having a standardised medication record, improved medicines distribution systems and technology, smart pump infusions for intravenous medicine administration, electronic medication management system for prescribing medicines and medication reconciliation.

A Health Service Executive report entitled 'safermeds'^{§§§§§§§§§§} published in 2016 identified areas for improvement with medication safety.¹³² HIQA found, during inspections, that a number of medicines quality improvement initiatives had been implemented consistent with recommendations relating to the 'safermeds' report 2016.

HIQA found that a little more than half of the hospitals inspected had medication safety quality improvement initiatives that were strategically driven by learning gained from analyses of medication incidents or near misses. Other hospitals had implemented some quality improvement initiatives to support medication safety although these were not strategically driven.

HIQA found that medication quality improvement initiatives were sometimes implemented in response to a medication incident focusing on specific, circumscribed or restricted safety initiatives to manage the incident. HIQA recognise that this is a necessary and important endeavour. However, this approach is reactive in nature and it means that action is only taken after something goes wrong. Quality improvement with medication safety could be further enhanced with a strategic focus on targeted risk areas identified through other means, such as national or international trends.^{29,127,130,131} A proactive strategic approach means that improvements with medication safety are implemented before an incident occurs and harms a patient.

HIQA found that of the 34 hospitals inspected, 16 were significantly advanced in comparison to other hospitals in implementing medication safety quality improvement initiatives. A further 11 had implemented some quality improvement initiatives, and seven hospitals had only implemented one or two medication quality improvement initiatives.

^{§§§§§§§§§§} The National Medication Safety Programme, "Safermeds", is one of the priority safety programmes within the HSE Quality Improvement Division.

In many hospitals with fewer quality improvement initiatives there was some correlation with resources. However, despite a lack of resources in other hospitals, HIQA found examples of quality improvements implemented due to considerable effort and leadership by individual clinicians and managers. Although commendable, medication safety initiatives that depend on individuals to implement and monitor progress are less sustainable in the long term.

HIQA found that while 20 of the 34 hospitals inspected had implemented similar medication safety quality improvement initiatives within the previous two years as outlined in Figure 11 below, other hospitals were more advanced and used electronic technology to support medication safety.

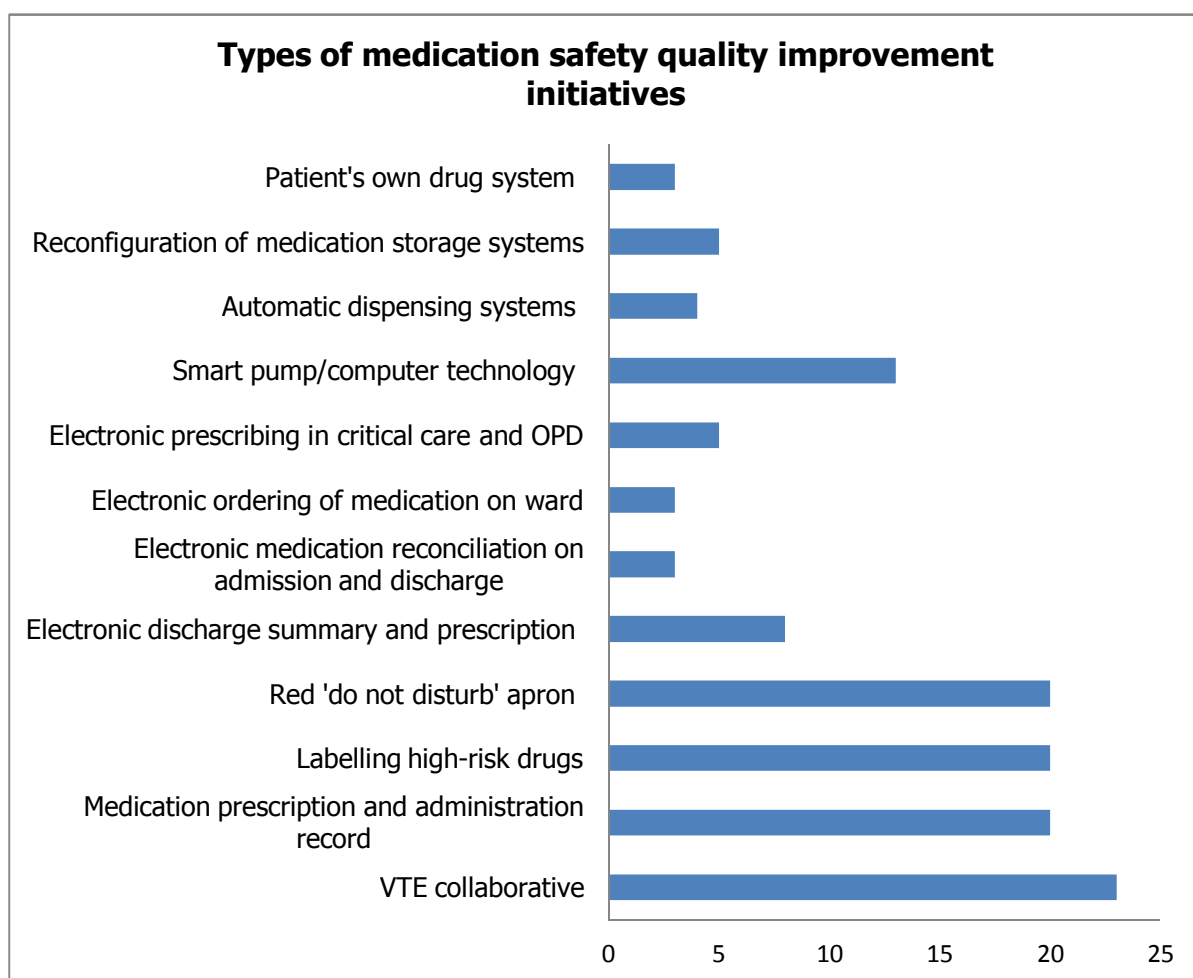


Figure 11. Medication safety quality improvement initiatives implemented by public acute hospitals. (Red apron *****)

***** Red 'do not disturb' aprons: were worn by nurses to reduce interruptions during medicines administration as interruptions during medication administration rounds can contribute to medications errors.

One example used in the Rotunda Hospital is detailed below.

Medication safety bundle, Rotunda Hospital

The Rotunda Hospital had implemented a medication safety bundle containing multi-faceted risk-reduction strategies to reduce the risks associated with the use of high-risk continuous infusions in the Neonatal Intensive Care Unit (NICU).

Risk-reduction strategies included an electronic dose calculator for high-risk continuous infusions, standard concentration intravenous infusions, electronic prescriptions and syringe labels for high-risk continuous infusions, and smart pump technology.

The numbers of medication therapy issues which warranted intervention by the clinical pharmacist in the Neonatal Intensive Care Unit were measured before and after implementation of the medication safety bundle. Inspectors were informed that the implementation of the care bundle had resulted in a significant reduction in the number of clinical pharmacist interventions related to high-risk continuous infusions in the NICU.

Improvements with medication prescribing records

Common to all public acute hospitals inspected were prescribing errors identified through incident reporting, prescribing audits or nursing metric data. Hospitals responded with a revision of their medication prescription and administration record to reduce medication errors. For example, some adult medication prescription and administration charts were redesigned to include sections designated to antimicrobials, venous thromboembolism risk assessment and allergy status in response to medication incidents.^{133,134,135}

Overall, HIQA found that 20 of the 34 hospitals inspected had reviewed their local medication prescription and administration record to reduce procedural or clinical prescribing errors and inspectors found many examples of different designed medication prescription and administration records in hospitals inspected. Two paediatric hospitals had collaborated to develop a new medication prescription and administration record with features to reduce medication errors.

Medication prescription and administration records were not standardised between hospitals or within hospital groups. During the course of these inspections the HSE

published a National Medication Record Template for Adult Acute Care. These templates were intended to be used as an aid in the development or revision of local medication records, to incorporate good and safe practice but not be regarded as a definitive national standard. The HSE recommended that each hospital should take responsibility to ensure that its medication record is designed, tested, used and revised appropriately and safely.¹³⁶

Venous thromboembolism prophylaxis

HIQA found that the majority of hospitals inspected reported that they had implemented the Health Service Executive's (HSE) Quality Improvement Division initiative to improve venous thromboembolism⁺⁺⁺⁺⁺ (VTE) prevention.¹³³ This was a collaboration among multidisciplinary teams in Irish adult public acute and voluntary hospitals to achieve appropriate thromboprophylaxis⁺⁺⁺⁺ for their hospital's inpatients, to reduce the risk of venous thromboembolism and to minimise harm and expenditure associated with unnecessary thromboprophylaxis.

Improving medication safety practices in operating theatres

A hospital's operating theatre can be a high-risk area for medication errors.^{137,138, 139} High risks with intravenous medications were identified in previous reports as part of HIQA's prevention and control of healthcare-associated infection programme as outlined below:

'Scope to improve preparation, labelling and storage of intravenous medication in the clinical area was a re-occurring finding in 19 of the 32 inspections. Inspectors found risks relating to the preparation of intravenous anaesthetic and emergency medicines and intravenous fluids in advance of giving these medicines to patients. These medicines had been stored inappropriately, left unattended and were not sufficiently and safely labelled. This was especially noticeable in operating theatres'.¹⁴⁰

HIQA found that a number of hospitals had implemented medication related quality improvement initiatives in operating theatres due to the high-risk nature of this area. This included the introduction of pre-filled labelled syringes in operating theatres to prevent the risk of patients getting the wrong medicine.

