Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Guide to HIQA's Medication Safety Monitoring Programme against the *National Standards for Safer, Better Healthcare* in acute healthcare services in 2019

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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.

Contents

1. Purpose of this guide

The purpose of this guide is to provide an understanding of the Health Information and Quality Authority's (HIQA) 2019 approach to HIQA's Medication Safety Monitoring Programme against the *National Standards for Safer, Better Healthcare* [1] (thereafter called the National Standards) to ensure patient safety in relation to medication safety.

This guidance document includes information about the:

- background to HIQA's medication safety monitoring programme
- the next phase of this monitoring programme
- focus on high-risk medications and high-risk situations
- format of HIQA's hospital inspections
- risk identification and notification processes
- HIQA inspection reports

This guide replaces the previous document entitled 'Guide to the Health Information and Quality Authority's Medication Safety Monitoring Programme in Public Acute Hospitals'[2] sent to all hospitals and published on www.hiqa.ie in October 2016.

The guide may be revised periodically as this monitoring programme progresses and or changes. Explanations of some terms used in this guide are contained in a glossary at the end of this document.

2. Background to HIQA's medication safety monitoring programme

Medications are the most commonly used intervention in healthcare. They play an essential role in the treatment of illness, managing chronic conditions and maintaining health and wellbeing. 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.[3]

Medication safety has been identified internationally as a key area for improvement in all healthcare settings. In March 2017, the World Health Organization (WHO)

identified medication safety as the theme of the third Global Patient Safety Challenge.[4] The WHO aims to reduce avoidable harm from medications by 50% over 5 years globally.

To achieve this aim the WHO have identified three priority areas including:

- improve medication safety at transitions of care
- reduce the risk in high-risk situations
- reduce the level of inappropriate polypharmacy.

Medication safety has also been identified by a number of bodies in Ireland as a key focus for improvement.[5,6,7,8,9,10] Medication safety programmes have been introduced in many hospitals to try to minimise the likelihood of harm associated with the use of medications, 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 a leadership level in the organisation, and through the introduction of s and processes that prevent and or mitigate the impact of medication-related risk.[11]

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's medication safety monitoring programme aims to:

Examine and positively influence the adoption and implementation of evidence-based practice in relation to medication safety in acute healthcare services in Ireland.

2019 will mark the third and final year of this specifically targeted monitoring programme. At the beginning of this programme, a Special Purpose Advisory Group was formed to assist with the development of the of the medication safety monitoring programme. This group has provided advice to HIQA in relation to the medication safety monitoring programme to date and this guidance has continued throughout this programme. The advisory group membership includes patient representation, alongside members with relevant expertise from across the Irish health service. See Appendix 1 for a list of members of the Special Purpose Advisory Group.

From 2016 to 2018, HIQA completed 44 hospital inspections including four re-inspections as part of the first phase of HIQA's medication safety monitoring programme.

A national overview report of the medication safety monitoring programme *'Medication safety monitoring programme in public acute hospitals- an overview of findings'* [12] was published in January 2018 which presented the findings from thirty-four public acute hospitals inspected during phase one of the programme (the report is available on HIQA's website, www.hiqa.ie).

HIQA's overview report identified areas of good practice in relation to medication safety and areas that required improvement to ensure medication safety systems were effective in protecting patients. A number of recommendations were made focusing on improving medication safety at a local and national level as detailed in the next section.

Key recommendations from HIQA's medication safety monitoring programme

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.

3. The next phase of HIQA's medication safety monitoring programme

To build on the first phase of the medication safety monitoring programme, HIQA has updated and developed their approach. From January 2019, HIQA will begin the next and final phase of the medication safety monitoring programme which will, as before, involve **announced inspections** of public acute hospitals in Ireland to examine and analyse systems in place to support safe practice in relation to medication safety against the *National Standards for Safer Better Healthcare* [1].

Inspection teams will assess the governance arrangements and systems in place to support medication safety in public, acute hospitals to determine if they are in line with international best practice and research. A particular focus for this phase of the medication safety monitoring programme will be **high-risk medications**[*] and **high-risk situations**[†].