⁺⁺⁺⁺ Venous thromboembolism (VTE): a blood clot consisting of deep veins thrombus (DVT) and pulmonary embolism (PE). Blood clots (thrombus) can form within deep veins (DVT) and these clots can fragment and travel to lungs leading to Pulmonary Embolism (PE).

⁺⁺⁺⁺ Thromboprophylaxis: any preventive measure or medication that reduces the likelihood of the formation of blood clots.

2.6 Evaluation and audit of medication safety

Line of enquiry:

- The effectiveness of medication management systems are systematically monitored and evaluated to ensure they are effective.

Hospitals should have arrangements in place to ensure the effectiveness of healthcare is systematically monitored and continuously improved. Review and evaluation of performance should use evidence-based information and metrics, focused on quality and safety outcomes for patients, using measures such as key performance indicators, audit and local, regional, national and international benchmarks. The information gathered should be used to improve services, and the learning gained should be shared throughout the hospital and, where relevant, with external organisations.¹²

Good clinical governance***** processes support and ensure the effectiveness of medication management systems through monitoring, evaluation and audit.¹⁷ A governing committee, such as the Drugs and Therapeutics Committee, should be responsible for planning and oversight of the performance of medication systems and how the medication safety is monitored.¹⁷

Evaluation of the use and safety of medicines should be planned in line with the hospital's overall priorities and the medication safety strategic plan. Evaluation of medication safety should be formally planned, regularly reviewed and centrally coordinated to ensure that recommendations and improvements required are undertaken, with a lead person identified for the implementation of audit findings within specific timeframes.¹⁷ Areas for focus could also include areas of high risk or poor quality identified through a variety of sources such as complaints, incidents, adverse outcomes, or variation in clinical practice.^{17,141} Hospital managers and clinical leaders should ensure that recommendations are implemented to provide assurance that changes made result in improvement for medication safety.

Learning from audit and evaluation of medication management systems should be shared locally via the most appropriate and effective mechanisms,¹⁴² so that the clinical workforce are informed of the areas that need improvement. Sharing findings also motivates staff to change practice and participate in improvement activities,^{17,141} while contributing to a culture of transparency and accountability. Collaboration between internal hospital departments and external hospitals can also be beneficial

***** Clinical governance is a system through which service providers are accountable for continually improving the quality of their clinical practice and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish. This includes mechanisms for monitoring clinical quality and safety through structured programmes, for example, clinical audit.

as the outcomes of a successful audit in one service may be transferable to other services.^{17,141}

HIQA found that elements of medication safety were evaluated and audited in the majority of hospitals inspected. However, monitoring of medication safety arrangements in many hospitals could be strengthened and formalised to provide assurances to senior management and clinician leaders. The establishment of a formal programme of evaluation and audit of medication safety could support this.

One in three hospitals inspected had medication audit plans, presented mostly as a list of the medication audits which the hospital planned to undertake within a given period of time, usually a year. Compliance with these audit plans was demonstrated in some hospitals through a review of completed audits, but some hospital's audit plans had only recently been developed.

Two hospitals had audit plans that were aligned to a formalised medication safety strategy. All hospitals demonstrated evidence of medication safety audits completed for example, audits of:

- medicines reconciliation
- adherence to prescribing guidelines
- appropriate thromboprophylaxis in adult medical and surgical patients
- nurse prescribers' medicinal product prescribing practices
- prescriber's compliance with revised hospital prescription and administration record
- point prevalence survey of healthcare-associated infection and antimicrobial use
- compliance with prescribing guidelines in the care of the patients with diabetes
- medication fridges security, temperature and contents
- postnatal analgesia audits.

HIQA found that only a small number of hospitals reported the results of audits to the governance group with responsibility for medication safety.

A number of hospitals reported that audit planning was influenced by medication incident reports and trends. One hospital conducted an annual medication management systems review and this supported the development of the annual audit plan. In addition to an annual audit plan, hospitals reported that other audits were commissioned if a concern was identified that needed further evaluation of potential or actual risk to patients.

HIQA found that areas of good practice and areas for improvements were identified in most audits undertaken by hospitals. However, where audits identified areas for improvement, the monitoring of these recommendations was not consistent. HIQA found that time frames and the person responsible for medication safety quality improvement implementation was often not identified. HIQA observed evidence of re-audit occurring in some, but not all, hospitals inspected in order to provide assurance that the desired improvements have been made against the outlined standards.

In addition, ownership of audits and responsibility for the management of audit findings and recommendations were identified as problematic in some hospitals. For example, this occurred when audits were initiated by doctors in training who moved regularly between hospitals and the recommendations in their audit reports were not handed over when they left.

One hospital identified this and took steps to address this as outlined below.

The Coombe Women & Infants University Hospital

The Coombe Women & Infants University Hospital informed inspectors that all non-consultant hospital doctors undertaking audits informed the Master of the hospital before commencing the audit.

Each non-consultant hospital doctor's audit was assigned a leader and or trainer, and in the event that the doctor left the hospital before that audit cycle was completed, the Master reallocated the audit to another non-consultant hospital doctor to ensure the audit cycle was completed and that learning was achieved by the hospital.

A few hospitals demonstrated good examples of medication safety quality improvement initiatives which were audited post implementation to ensure resultant improvement in practice occurred. An example of this is detailed in the box below.

Lean medicine management project in Our Lady of Lourdes Hospital, Drogheda

In 2016 the pharmacy department in this hospital had introduced a 'lean medicine management project' on selected wards to enhance patient care by ensuring the correct medicines were available with minimum effort, reducing staff time being spent on stock control and releasing staff time for patient care.

Following analysis of dispensing data, key interventions were introduced including revision of wards: medicines storage, medicines stock lists, top-up systems and ordering processes. The interventions resulted in significant improvement in efficiency with a 44% reduction in stock items being ordered, 40% reduction in nurses' time being spent requesting stock items, a 38% reduction in pharmacy technician time being spent on medicine stock top up and 56% reduction in medicines required from pharmacy out of hours.

Following the success of this project the pharmacy department planned to monitor and maintain progress on the current ward and extend the project hospital wide.

Audits should be centralised to promote quality management of the audit process and shared learning.¹⁴³ A number of hospitals reported that clinical audits were centrally coordinated, mostly by the clinical audit department, the quality department, or the medication safety officer. Two hospitals reported using the audit module within the hospital electronic document control system to support central coordination of audit and provide staff access to audit data.

Hospitals outlined a variety of methods used to share audit findings with staff including department quality and safety meetings, journal club meetings, the intranet, newsletters and local conferences and seminars. A number of hospitals held clinical audit days providing an opportunity for multidisciplinary staff to present to hospital staff on audits undertaken. Grand rounds, education sessions and hospital meetings were also identified as opportunities to share audit results. A few hospitals reported that audit results were distributed to clinical staff in hard copy, or were available to staff on the hospital's intranet or document management system.

Areas for improvement in the dissemination of audit results was identified by inspectors in a number of hospitals visited.

Other processes used by hospitals for evaluating the quality of the medication management services included key performance indicators and nursing metrics.

Nursing metrics

Nursing and Midwifery Quality Care-Metrics are a process of performance quality indicators which provide a framework for how fundamental nursing care can be measured. Nursing metrics were monitored across almost all hospitals inspected. Most hospitals were using the HSE's Nursing and Midwifery Quality Care Metrics,¹⁴⁴ while other hospitals had developed or adapted nursing metrics for local use. The majority of hospitals collected the metric data monthly, with frequencies of every two months and every quarter reported in other hospitals.

Nursing and midwifery and paediatric quality care metrics included a review of practices around prescribing, storage, custody and administration of medicines. The results were available in clinical areas and displayed on notice boards visible to staff and members of the public in a number of hospitals. Areas for improvement in prescribing-related metrics were identified by inspectors in almost all hospitals visited.

Key performance indicators

Key performance indicators⁺⁺⁺⁺⁺ were used by 28 hospitals to monitor performance and contribute to improvement. The number of key performance indicators measured varied between hospitals from measuring one indicator to measuring seven indicators. Key performance indicators are standards devised from evidence-based literature or consensus of experts to measure the quality of care, determine improvements required and positively impact care for patient.¹⁴⁵ The key performance indicators measured were reported to the Drugs and Therapeutics Committee and senior management in most hospitals. Results were also reported to prescribers, but to a lesser extent.

The Drugs, Therapeutics and Antimicrobial Stewardship Committee at the Royal Victoria Eye and Ear Hospital monitored medication safety using a number of key performance indicators as detailed below.

⁺⁺⁺⁺⁺ Key performance indicator: specific and measurable elements of practice that can be used to assess quality and safety of care.

Royal Victoria Eye and Ear Hospital: key performance indicators

Medication safety was monitored and evaluated at the Royal Victoria Eye and Ear Hospital through a number of key performance indicators.

Performance in relation to these key performance indicators was reported to prescribers, the Drugs and Therapeutics Committee and senior hospital management.

There was evidence of review, revision and expansion of these key performance indicators by the Drugs, Therapeutics and Antimicrobial Stewardship Committee for 2017 in documentation viewed by HIQA.

The types of key performance indicators demonstrated in the hospitals inspected included:

- concentrated potassium chloride usage
- medication safety incidents reported
- medication safety incidents which resulted in patient harm
- clinical pharmacists intervention
- antimicrobial consumption
- chemotherapy extravasations
- medication reconciliation undertaken by clinical pharmacist within 24 hours of admission
- compliance with prescribing guidelines.

2.7 Training and education

Line of enquiry:

- Safe prescribing and drug administration practices are supported by mandatory and practical training on medication management for relevant staff.