As before, HIQA plans to monitor medication safety in public acute hospitals in Ireland to determine if they have:

- the required governance arrangements in place to drive improvement in medication safety
- a medication safety plan or strategy in place with appropriate supports
- the essential elements of a medication safety programme in place
- effective arrangements in place to protect patients from harm related to medication use, particularly in relation to high-risk medications and high-risk situations, in line with national and international best practice and research
- recognised medication safety as a priority at a senior management level

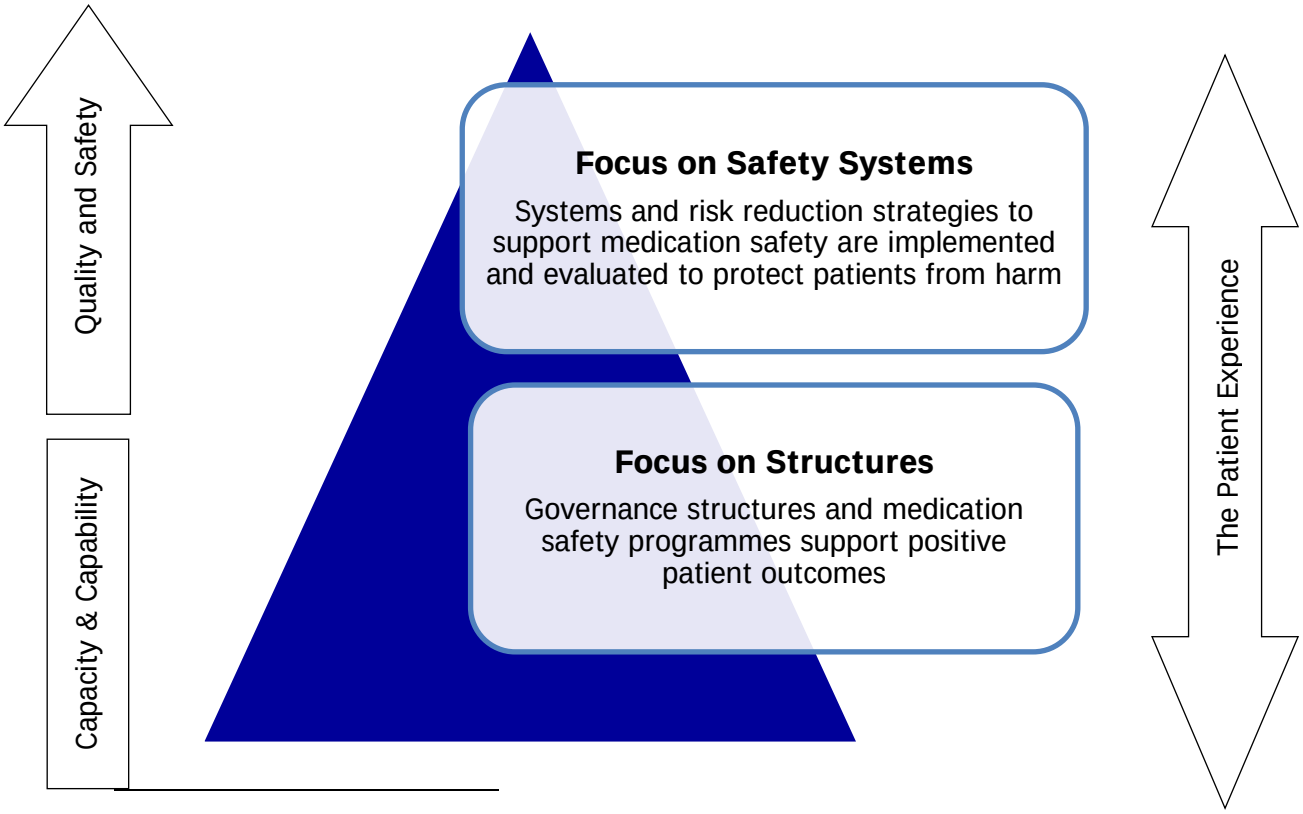
[*] High-risk medications are medications that have a high risk of causing significant patient harm or death when used in error.

† High-risk situations is a term used by the World Health Organization to describe situations where there is an increased risk of error with medication use. These situations could include high risks associated with the people involved within the medication management process (such as staff or patients), the environment (such as higher risk units within a hospital or community) or the medication. High-risk situations require risk reduction strategies to reduce avoidable errors.

A key difference of this phase of the medication safety monitoring programme will be an increased focus on evaluating clinical areas during inspections. This is to determine if the appropriate safety measures are in place to reduce risks associated with known high-risk medications and high-risk situations and whether these measures have been effectively implemented in practice (see figure 1 below). The monitoring approach outlined in this guidance document has been designed to ensure that HIQA focuses its monitoring activity in the areas of highest risk and avoidable harm for patients.