Research has shown that errors in healthcare are due to systems failures. For this reason, medication safety training and education should not primarily focus on making the individual healthcare worker more vigilant but should be delivered in conjunction with other risk-reduction strategies (Appendix 7). High-reliability organisations^{*****} use a systems approach to safety, and characteristics of these organisations include: well-trained personnel, teamwork, ongoing training, audits and continuous improvement initiatives.¹⁴⁶

The National Standards state that healthcare providers should recruit people with the required competencies to provide high-quality, safe and reliable healthcare. Those responsible for governance of healthcare organisations and hospitals should ensure that their workforce have these required competencies.¹²

The World Health Organization has recognised the importance of educating healthcare professionals on the principles and concepts of patient safety. There must be a prioritisation of education, training and research in relation to patient safety (which encompasses medication safety) in both undergraduate and postgraduate education, but this must also be incorporated in a systematic way into ongoing and lifelong learning for clinicians and healthcare managers.¹⁴⁷ Facilitating the development of collective knowledge, education, training and shared learning about unsafe practices is key to proactively supporting medication safety as individuals are rarely the single causes of errors.

Healthcare providers should plan and devise training and education programmes for their workforce based on strategic objectives and the needs of their patient population. New staff should attend formal induction training programmes and all staff should be provided with the required ongoing education and training to maintain their competency, skill and knowledge.¹²

***** High-reliability organisations are those which consistently or reliably seek to balance both safety and effectiveness while operating in a high-risk environment. High-reliability organisations operate within complex environments with the potential for risk or error with serious consequences. They use technologies and processes to minimise these risks with well-trained staff who focus on continuous improvement within a good safety culture, adaptable to change. They have collective mindfulness where responsibility and accountability for reliability is distributed throughout the organisation. Such organisations aim to increase the quality of attention and alertness across all departments and teams.

Investment in ongoing education for healthcare professionals must be seen as a priority and supported at a senior and executive level as it is important to improve patients' outcomes and is a pre-requisite to a high-quality, guideline-driven, evidence-based healthcare.¹⁴⁸

Education and training in relation to medication safety must be planned to ensure that staff can attend training, for example allocating time for frontline staff to attend in-house training. Some core characteristics of an effective medication safety training and education programme are listed below:^{17,43}

- providing education on induction and on an ongoing basis to inform the workforce of safe procedures for prescribing, supplying, dispensing, storing, compounding, administration and monitoring of medications
- providing education to clinicians about new medicines and associated protocols, guidelines and restrictions for their use
- ensuring all staff receive patient-safety training that includes high-risk medications and associated risk-reduction strategies
- providing risk management education including incident reporting, learning from errors that occurred in the hospital and other facilities, and human factors that lead to errors
- evaluation of the competency of new staff and ensuring clinicians have the requisite training, especially before working in specialist areas, e.g. oncology or critical care
- ensuring staff have the necessary support and time to attend training, this includes those that provide education and training
- involving pharmacists in education on medication management processes.

HIQA found that five hospitals had a comprehensive, ongoing medication safety training programme for staff. One hospital had an ongoing education programme for medication safety which was part of their overall strategy to increase awareness of the importance of medication safety. This programme was specific to medical consultants, non-consultant hospital doctors, nurses, clinical pharmacists and undergraduate students.

All hospitals inspected had provided some training in relation to medication safety for clinical staff. However, considering the high risk related to the use of medications in hospital, inspectors found in general there was a lack of strategic planning in

relation to education and training in medication safety and a lack of formal, ongoing education programmes.

Training conducted in relation to medication use and safety was usually limited to induction training for nurses and non-consultant hospital doctor's. However, there were some additional medication safety sessions provided for some staff on a variety of topics.

Documentation such as sign in sheets and ward lists provided assurance to hospital management regarding attendance. However, there was limited evidence of systems in place to monitor those who had, or had not, completed education sessions. It is the responsibility of managers to ensure that there is an appropriate method in place for the recording of all training. These records must be appropriately maintained and managed.

Some hospitals with well-developed medication safety programmes had devised novel and innovative ways to provide education to front-line staff to supplement formal education sessions. Examples observed by inspectors in hospitals included; 'one minute' tutorials^{§§§§§§§§§§§§§§§§}, 10 minute ward-based education sessions, lunchtime education sessions, e-learning programmes and medication safety newsletters.

§§§§§§§§§§§§§§§§ . 'One minute' tutorials involving a one minute presentation on one slide, circulated to staff through a variety of mediums, designed for multidisciplinary access to educational information.

Staff induction

All hospitals reported that nurses completed some elements of medication safety education on induction. The types of training included in nurses' induction are outlined in the figure 12 below.

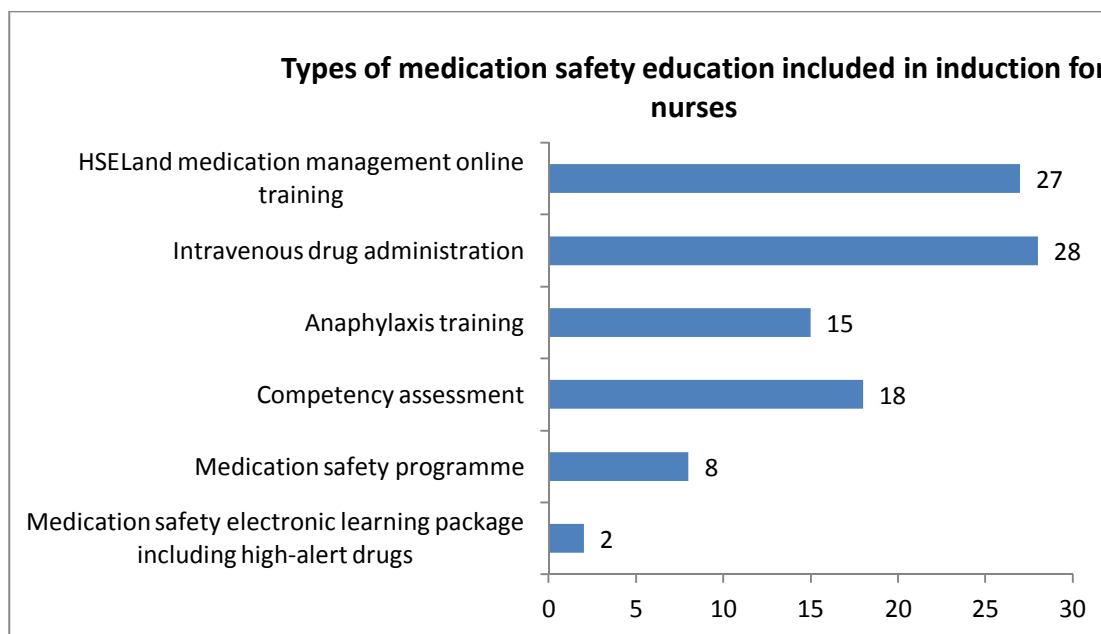


Figure 12: Types of medication safety education included in induction for nurses.

Almost all hospitals reported some form of medication safety training for non-consultant hospital doctors on induction, although the quantity and quality of the training varied across each hospital, some hospitals reported only 10 to 15 minutes allocated to medicines-related education on induction. To enhance staff education, some hospital pharmacy departments had provided additional medicines-related education sessions for non-consultant hospital doctors, but ensuring full attendance was identified as an ongoing challenge for the hospitals.

Ongoing education

No one method of providing education and information to staff has been proven to improve quality of healthcare; however, when a range of educational interventions are used together the effects may be improved.^{149,150,151} For example, a combination of individual, group and web-based training, discussion groups, conferences, local leaders, audit and incident feedback, educational material and reminders could support improvements in clinical care. HIQA observed a combination of these educational interventions in practice.

Awareness campaigns were untaken by some hospitals in relation to information on new medicines such as direct oral anticoagulants (DOAC). Inspectors were informed that these sessions were held during lunchtime meetings, grand rounds,^{*****} nurses' study days or ward-based education sessions.

Two hospitals inspected had held medication safety awareness weeks where different elements of medication safety were highlighted each day via promotional stands and information sessions. In addition a number of hospitals inspected reported that they had held medication safety awareness days.

A number of hospitals held multidisciplinary lunchtime education fora which included medication management topics; while another hospital facilitated ward-based medication safety awareness session and included medication issues and updates in the wards daily safety huddle.⁺⁺⁺⁺⁺ For example, a number of hospital informed inspectors that they used 'safety huddles' on the wards and in the pharmacy department to provide education sessions or updates to staff on specific topics relating to medication, to highlight areas for improvement and to encourage discussion around medication safety.

In addition to education and training, inspectors were given an account of how some hospitals distributed information regarding medication safety. These included:

- newsletters and memos
- ward communication books
- meetings
- journal clubs
- grand rounds
- development of booklets for staff.

Although all hospitals demonstrated evidence of medication management education at induction, with some additional education sessions, there was very limited evidence of structured ongoing medication safety education aligned to a medication safety programme.

^{*****} Grand rounds: are formal meetings where physicians and other clinical support and administrative staff discuss the clinical case of one or more patients. Grand rounds originated as part of medical training.

⁺⁺⁺⁺⁺ Safety huddles: are brief and routine meetings for sharing information about potential or existing safety problems facing patients or workers. They aim to increase safety awareness among front-line staff, allow for teams to develop action plans to address identified safety issues, and foster a culture of safety.

Recommendation

1. Hospitals must ensure healthcare professionals have the necessary competencies to deliver high-quality medication safety through induction and ongoing training. This should include a structured, targeted programme of education for medication safety aligned with the hospitals medication safety strategy.

3. Conclusion

'Medication without harm' is the challenge set by the World Health Organization in its Global Patient Safety Challenge on Medication Safety. Part of this challenge involves global and national programmes for medication safety including strategies, guidelines, plans and tools to make medication use safer for patients. The challenge to the wider healthcare service means mobilising resources and clearly mapping out a vision for medication safety based on international research and best practice to ensure that patients are protected from harm.³

To focus on this priority area for all public acute hospitals in Ireland, HIQA commenced a monitoring programme of medication safety in October 2016 and inspected 34 hospitals from this time to the end of 2017. During this monitoring programme HIQA identified significant variation between hospitals in relation to systems in place to support medication safety.

To achieve medication safety, clear corporate and clinical governance arrangements, with a formal strategy to map out a programme for improving the medication management process is required. While HIQA found that the majority of hospitals had evidence of planning current and future medication safety activities, there is a need for all hospitals to outline future direction in relation to medication safety.

While most hospitals had a Drugs and Therapeutics Committee, or formalised links with a committee located at a larger regional hospital, it is essential that all hospitals have a functioning Drugs and Therapeutics Committee to strengthen their governance arrangements and drive improvement in medication safety.

Although many hospitals had invested dedicated resources, time and effort into clinical pharmacy services and medication safety programmes over a number of years, HIQA found disparities in clinical pharmacy services, both in how they were provided and resourced. Therefore, there is a requirement for national planning to target resourcing to ensure consistency in baseline clinical pharmacy service provision across all models of hospitals to ensure the safe use of medicines. While there may be a case for targeted investment in some hospitals, it is important that any investment is accompanied by a clear strategic vision of what needs to be achieved.

Any evaluation of need should also be cognisant of the desired model of care to be adopted, and the key role that technology plays in driving efficiency and ensuring safety for patients. Should increased investment in clinical pharmacy resources be forthcoming, there will also need to be significant investment in support for clinical pharmacy management staff within Pharmacy Departments, through structured

training and peer support, to fully realise any potential benefits that might be expected.

Patients and their families should be given information and educated about the medications they are prescribed so that they can protect themselves from harm. However, considerable variation in how patients were given information about new medicines across the hospitals inspected was identified both by the questionnaire distributed as part of this monitoring programme and in the findings of the first National Patient Experience Survey 2017.¹¹¹ Hospitals must ensure that patients receive appropriate information in relation to their medicines.

While HIQA identified the existing presence of some collaboration and cooperation between hospitals during this monitoring programme, there is much more potential for this to yield benefits, especially within the framework of hospital groups. All healthcare providers, hospital managers and clinical leaders should work together to ensure evidence-based improvements are implemented and that learning is shared with the wider healthcare system in the interests of patient safety. It is recommended that individual hospitals should also look to engage with their peer hospitals in working to address similar improvement priorities.

Key to future developments is progressing eHealth and the use of technology to drive improvement and reduce human error in busy, complex and challenging environments. Inspection teams observed where hospitals had implemented technology-driven medication safety quality improvements. Many of these projects if shared could at local, regional and national level rapidly improve patient safety.

Overall, during this monitoring programme HIQA observed many examples of good practices and medication safety initiatives, driven by dedicated hospital staff, managers and clinicians who were committed to improving patient safety. This considerable body of work should be shared to improve patient safety and reduce variation throughout the Irish healthcare system, but requires commitment and effective planning to build on the progress achieved by individual hospitals to date. Strategic national planning and targeted investment is required to achieve genuine system improvement for patients and meet the challenge of medication without harm.

4. Glossary of terms

This glossary details key terms and a description of their meaning within the context of this document.

Accountability: being answerable to another person or organisation for decisions, behaviour and any consequences.

Acute services: hospital-based healthcare services for inpatients, outpatients and people having day-case treatments.

Adverse drug reaction: a response to a medicine which is noxious and unintended, and which occurs at doses normally used in humans for the prevention, diagnosis, or treatment of disease.

Anticoagulant: a medicine that is commonly referred to as blood thinners that prevent or treat blood clots, but these medicines also carry an increased risk of bleeding or clots, so patient education and regular monitoring of blood levels are essential to maintain patient safety and ensure good patient outcomes.

Assurance: being sure or certain about systems, processes and procedures and standing over business objectives. It involves monitoring risk and implementing controls to mitigate that risk.

Audit: a quality improvement process that seeks to improve service-users care and outcomes through systematic review of care against explicit criteria and the implementation of change.

Automation: is the method of making a machine, a process, or a system work without being directly controlled by a person.

Best practice: clinical, scientific or professional practices that are recognised by a majority of professionals in a particular field. These practices are typically evidence based and consensus-driven.

Best possible medication history: A standardised method of collecting and documenting an accurate current list of prescribed and non prescribed medication for an individual patient using as many sources of information as possible.

Clinical Audit: a quality improvement process that seeks to improve care and outcome through systematic review of care against explicit criteria and the implementation of change.

Clinical governance: a system through which service providers are accountable for continually improving the quality of their clinical practice and safeguarding high

standards of care by creating an environment in which excellence in clinical care will flourish. This includes mechanisms for monitoring clinical quality and safety through structured programmes, for example, clinical audit.

Clinical guidelines: systematically developed statements, based on a thorough evaluation of the evidence, to assist healthcare professional and patient decisions about appropriate healthcare for specific circumstances, across the entire clinical spectrum.

Clinical nurse specialist: a nurses with specially focused knowledge and skills, required to improve the quality of patient care with a clinical focus on assessment, planning, delivery and evaluation of care given to patients and their families.

Clinical pharmacist: qualified pharmacist who develops and promotes the rational, safe and appropriate medication usage.

Clinical pharmacy service: describes the activity of pharmacy teams in ward and clinic settings.

Corporate governance: the system by which services direct and control their functions in order to achieve organisational objectives, manage their business processes, meet required standards of accountability, integrity and propriety and relate to external stakeholders.

Culture: the shared attitudes, beliefs and values that define a group or groups of people and shape and influence perceptions and behaviours.

Decision support tools: are resources that provide guidance or incorporate knowledge to help clinicians make the most appropriate clinical decision for patient care.

Direct oral anticoagulants (DOAC): medications used to treat or prevent blood clots. However, there is a potential for bleeding with their use or clotting leading to stroke with missed doses. Options for anticoagulation have been expanded recently with the introduction of new anticoagulants called direct oral anticoagulants

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

Drugs and therapeutics committee: a multidisciplinary group of people from within and outside a hospital or group of hospitals, which reports to senior management. The committee is responsible for expert governance, oversight and

review of the service to ensure safe and effective medication usage in the hospital or hospitals in question.

Effective: a measure of the extent to which a specific intervention, procedure, treatment, or service, when delivered, does what it is intended to do for a specified population.

Efficient: use of resources to achieve best results with minimal waste.

Electronic Health (eHealth): involves the integration of all information and knowledge sources involved in the delivery of healthcare via information technology-based systems. eHealth Ireland was established by the Department of Health in 2015 to focus on the promotion and implementation of an eHealth agenda across the Irish Health Service. It is managed through the Office of the Chief Information Officer.

Electronic prescribing and administration record: computerised system which facilitates the communication of prescriptions enabling prescriptions to be reviewed modified and generated with better oversight of medication management processes. The system supports legible and complete prescriptions and facilitates better communication, traceability, audit, improved access for prescribers and potential savings on costs and resources.

Forcing functions: are design processes so errors are virtually impossible to make, for example removal of a product from use such as potassium.

Formulary: a managed list of preferred medicines that have been approved by the hospital's Drugs and Therapeutics Committee for use at the hospital. Use of a formulary ensures governance oversight of the introduction and ongoing use of medicines in practice at the hospital, and in doing so ensures an appropriate level of management control over medicines use, in the interest of both patient safety and financial management.

Grand rounds: formal meetings where physicians and other clinical support and administrative staff discuss the clinical case of one or more patients. Grand rounds originated as part of medical training.

Governance: in healthcare, an integration of corporate and clinical governance; the systems, processes and behaviours by which services lead, direct and control their functions in order to achieve their objectives, including the quality and safety of services for service users. See also **Clinical governance** and **Corporate governance** above.

Harm: impairment of structure or function of the body and or any detrimental effect arising from this, including disease, injury, suffering, disability and death. Harm may be physical, social or psychological. The degree of harm relates to the severity and duration of harm, and the treatment implications, that result from a patient safety incident. Degrees or levels of harm include:

- None — service-user outcome is not symptomatic or no symptoms have been detected and no treatment is required.
- Mild — service-user outcome is symptomatic, symptoms are mild, loss of function or harm is minimal or intermediate but short term, and no or minimal intervention (for example, extra observation, investigation, review or minor treatment) is required.
- Moderate — service-user outcome is symptomatic, requiring intervention (for example, additional operative procedure or additional therapeutic treatment), an increased length of stay, or causing permanent or long-term harm or loss of function.
- Severe — service-user outcome is symptomatic, requiring life-saving intervention or major surgical or medical intervention, shortening life expectancy or causing major permanent or long-term harm or loss of function.
- Death — on balance of probabilities, death was caused or brought forward in the short-term by the incident.

Healthcare: services received by individuals or communities to promote, maintain, monitor or restore health.

Health Service Executive (HSE): provider and or funder of all of Ireland's public acute healthcare services or any subsequent agency that takes on the HSE's statutory functions.

High-risk medications: medicines that bear a heightened risk of causing significant patient harm when they are not used correctly. Errors with these medicines may not be more common than those from other groups but their consequences can be more devastating as they have smaller margins of safety than other medications and therefore warrant particular caution in their handling. These are also known as 'High-Alert' Medications.