The revised programme will also explore, where present, some elements of medication optimisation[‡] to ascertain how hospitals both involve patients and mitigate risks associated with high-risk patient groups, high-risk medication and transitions of care.

Figure 1: Programme of monitoring medication safety in acute hospitals



[‡] Medications optimisation is 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.

4. Monitoring programme

The focus for the next phase of the medication safety monitoring programme is outlined below in eight lines of enquiry. Lines of enquiry are the key questions or prompts that inspectors use to help inform their inspection, assessment or investigation.

These lines of enquiry were developed based on international best practice and research, and are aligned to the National Standards[1].

The eight themes of the National Standards for Safer, Better Healthcare are aligned to dimensions of quality and safety (person-centred care and support, effective care and support, safe care and support, better health and wellbeing) and key areas of a service's capacity and capability (leadership, governance and management, workforce, use of resources and use of information). Each line of enquiry has been developed to reflect dimensions of quality and safety and key areas of capacity and capability and the National Standards as highlighted in Table 1 below. Some lines of enquiry listed below are aligned to National Standards that reflect both dimensions of quality and safety and key areas of a service's capacity and capability (for example line of enquiry 7). In these cases the dimensions/key areas that best reflect the intention and focus of the line of enquiry was selected.

Table 1: Lines of enquiry and associated National Standard for Safer Better Healthcare

Dimensions/ Key Areas	Line of Enquiry	Change from phase 1	National Standard
Capacity and capability	1. Patient safety is enhanced through an effective medication safety programme underpinned by formalised governance structures and clear accountability arrangements.	As per phase 1	3.7, 5.1, 5.2, 5.5, 5.4, 5.6, 5.11
Quality and Safety	2. There are arrangements in place to proactively identify, report and manage risk related to medication safety throughout the hospital.	Revised line of enquiry	3.1,3.2,3.3,3.6, 5.8, 5.11, 8.1
Quality and Safety	3. Hospitals implement appropriate safety measures for high-risk medications that reflect national and international evidence to protect patients from the	New line of enquiry	2.1, 3.1

	risk of harm.		
Quality and Safety	4. There is a person centred approach to safe and effective medication use to ensure patients obtain the best possible outcomes from their medications.	Revised line of enquiry	1.1, 1.5, 3.1, 2.2, 2.3
Quality and Safety	5. The model of service and systems in place for medication management are designed to maximise safety and ensure patients' healthcare needs are met.	Revised line of enquiry	2.1, 2.2 ,2.3, 2.6, 2.7, 3.1,3.3, 5.11, 8.1
Quality and Safety	6. Essential information on the safe use of medications is readily available in a user-friendly format and is adhered to when prescribing, dispensing and administering medications.	As per phase 1	2.1, 2.5, 8.1
Quality and Safety	7. Hospitals systematically monitor the arrangements in place for medication safety to identify and act on opportunities to continually improve medication.	As per phase 1	2.8, 5.8
Capacity and capability	8. Safe prescribing and drug administration practices are supported by mandatory and practical training on medication management for relevant staff.	As per phase 1	6.2, 6.3

The following areas will be out of scope of the current medication safety monitoring programme:

- medication management issues unrelated to patient safety
- management of controlled drugs
- antimicrobial stewardship
- non preventable adverse drug reactions or side effects.

Although these areas are considered to be out of scope of the next phase, should inspectors identify specific issues during the course of the inspection associated with the above areas, these risks will be communicated to hospital senior management in line with HIQA's risk escalation process (see section 7 of this guide).

5. Focus on high-risk medications and high-risk situations

High-risk medicines are those medicines that **have a high risk of causing significant patient harm or death when used in error**. Although the potential for error with high-risk medicines may or may not be more common than with other medicines, the consequences of errors with these medicines can be more harmful to patients.[13,14,15,16]

Medications identified as high risk may differ between hospitals and clinical units within hospitals depending on the types of medications used and patients treated. However certain group of medicines should universally be considered as high risk based on information and analysis of medication incident data and from research into medication safety. These medicines include anti-infective agents, anti-psychotics, intravenous potassium, insulin, narcotics and sedative agents, chemotherapy, heparin and other anticoagulants and are often represented by the acronym 'A PINCH' (see Appendix 2).