Hospital Groups: the hospitals in Ireland are organised into Seven Hospital Groups. 1. Ireland East Hospital Group. 2. Dublin Midlands Hospital Group. 3. South/South West Hospital Group 4. Saolta Hospital Group. 5. University Limerick Hospitals Group. 6. RCSI Hospitals Group. 7. National Children's Hospital Group. The

services delivered include inpatient scheduled care, unscheduled/emergency care, maternity services, outpatient and diagnostic services. The Group Chief Executive of each Hospital Group reports to the National Director for Acute Services and is accountable for their Hospital Groups planning and performance under the HSE Accountability Framework.

Indicators are measurement tools, screens, or flags that are used as guides to monitor, evaluate, and improve the quality of patient care, clinical support services, and organisational function that affect patient outcomes.

Information and communication technology (ICT): the tools and resources used to communicate, create, disseminate, store and manage information electronically.

Intravenous medication monographs: an approved set of standardised and approved instructions for the correct preparation and administration of intravenous medication, that have been designed to reduce the risk of error, and that are specifically tailored to the intravenous medicines stocked within the hospital.

Just culture: an environment which seeks to balance the need to learn from mistakes and the need to take disciplinary action.

Key performance indicator: specific and measurable elements of practice that can be used to assess quality and safety of care.

Latent failure: a failure that lies dormant in the system, usually removed from the direct control of the practitioner that may or may not become an active error.

Medication incident: any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing, order communication, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

Medication management: clinically-effective cost-effective and safe use of medicines to ensure that service users get the maximum benefit from the medicines they need while at the same time minimising the potential harm.

Medication management process: including; selection, procuring storing, ordering, prescribing, transcribing, distribution, preparing, dispensing, administration documentation, reconciliation, monitoring and disposal of medications

Medication reconciliation: involves using a systematic process to obtain an accurate and complete list of all medications taken prior to admission, discharge and other transitions in care.

Medication safety: freedom from preventable harm with medication use.

Medication safety officer: a clinical practitioner designated by the hospital to serve as the authoritative expert in safe medication use.

Medications optimisation: a person-centred approach to safe and effective use of medications, to ensure people obtain the best possible outcomes from their medications. Medications optimisation differs from medication management in a number of ways with a focus on outcomes and patients rather than process and systems.

Medication safety programme: a programme designed to drive best practice in medication safety by guiding and collaborating with healthcare professionals involved in the medication use process in order to proactively assess and minimise patient risk, and implement quality initiatives to eliminate avoidable harm from medication.

Metrics: parameters or measures of quantitative assessment used for measurement and comparison or to track performance.

Model 1, 2, 3 and 4 hospitals: in 2010, the HSE's National Acute Medicine Programme described four generic acute hospital models (model 1, 2, 3 and 4). Their purpose was to define the level of service that can be safely provided at acute hospitals within the constraints of available facilities, staff, resources and local factors.

Model-1 hospitals are community and or district hospitals and do not have surgery, emergency care, acute medicine (other than a select group of low-risk patients) or critical care.

Model-2 hospitals can provide the majority of hospital activity including extended day surgery, selected acute medicine, local injuries, a large range of diagnostic services, including endoscopy, laboratory medicine, point-of-care testing, and radiology – computed tomography (CT), ultrasound and plain-film X-ray – specialist rehabilitation medicine and palliative care.

Model-3 hospitals admit undifferentiated acute medical patients; provide 24-seven acute surgery, acute medicine, and critical care.

Model-4 hospitals are tertiary hospitals and are similar to model-3 hospitals but also provide tertiary care and, in certain locations, supra-regional care.

Monitoring: systematic process of gathering information and tracking change over time. Monitoring provides a verification of progress towards achievement of objectives and goals.

Multidisciplinary: an approach to the planning of treatment and the delivery of care for a service user by a team of healthcare professionals who work together to provide integrated care.

National incident management system: National Incident Management System (NIMS) is a risk management system that enables hospitals to report incidents in accordance with their statutory reporting obligation to the State Claims Agency (Section 11 of the National Treasury Management Agency (Amendment) Act, 2000).

Near miss: a near-miss incident is an incident which could have resulted in harm, but did not either by chance or timely intervention.

Non-consultant hospital doctor: doctors that have not yet reached hospital consultant grade. Non-consultant hospital doctors include specialist registrars, registrars, senior house officers and interns.

Open disclosure: an open, consistent approach to communicating with service users when things go wrong in healthcare. This includes expressing regret for what has happened, keeping the service user informed, providing feedback on investigations and the steps taken to prevent a reoccurrence of the adverse event.

Patient: a person who is receiving healthcare or treatment (sometimes referred to as a service user).

Patient safety: is the term used nationally and internationally to describe the freedom from unnecessary harm or potential harm associated with healthcare services and the reduction of risk of unnecessary harm to an acceptable minimum (World Health Organization, 2009).

Patient safety incident: as defined in the Health Information and Patient Safety Bill Revised General Scheme (2015) a 'patient safety incident' means:

- a) any unintended or unanticipated injury or harm to a service user that occurred during the provision of a health service,
- b) an event that occurred when providing a health service to a service user that did not result in actual injury or harm but there are reasonable grounds

to believe that the event concerned placed the service user at risk of unintended or unanticipated injury or harm,

c) an incident that was prevented from occurring due to timely intervention or chance and which there are reasonable grounds for believing could have resulted, if it had not been so prevented, in unintended or unanticipated injury or harm to a service user during the provision of a health service to that service user.

Policy: a written operational statement of intent which helps staff make appropriate decisions and take actions, consistent with the aims of the service provider, and in the best interests of service users.

Prophylaxis: a medication or a treatment designed and used to prevent a disease from occurring.

Quality improvement: a systematic approach using specific methods to improve quality through achieving successful and sustained improvement.

Risk: the probability of danger, loss or injury within the healthcare system. Risk is the effect of uncertainty on objectives. It is measured in terms of consequences and likelihood.

Risk assessment: refers to the overall process of risk analysis and risk evaluation. Its purpose is to develop agreed priorities for the identified risks. It involves collecting information through observation, communication and investigation.

Risk management: the systematic identification, evaluation and management of risk. It is a continual process with the aim of reducing the risk of injury to patients, staff, and visitors and the risk of loss to the organisation itself.

Risk Register: a risk register is a risk management tool. It acts as a central repository for all risks identified by an organisation and, for each risk includes information such as risk probability, impact controls and risk owner.

Safety culture: an integrated pattern of individual and organisational behaviour, based upon shared beliefs and values, which continuously seeks to minimise service-user harm which may result from the processes of care delivery.

Safety huddles: brief and routine meetings for sharing information about potential or existing safety problems facing patients or workers. They aim to increase safety awareness among front-line staff, allow for teams to develop action plans to address identified safety issues, and foster a culture of safety.

Service user: a 'service user' refers to a person who uses healthcare (including mental health) services.

Smart-pumps: computerised infusion devices with multiple safety features that include customised drug libraries, dose calculations based on programmed patient weights and the setting of dose limits.

Strategic plan: a focused guide which outlines future direction for an organisation through the development of targets to achieve strategic goals. It generally projects a medium to long-term vision (three to five years) and enables the development of an operational plan, aligned to identify needs.

System: a set of interdependent elements, both human and non-human, interacting to achieve a common aim.

Staff: the people who work in, for or with the service provider. This includes individuals who are employed, self-employed, temporary, volunteers, contracted or anyone who is responsible or accountable to the organisation when providing a service to patients.

Standard: describes the high-level outcome required to achieve a quality, safe service.

Standard treatment guidelines or prescribing guides: these consist of systematically developed statements to help prescribers make decisions about appropriate treatments for specific clinical conditions.

Terms of reference: a set of terms that describe the purpose and structure of a project, committee or committee.

Transition of care is the movement of a patient from one setting of care to another. Settings of care may include hospitals, primary care, long-term care facilities, home health, and rehabilitation facilities. Transitions increase the risk of error due to the potential for miscommunication.

Venous thromboembolism: is a blood clots consists of deep veins thrombus DVT and pulmonary embolism (PE). Blood clots (thrombus) can form within deep veins (DVT) and these clots can fragment and travel to lungs leading to Pulmonary Embolism (PE).

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6. Appendices

Appendix 1

List of hospitals inspected (in chronological order)

Number	Date of inspection	Hospital	Model of hospital
1.	November 2016	Bantry General Hospital	2
2.	November 2016	Connolly Hospital	3
3.	November 2016	Mater Misericordiae University Hospital	4
4.	November 2016	Naas General Hospital	3
5.	December 2016	Nenagh Hospital	2
6.	December 2016	Sligo University Hospital	3
7.	December 2016	University Hospital Waterford	4
8.	March 2017	Midland Regional Hospital Tullamore	3
9.	March 2017	Rotunda Hospital	Specialist
10.	March 2017	St Michael's Hospital	2
11.	April 2017	National Maternity Hospital	Specialist
12.	April 2017	Midland Regional Hospital Mullingar	3
13.	April 2017	St Vincent's University Hospital	4
14.	May 2017	Galway University Hospital	4
15.	May 2017	Our Lady's Children's Hospital	Specialist
16.	May 2017	Tallaght Hospital	4
17.	May 2017	University Hospital Limerick	4
18.	June 2017	Kilcreene Orthopaedic Hospital	Specialist
19.	June 2017	Roscommon University Hospital	2
20.	June 2017	St Columille's Hospital	2
21.	June 2017	St Luke's Hospital, Rathgar	Specialist
22.	July 2017	Cappagh National Orthopaedic Hospital	Specialist
23.	July 2017	Mallow General Hospital	2
24.	July 2017	Portiuncula University Hospital	3
25.	July 2017	St James' Hospital	4
26.	August 2017	Letterkenny University Hospital	3
27.	August 2017	Mayo University Hospital	3
28.	August 2017	Our Lady of Lourdes Hospital	3
29.	August 2017	South Infirmary Victoria University Hospital	2
30.	September 2017	Mercy University Hospital	3
31.	September 2017	Midlands Regional Hospital Portlaoise	3
32.	September 2017	Royal Victoria Eye and Ear Hospital	Specialist
33.	October 2017	Coombe Women & Infants University Hospital	Specialist
34.	October 2017	St Luke's General Hospital, Kilkenny	3

Appendix 2: Monitoring methodology

HIQA’s medication safety monitoring programme was planned to broadly follow three distinct phases (P1, P2, P3) as outlined in Figure A2.1 below. The rationale for using a phased approach was to allow and encourage incremental improvement in the systems in place in public acute hospitals.