In addition to lists such as APINCH, the Institute for Safe Medication Practices periodically publishes a list of High-Alert Medications in Acute Care Settings based on their data regarding errors with the use of medications and evidence from published literature. This serves to determine which medications require special safeguards to reduce the risk of errors and minimise harm.[17]

Some medications or classes/categories that have been identified on the Institute for Safe Medication Practices (ISMP) list include:

- antithrombotic/anticoagulants/antiplatelet agents such as warfarin, heparin, direct oral anticoagulants
- certain antibiotics
- fluids for intravenous, irrigation or parenteral nutrition use
- chemotherapeutic agents
- concentrated electrolytes

- medications given by epidural and intrathecal route
- medications used in critical care/operating theatres
- medications used to treat diabetes, such as insulin,
- methotrexate
- opioids including those given orally, intravenously and via transdermal patches
- sedation agents.

See www.ISMP.org for the latest version of the ISMP List of High-Alert Medications in Acute Care Settings.[17]

International literature recommends that hospitals identify high-risk medications and high-risk situations specific to their services based on published literature, existing high-risk lists available (such as APINCH) and based on the hospital's medication incident data as the type of medicines used and patients treated may vary between hospitals and healthcare settings.[1,14,15,17,19,18]

Best practice suggests that hospitals formally identify a list of high-risk medicines in use in their hospital as a means to clearly identify and mitigate risks associated with their safe use. A list of high-risk medicines should be created and customised to best suit the hospital and this may also include different lists for different settings within a hospital, for example critical care areas or operating theatre departments.

A list of high-risk medications should be updated regularly or as required should emergent risk with medications arise and approved by the hospital's Drugs and Therapeutics Committee or equivalent. Consideration should also be given during decision making for approval of new medications by the Drugs and Therapeutics Committee whether a medication is a high-risk medication.[19]

Once a list of high-risk medications is created, hospitals should employ risk reduction strategies to reduce the risk associated with these medications. Risk reduction strategies aim to also reduce the occurrence of medication incidents associated with these identified high-risk medications and improve the safety and quality of medicines use in accordance with National Standards and best practice (see Appendix 3 for the Institute for Safe Medication Practices Canada hierarchy of effectiveness of risk reduction strategies in medication safety).

It should be noted that focusing on higher-risk medicines and situations should be supplemented by good governance and risk management arrangements for the use of all medicines, so emergent risks across the full range of medicines used in a hospital might be anticipated/identified and mitigated.

Hospitals can develop risk-reduction strategies using the hierarchy of effectiveness framework to inform medication quality initiatives. This framework divides strategies into 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.

Staff must be aware of the high-risk medication list and follow risk reduction strategies in place to mitigate risks associated with high-risk medications. Examples of risk reduction strategies that could be employed to reduce the risks associated with high-risk medications may include:

- employing redundancies, for example prohibiting the storage and use of high-risk medications on general wards
- standardisation of how these medications are prescribed, stored, prepared and given to patients
- limiting access to high-risk medications
- using labels on packaging
- using automated alerts on information systems
- improving access to information about these drugs for both staff and patients.

Higher leverage strategies, such as forcing functions, are most effective and multiple risk-reduction strategies should be considered and implemented to reduce risk.[20] Any risk-reduction strategy implemented should be monitored and evaluated to ensure that it is effective and achieving the desired outcome. The effectiveness of risk reduction strategies should be reported to the Drugs and Therapeutic Committee or equivalent.

During hospital inspections HIQA will determine what high-risk medications and high-risk situations have been identified by hospitals. Inspectors will explore what risk-reduction strategies have been implemented to address and mitigate risks

associated with these high-risk medications and high-risk situations as outlined in figure 2 below.

Figure 2. HIQA's approach to evaluating high-risk medications and high-risk situations

In addition to exploring identification of high-risk medications and risk reduction strategies employed by the hospital the following classes/categories of medications or specific risk issues, will be evaluated using a sampling methodology as part of this programme.

- anticoagulants [21,22,23]
- antimicrobials that require therapeutic monitoring [24,25,26]

- concentrated electrolytes [18,27,28]
- insulins [28,29,30,31,32]
- intravenous paracetamol [33,34,35]
- oral methotrexate [36,37,38]
- opioids [37,39,40]
- sound alike look alike drugs (SALADs) [41,42]
- medication used for procedural sedation [36,43,44,45,46,]
- safe medication use during the perioperative period. [47,48,49,50]

As this is not an exhaustive list of high-risk medications, if specific risks are identified during the medication safety programme or during an inspection (such as emergent risks with specific medications) or there are specific high-risk medications or high-risk situations identified by the hospital, these risks and associated risk reduction strategies will also be assessed during the inspection.

6. Hospital inspections

The approach for this medication safety monitoring programme will be to conduct one day on-site **announced inspections**. The aim of the on-site inspection in each hospital is to gather evidence through talking with staff and patients, formal interviews, observation in clinical areas and review of documentation.

At least 10 working days before an inspection, HIQA will issue a notification letter confirming the date of the on-site component of the announced inspection to the Chief Executive Officer (CEO) or the General Manager of the hospital.

All subsequent correspondence relating to the inspection should be communicated to HIQA from the Chief Executive Officer or the General Manager of the hospital.

A pre-inspection information request will be sent to the hospital with the notice of inspection. This must be completed and returned to HIQA **within 5 working days** and as specified in the notification letter.

The purpose of this is to provide background information about the governance arrangements and safety systems and processes in place to support medication safety in the hospital.

The pre-inspection information request also outlines documents to be submitted to HIQA before the inspection (see Appendix 4).

There is no requirement to submit other supplementary documentation or evidence in addition to what is requested. Service providers do not need to create supplementary information or supporting evidence where these documents do not exist.

6.1 Before the announced inspection

A schedule outlining the on-site component of the inspection will be provided with the notification letter. This will include a schedule of meeting times and who is required to attend in order to ensure that the relevant staff are available.

A sample outline of the inspection is detailed in figure 3, below. The inspection schedule is subject to change depending on the information provided by the hospital.

Figure 3: Outline of on-site inspection schedule

Prior to the inspection, key pieces of information relating to medication safety will be reviewed by HIQA. This information includes:

- pre information request and related documents submitted by the hospital to HIQA
- previous HIQA inspection reports

- National Patient Experience Survey (NPES) results for the hospital
- other relevant information received by HIQA in relation to the hospital.

6.2 The day of inspection

On arrival at the hospital, the inspection team will meet with the person with overall accountability and responsibility for the hospital, for example, the Chief Executive Officer or General Manager.

Hospitals will be asked to nominate a liaison person who will be responsible for engagement with HIQA during the course of the on-site inspection.

Practical information about hospital inspections

During the inspection, inspectors will:

- request access to a secure room for the purpose of interviews and documentation review
- request visitor name badges or door-access cards to facilitate movement throughout the hospital. These should be made available to the inspection team as soon as possible following arrival onsite and will be returned at the end of the inspection.

Documentation, data and information request

HIQA may request some outstanding or additional documentation on the day of inspection. However, this will be kept to a minimum. If any piece of documentation is not available on the day of the inspection, the hospital should submit this after the inspection in electronic format as requested to qualityandsafety@hiqa.ie.

Interviews

The inspection team will set out times and identify members of staff for interview in the inspection schedule. These will include the following members of staff; Chair of Drugs and Therapeutics Committee, Chief Pharmacist, Medication Safety Coordinator (where present), the CEO/General Manager, Clinical Director, Director of Nursing and Risk Manager.

The purpose of interviews is to gather information about the safety systems and processes that have been implemented and evaluated to support medication safety and to protect the patient from identified risk.

Interviews will focus on:

- the structures in place to provide governance and assurance of a safe medication management system
- the safety systems and processes that have been implemented to support medication safety, particularly for high-risk medications and high-risk situations
- clarification of any issues raised from pre-inspection information submitted and on site findings
- clarifications of any variance found during inspection or any variance from current national or international evidence.

Time and date details will be communicated in advance of the announced inspection so that necessary arrangements can be made to ensure staff availability on the day.

Clinical area inspections

Members of the inspection team will visit a number of clinical areas and gather information through direct observation, review of documentation and information systems there. Inspectors will also speak with patients and nurses, doctors and pharmacists working there.

Inspectors will gather information in relation to:

- systems and processes in place for high-risk medication
- systems and processes in place for risk management and incident reporting
- systems and processes in place for communication with clinical staff, for example, medication safety alerts
- access to and use of policies, procedures and guidelines to support the safe use of medication
- monitoring arrangements in place for medication safety
- staff training and sharing of learning relevant to medication safety.