During the first phase, the findings of which are detailed in this report, HIQA focused on the fundamental governance and structure requirements to support a medication safety programme.

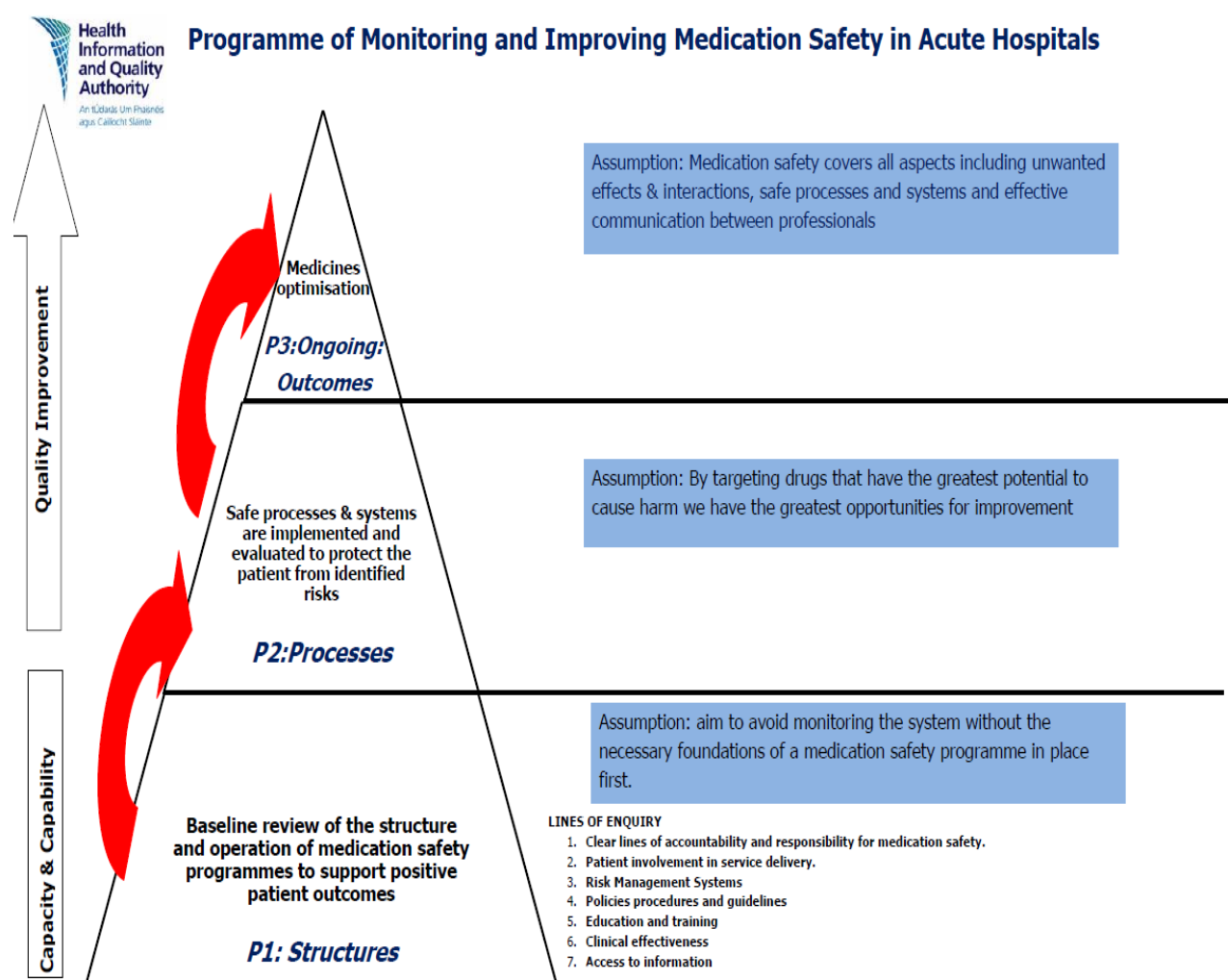


Figure A2.1: Programme of monitoring and improving medication in acute hospitals

In future phases, HIQA plans to build upon the approach taken in phase one and examine in further detail how hospitals have designed, implemented and are monitoring the ongoing effectiveness of defined medication safety processes and systems. Phase two will focus on how the medication safety systems operate in

practice to prevent latent failures contributing to medication error. Phase three will focus on medication optimisation.^{ccc} Phase three will include a focus on how hospitals both involve patients, and mitigate risks associated with high-risk patient groups, high-risk medicines, high-risk clinical settings and transitions of care.

This monitoring programme was guided by an expert advisory group which assisted with the development of the monitoring programme and methodology. Membership included representation from patient advocacy groups, clinicians and a number of national professional bodies with relevant expertise from across the Irish health service.

Phase one monitoring methodology

To assess whether hospitals had the basic foundations and structures to ensure an effective medication safety programme, phase one of HIQA's medication safety monitoring programme:

- **measured performance** by carrying out announced on-site inspections in order to assess the structures and systems in place for medication management and safety.
- **assessed** if hospitals had the essential elements of a medication safety programme in place, with a particular focus on governance of medication safety, risk management, audit and evaluation of practice, policies, procedures and guidelines, access to information, staff training and patient information.
- **established** if hospitals had effective and safe medication management systems in place to ensure patient safety in line with international best practice and research.
- **provided hospitals with the findings** of the inspections to highlight examples of good practice and areas for improvement.
- **published** the findings of inspections on our website www.hiqa.ie.

The focus for phase one inspections was outlined in seven lines of enquiry, which were developed based on international best practice and research, and were aligned to the National Standards.¹²

These lines of enquiry were initially published and communicated to hospitals in October 2016 ahead of onsite inspections in HIQA's 'Guide to the Health Information and Quality Authority's Medication Safety Monitoring Programme in Public Acute

^{ccc} Medication optimisation is defined as 'a person-centred approach to safe and effective use of medications, to ensure people obtain the best possible outcomes from their medications'.

Hospitals' (available on HIQA's website <https://www.hiqa.ie/reports-and-publications/guide/guide-medication-safety-monitoring-acute-hospitals>).

This guide also gave hospitals required information on the inspection and monitoring process.

Lines of enquiry and associated standards from the National Standards for Safer Better Healthcare

Area to be explored	Line of enquiry ^{ddd}	National Standards for Safer Better Healthcare
Clear lines of accountability and responsibility for medication safety	Patient safety is enhanced through an effective medication safety programme underpinned by formalised governance structures and clear accountability arrangements.	3.1, 5.1, 5.2, 5.4, 5.5, 5.6, 5.8, 5.9, 5.10, 7.1
Patient involvement in service delivery	Patients and or carers are informed about the benefits and associated risks of prescribed medicines in a way that is accessible and understandable.	1.4, 1.5, 1.7, 3.1, 4.1
Policies procedures and guidelines	Hospitals develop effective processes to promote medication safety that are implemented and supported by clear and up-to-date policies, procedures and or protocols.	2.1, 3.1, 3.2, 3.3, 3.5, 3.6, 3.7, 5.8, 5.11, 8.1
Risk management	There are arrangements in place to identify, report and manage risk related to medication safety throughout the hospital.	3.1, 3.2, 3.3, 3.5, 3.6, 3.7, 5.8, 5.10, 5.11, 8.1
Audit and evaluation	The effectiveness of medication management systems are systematically monitored and evaluated to ensure they are effective.	2.8, 3.1, 5.8, 8.1
Education and training	Safe prescribing and drug administration practices are supported by mandatory and practical training on medication management for relevant staff.	6.2, 6.3
Access to information	Essential information of the safe use of medications is readily available in a user-friendly format and is adhered to when prescribing, dispensing and administering medications.	2.5, 8.1

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

Before inspection

Hospitals were given 10 days written notice of announced inspections and requested to complete a pre-inspection information request and return to HIQA within five working days. The reason for conducting an announced inspection was that inspectors needed to meet with key hospital personnel, such as the Chair of the hospital's Drugs and Therapeutics Committee that may not be available if the inspection was unannounced. HIQA also requested copies of the following to be submitted to HIQA in advance of inspections, if available:

- most recent medication safety programme plan and annual plan,
- new medicines application request form,
- Drugs and Therapeutics Committees terms of reference and minutes from the previous twelve months,
- an organogram clearly showing the lines of communication and cooperation between the hospital's Drugs and Therapeutics Committee and or Medication Safety Committee, the pharmacy department, the risk management team and or department and the hospital's senior management team.

The purpose of the pre-inspection information request was to provide the inspection team with baseline information about the hospital's medication safety programme and the governance in place for medication safety.