Inspectors will also assess if the required reference material is available to clinicians at the point of care, for example, medication management policies, procedures, guidelines, intravenous medication guidelines, results of medication safety related audit activities and related quality improvement plans for that clinical area.

The National Patient Experience Survey

The National Patient Experience Survey is a nationwide survey asking people for feedback about their stay in a hospital. The survey is a partnership between the Health Information and Quality Authority (HIQA), the Health Service Executive (HSE) and the Department of Health. All adult patients discharged during May 2017 and May 2018 who spent 24 hours or more in a public acute hospital Ireland were asked to complete the survey.

HIQA will use hospital survey results relevant to medication safety from The National Patient Experience Survey to gather key information about the advice and information patients received in relation to their medication while in hospital.

Inspectors will discuss the hospital's survey results with hospital management and explore any actions taken or quality improvements relevant to medication safety implemented in response to the hospital's survey results.

Close out meeting

When the inspection has been completed, the inspection team will conduct a close-out meeting with the CEO/General Manager. The purpose of this meeting is to provide preliminary findings of the inspection and identify any high risks which require immediate action that have been identified, to allow them to rapidly address such risks (see section 7 for more detail).

Inspection teams

Inspection teams comprise of HIQA staff who have been appointed by HIQA as 'authorised persons' under the Health Act 2007 and work within the powers described in the Act to monitor compliance with standards.

Inspectors are obliged to comply with HIQA's Code of Conduct for staff, which is available at www.hiqa.ie.

Confidentiality

In line with current data protection legislation, HIQA requests that unless specifically requested to do so, hospitals do not send named patient information or information that could identify an individual patient to HIQA by email or by post. Hard copy documents provided to inspectors for removal from the hospital should not contain data that identifies individual patients.

Freedom of Information

HIQA is subject to the Freedom of Information Acts [51] and the statutory Code of Practice regarding Freedom of Information. [52]

7. Risk identification and notification processes

Risks identified by HIQA during this monitoring programme will be escalated to the hospital's CEO or General Manager in line with HIQA's risk management process:

- High risks identified during a hospital inspection which require immediate mitigation will be brought to the attention of the hospital's CEO or General Manager during the inspection. This is to allow them to immediately implement the actions necessary to mitigate such risks.
- Formal written notification of any identified risk arising during this monitoring programme will be issued to the hospital's CEO or General Manager by email within two working days of identifying the risk; with the requirement to formally report back to HIQA stating how the risk has been mitigated within a further two working days.
- In the case of high risks which do not require immediate mitigation, formal notification of the identified risk will be issued to the hospital's CEO or General Manager by email within two working days of identifying the risk; with the requirement to formally report back to HIQA with an action plan to reduce and effectively manage the risk within a further five working days of receiving correspondence from HIQA.

HIQA's risk matrix and escalation process is outlined in a diagram in Appendix 5 and 6.

A copy of this correspondence may also be sent to the relevant hospital group Chief Executive Officer, and the HSE's National Director for Operations.

8. HIQA inspection reports

An individual report will be generated for each hospital inspected and published on HIQA's website www.hiqa.ie following an inspection.

The report will outline HIQA's findings including areas of good practice and any identified opportunities for improvement. The report will include risks, if any, that were identified during the monitoring process and may include correspondence

between HIQA and the hospital's CEO or General Manager in relation to the management of such risk. Therefore HIQA recommends that the hospital does not include individual staff names in high risk correspondence.

In 2019, HIQA has revised its approach to receipt of feedback from hospitals on reports progressing through the drafting process. Under this new and enhanced process, each inspection report goes through three main stages as it is prepared for publication:

Stage 1 Inspection Report

A stage 1 inspection report will be issued with a feedback form, by email, to the hospital's CEO or General Manager. A copy of the draft report will also be sent by email to the hospital group Chief Executive Officer.

Preliminary findings will have been given during the close-out meeting. However, following review of the Stage 1 report the hospital's CEO or General Manager can return the feedback form to include any factual accuracy detail along with feedback on receipt of the stage 1 inspection report.

The hospital's CEO or General Manager is encouraged to engage with the lead inspector if deemed necessary and in advance of completion of the formal written documentation, to discuss specific concerns or queries they may have regarding the judgments in this stage 1 inspection report. This can be completed by phone and/or email.