Before the inspection, inspectors reviewed key pieces of information relating to the hospital such as previous inspection reports, any relevant information received by HIQA relating to the hospitals, and other available published data. Particular issues that may have needed to be addressed during the inspection were discussed by the inspection team in preparation for the inspection.

To enable the effective operation of inspections hospitals were provided with a provisional inspection timetable, which outlined the personnel required for interview on the day.

The inspection process

On the day of the announced inspection, the inspection team contacted the hospital's Chief Executive Officer (CEO) and or General Manager on arrival at the hospital reception and met with the relevant hospital representatives. The inspection team began by outlining the purpose of the inspection and the plan for the day. Inspectors requested a list of additional documentation for review and requested that anonymous patient surveys be distributed to a small number of patients in the outpatient's clinic. The survey was offered to patients who were discharged from the hospital within the past year on regular medications.

Hospital management were informed that during the course of the day's inspection, inspectors would gather evidence relevant to medication safety through interviews with senior management and front-line staff, general observation in clinical areas, patient surveys and review of documentation at both ward and senior management levels.

Management were advised that if during the course of the inspection any specific risks were identified (that inspectors believe presented a risk to the health or welfare of patients) these would be escalated in line with HIQA's escalation process (Appendix 3 and 4).

Details on key findings from the inspection were communicated by the inspection team to hospital management on completion of the inspections. In addition, any specific risks identified by the inspection team were communicated to senior management and the hospital's CEO and or general manager.

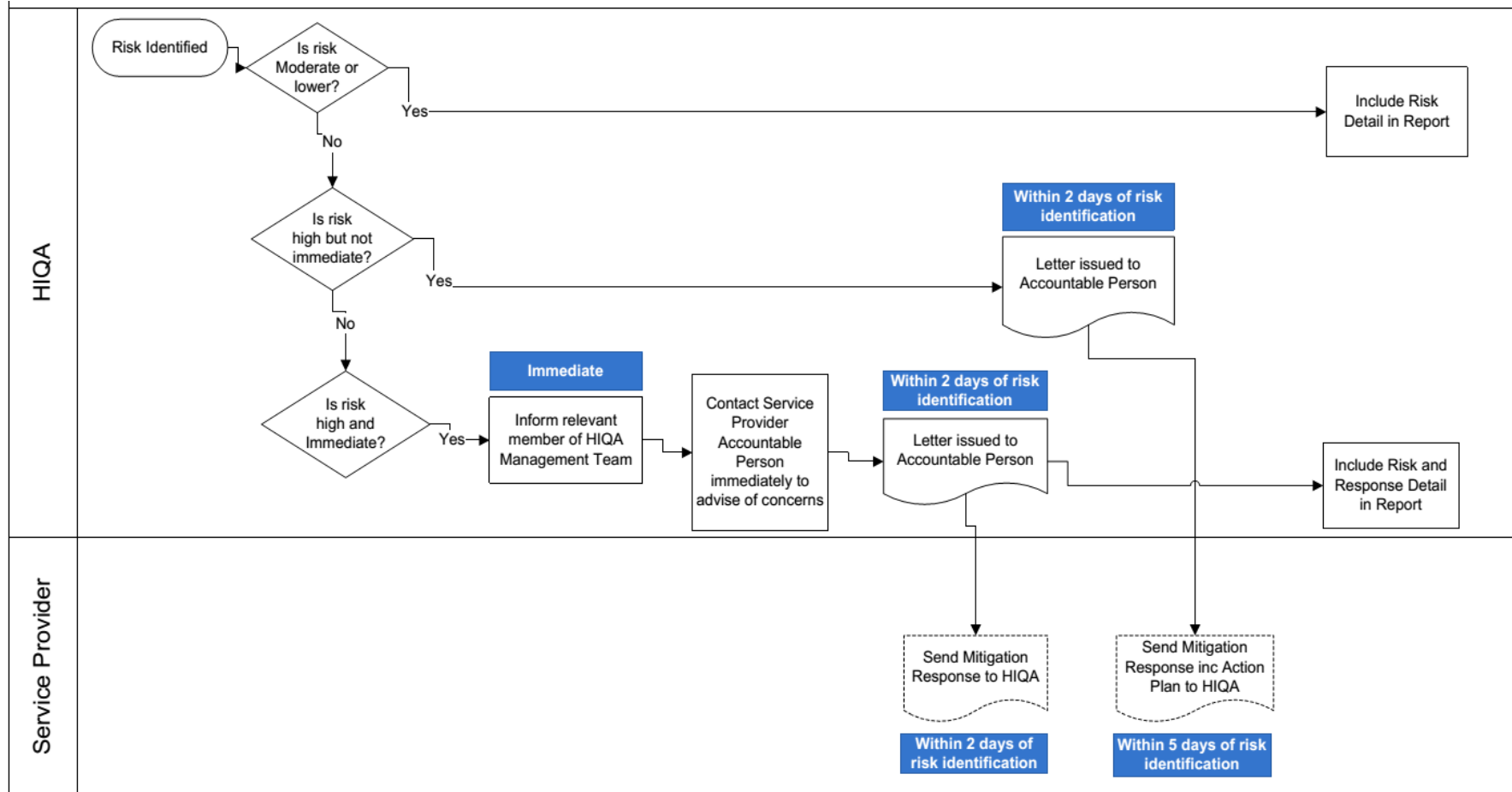
Where high risks were identified, the hospital was notified in writing within two days of the inspection and requested to formally report back to HIQA within five working days with an action plan detailing how the hospital were mitigating and managing these identified risks. Senior management in the Health Service Executive (HSE) were also notified in writing of identified risks.

A draft report detailing the findings from the inspection was returned to each hospital for a factual accuracy check, and final reports were subsequently published on HIQA's website.

Inspection teams conducted on-site monitoring in 34 hospitals in a variety of hospital models and geographical areas. Selection of sites (for inspection) was planned considering other HIQA monitoring activity to minimise hospitals having inspections by different HIQA programmes within a short period of time.

During the course of the inspections, HIQA identified specific issues in six hospitals that they believed presented a risk to the health or welfare of patients as summarised in Appendix 5. These were communicated verbally during the inspections, in writing to the hospitals immediately following inspection and detailed in individual hospital reports.

Appendix 3: HIQA Risk Escalation Process Map



Note: Accountable Person: identified individual who has overall executive accountability, responsibility and authority for the delivery of high quality, safe and reliable services.

Appendix 4: Risk matrix

Risk assessment process: the authorised persons will assess the consequence of the risk to patients and the probability of reoccurrence to determine the level of risk, using the tables below. The consequence of the risk and the probability of occurrence are both assessed and given a score from 1 to 5. The risk matrix is then used to give an overall risk score. This score then corresponds with the classification of risk table.

Consequence of the risk: what is the actual impact of the risk?

Consequence category	Impact on individual/future patients
1 Negligible	No obvious harm No injury requiring treatment
2 Minor	Minor injury No permanent harm
3 Moderate	Significant injury or ill health Some temporary incapacity
4 Major	Major injuries or long-term incapacity or disability Major permanent harm as result of clinical or non-clinical incident injuries or long-term incapacity or disability Major permanent harm
5 Catastrophic	Death

Probability of reoccurrence: what is the chance of this event occurring or reoccurring? Identify the 'probability rating' for reoccurrence from the following table:

Probability Score	Descriptor	Frequency
1	Rare	This will probably never happen or reoccur
2	Unlikely	Do not expect it to happen or reoccur again but it is possible
3	Possible	Might happen or reoccur occasionally
4	Likely	Will probably reoccur, but it is not a persistent issue
5	Almost certain	Will undoubtedly reoccur, possibly frequently

The lead authorised person classifies the risk using the risk matrix below and documents the findings that indicate the risk.

Risk Matrix

Probability ↓	Consequence category →				
	Negligible (1)	Minor (2)	Moderate (3)	Major (4)	Catastrophic (5)
Almost certain (5)	5	10	15	20	25
Likely (4)	4	8	12	16	20
Possible (3)	3	6	9	12	15
Unlikely (2)	2	4	6	8	10
Rare (1)	1	2	3	4	5

The risk is then classified as high, moderate, low or very low as per the risk matrix score. See classification of risk table below.

Classification of risk	Risk matrix score
High risk (red)	15, 16, 20 or 25
Moderate risk (orange)	8, 9, 10 or 12
Low risk (yellow)	4, 5 or 6
Very low risk (green)	1, 2 or 3

Appendix 5:

Risks identified

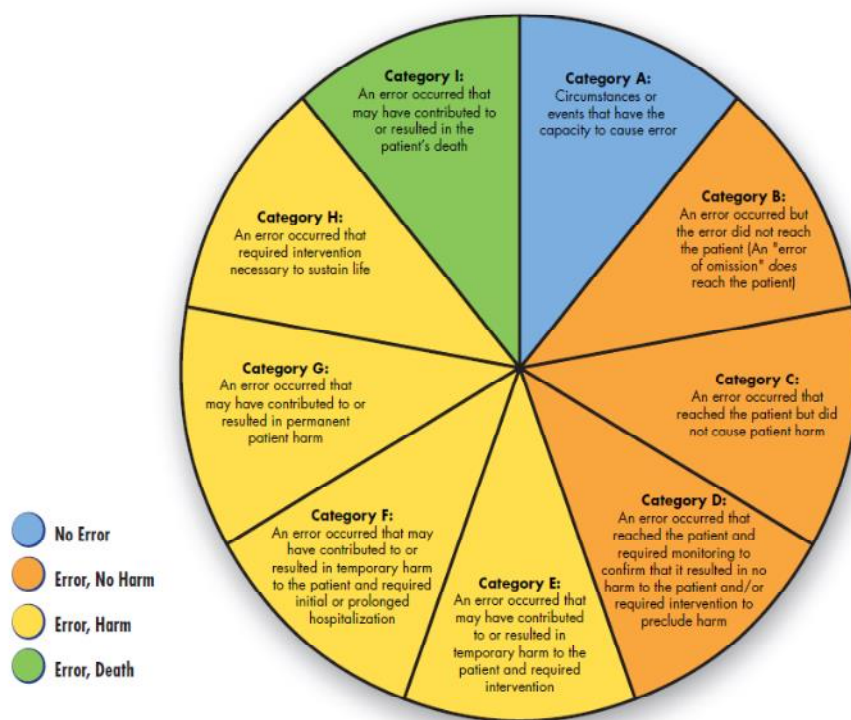
The risks identified during the medication safety monitoring programme in November 2016 to October 2017 are detailed below. These were escalated at the time of inspection as per HIQA escalation process.