To complete the feedback process (and having engaged via telephone call or email with the lead inspector if deemed necessary) the hospital's CEO or General Manager should formally complete the factual accuracy and feedback form provided with the draft report, and return this to HIQA within **15 working days of receipt.**

Stage 2 Inspection Report

On receipt of feedback from the hospital on a stage 1 report, HIQA will consider the feedback in the context of evidence gathered on inspection. Consequently, a stage 2 inspection report will be produced which will include any required amendments made by the inspector resulting from the feedback process. This stage 2 report will then be again issued to the hospital for review.

If the hospital's CEO or General Manager believes that the judgment(s) contained in the stage 2 inspection report are not based on the evidence made available to inspectors at the time of the inspection, or if they believe that the judgment(s) are

disproportionate to the evidence reviewed, they may decide to make a formal submission to HIQA to challenge a regulatory judgment or judgments contained in the stage 2 report.

Should a hospital's CEO or General Manager decide on making a formal submission this must be made within **10 working days of receipt of the stage 2 report.** The process for making a formal submission is detailed below. Should 10 days elapse without receipt of submission on a regulatory judgment, reports will proceed to stage 3 and publication as outlined below.

Stage 3 Inspection Report

A stage 3 inspection report is issued to the hospital's CEO or General Manager prior to publication. The stage 3 report is the version of the report that will be published and if a submission has been received the stage 3 inspection report will have taken into consideration any decisions of the Submissions Decision Panel.

The stage 3 inspection report will be sent to the hospital's CEO or General Manager **five working days** before publication. A copy of the draft report will also be sent by email to the hospital group Chief Executive Officer, and other relevant personnel as formally agreed with the HSE and Department of Health.

Making a submission on judgments contained in a Stage 2 Inspection Report

The hospital's CEO or General Manager can make a formal submission if they believe that the judgment(s) contained in the stage 2 inspection report are not based on the evidence made available to inspectors at the time of the inspection or the judgment(s) are disproportionate to the evidence reviewed.

As part of this process, the hospital's CEO or General Manager may formally submit comments, evidence or descriptors of circumstances that supports their case.

A hospital's CEO or General Manager wishing to make a submission on a regulatory judgment must first engage in the feedback process with the lead inspector as described in the section above on page 25 'Stage 1 Inspection report'.

Further information on HIQA's submissions procedure and how to make a submission can be found on the HIQA website (www.hiqa.ie).

9. Expected hospital response

Each hospital's CEO or General Manager is accountable for the development of a quality improvement plan that prioritises the improvements necessary to comply with the National Standards. Quality improvement plans must be approved by the hospital's identified individual who has overall executive accountability, responsibility and authority for the delivery of high-quality, safe and reliable services.

During future inspections, the inspection team will check for evidence that hospitals have taken account of the findings of their individual inspection report and, if appropriate, that plans have been put in place to address any required areas of improvement identified by HIQA.

10. Contact HIQA

General queries or questions in relation to this programme or the information contained within this guide can be sent by email to qualityandsafety@hiqa.ie (specific instructions in relation to hospital inspections will be sent to the hospital manager in advance of an inspection).

Such queries will be referred to a member of the healthcare team involved in the medication safety programme for reply. It should be noted however that specific queries about an inspection can only be accepted from the hospital's CEO or General Manager.