Hospital name (in chronological order)	Summary of risk(s) identified by HIQA
Bantry General Hospital	HIQA identified a specific issue related to: Compatibility checking prior to the sharing of intravenous drug administration guidance documentation with another hospital.
Letterkenny University Hospital	HIQA identified an immediate high risk at the hospital related to a relative lack of leadership, governance and management of medication safety related risk at the hospital.
Midland Regional Hospital, Mullingar	<p>HIQA identified a composite of medication safety related risks at the hospital that may collectively present a serious risk to the health or welfare of patients, and immediate measures needed to be put in place to mitigate these risks.</p> <p>The immediate risks related to:</p> <ul style="list-style-type: none"> ▪ An identified relative lack of effective systems in place to ensure minimum standards of safety and quality are met relating to medication safety. In addition, the hospital had failed to act to fully address risks previously identified and communicated by HIQA to the hospital following an inspection related to antimicrobial stewardship in November 2015 relating to: <ul style="list-style-type: none"> – the ongoing lack of a Clinical Pharmacy service – the lack of up-to-date approved set of intravenous product information monographs – the ongoing presence of potentially conflicting reference information in the ward setting relating to advice in the reconstitution and administration of intravenous medication. <p>In addition, in reviewing the totality of findings from the inspection, the inspection team had determined that the current approach at the hospital to the leadership, governance and management of medication safety related risk was not sufficiently effective and represented a potential risk to</p>

	<p>patients. The risks concerned included:</p> <ul style="list-style-type: none"> ▪ The absence of strategic medication safety and operational plans detailing the development, implementation and maintenance of hospital wide medication safety systems. ▪ Inadequate arrangements in place to identify report and manage risks associated with medication use. ▪ An ongoing absence of a drug formulary to ensure that there are robust and transparent criteria for adopting, removing or updating the hospital’s drug prescribing list. ▪ A relative lack of current policies, protocols, and guidelines to support relevant clinical staff in safe prescribing and administration of medications at ward level.
<p>St Luke’s General Hospital, Kilkenny</p>	<p>HIQA identified specific risks related to:</p> <ul style="list-style-type: none"> ▪ the accommodation of paediatric patients undergoing medical assessment in an ancillary room with unsecure access to medications , clean and sterile consumables including needles, syringes, intravenous cannulae and sharps waste disposal bins ▪ preparation of intravenous medications within the patient zone.
<p>University Hospital Limerick</p>	<p>HIQA identified a composite of medication safety related risks at the hospital that need to be collectively and comprehensively addressed. The inspection identified an underdeveloped approach to medication safety at the hospital, and an apparent ongoing fragmented approach to leadership, governance and management of medication related risk across the group through the group Drugs and Therapeutics Committee.</p> <p>The risks concerned included:</p> <ul style="list-style-type: none"> ▪ inadequate arrangements in place to identify, report and manage risks associated with medication use - this results in poor awareness and underreporting of medication errors and near misses ▪ a lack of a cohesive approach to governance and oversight on the provision of pharmacy services to the five sites within the group ▪ poor compliance by the hospital Drugs and Therapeutic Committee with its own terms of reference ▪ the absence of an overarching strategy for medication safety, and associated operational plans detailing the development, implementation and maintenance of hospital wide medication safety systems. ▪ a relative lack of current policies, procedures, protocols and guidelines to support relevant clinical staff in safe prescribing and administration of medications at ward level. ▪ limited Clinical Pharmacy services, and the lack of formalised medication reconciliation process

	<ul style="list-style-type: none"> ▪ the absence of an evidence based local formulary of medications accepted for use in the organisation. <p>Notwithstanding these identified areas in need of improvement, Authorised Persons also identified more recent efforts to try to reconfigure the role and functioning of the Drugs and Therapeutics Committee, including new leadership of this committee. Moreover, HIQA acknowledged the intention to try to harmonise medication safety efforts through a group approach to governance.</p>
<p>University Hospital Waterford</p>	<p>HIQA identified a specific issue that may present a serious risk to the health or welfare of patients, and immediate measures need to be put in place to mitigate this risk. The immediate risk identified related to:</p> <ul style="list-style-type: none"> ▪ The availability of outdated and potentially conflicting reference information in clinical areas relating to advice in the reconstitution and administration of intravenous medication <p>During the course of onsite observation by authorised persons on three wards, it was observed that nurses continued to use different versions of legacy IV medication reference posters. This represents a risk as these were not current approved information sources, and it is possible that the instructions on the posters may not be compatible with the intravenous medicines currently used in the hospital. The hospital must ensure that out of date intravenous drug administration information in clinical areas are immediately retrieved and replaced throughout the facility with updated and standardised versions.</p> <p>In addition, in reviewing the totality of findings from the inspection, the inspection team has determined that the current approach at the hospital to the leadership, governance and management of medication safety related risk is ineffective and represents a risk to patients. The risks concerned include:</p> <ul style="list-style-type: none"> ▪ The absence of strategic and operational plans detailing the development, implementation and maintenance of hospital wide medication safety systems. ▪ Inadequate arrangements in place to identify, report and manage risks associated with medication use. ▪ A lack of systematic monitoring and evaluation of the effectiveness of medication management systems to ensure they are effective. ▪ A relative lack of policies, procedures, protocols and guidelines to support medical staff in safe prescribing and administration of medications.

Appendix 6: National Coordinating Council for Medication Error Reporting and Prevention. Index for Categorising Medication Errors



Definitions

Harm

Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting there from.

Monitoring

To observe or record relevant physiological or psychological signs.

Intervention

May include change in therapy or active medical/surgical treatment.

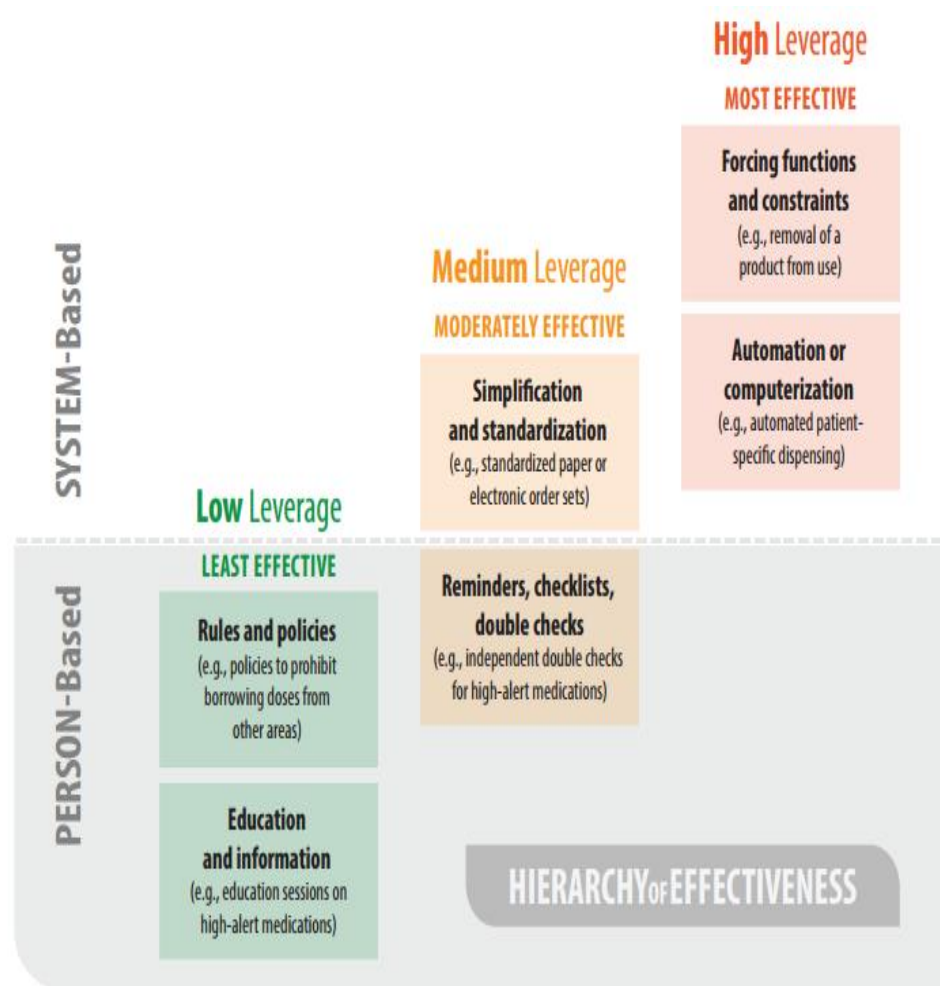
Intervention Necessary to Sustain Life

Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)

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Appendix 7: Hierarchy of effectiveness of risk reduction strategies in medication safety



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