11. References

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12. Appendices

Appendix 1: Membership List of the Special Purpose Advisory Group

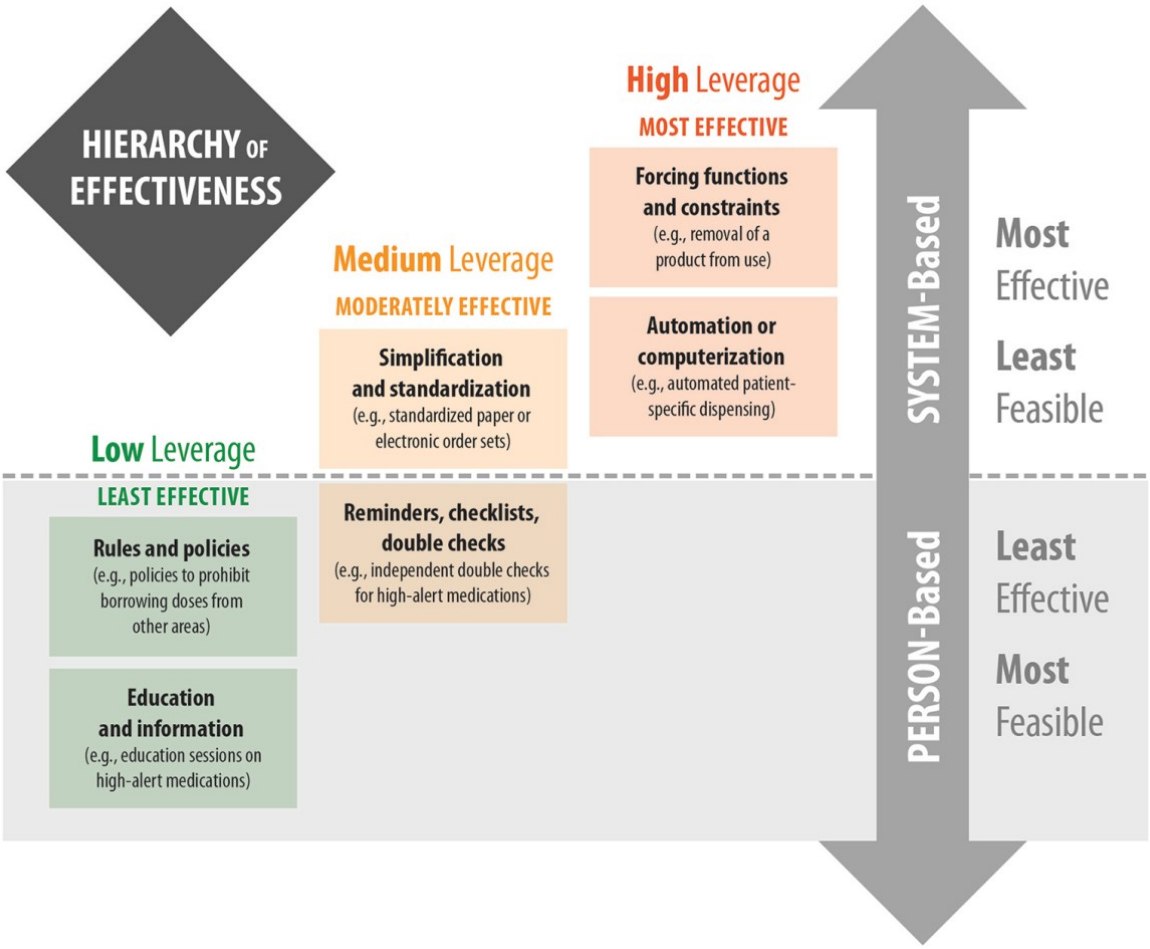
Name		Representing
Margaret	**Brennan**	Health Service Executive Acute Hospitals
Niamh	**Hayes**	College of Anaesthesiologists of Ireland
Ciara	**Kirke**	Quality Improvement Division, Health Services Executive
Rosari	**Lynch**	Department of Health
Clare	**Mac Gabhann**	Office of the Nursing and Midwifery Services Director
Mark	**McCullagh**	National Treasury Management Agency
Cora	**Nestor**	Pharmaceutical Society of Ireland
Carmel	**O' Donnell**	Nursing and Midwifery Board of Ireland
Brian	**Osborne**	Irish College of General Practitioners
Ruth	**Rock**	Medical Council
Almath	**Spooner**	Health Products Regulatory Authority
Mervyn	**Taylor**	SAGE – Patient representative
Paul	**Tighe**	Irish Medication Safety Network
Laura	**Viani**	Royal College of Surgeons in Ireland

Appendix 2: APINCH Acronym for high-risk medications

A	Anti-infectives	Amphotericin, vancomycin, and aminoglycosides, but may also include others
P	Potassium and concentrated electrolytes	Injectable electrolyte preparations, for example potassium chloride and magnesium sulphate, but may also include other medicines
I	Insulin	All insulins
N	Narcotics and sedatives	All opioids, sedatives may include benzodiazepines and other sedating agents
C	Chemotherapy agents	Cytotoxic chemotherapy
H	Heparin and other anticoagulants	Heparins and all anticoagulants, including the New Oral Anticoagulants

APINCH is not an exhaustive list and variations of the 'APINCH' can also include other high-risk medications or high-risk situations such as epidural, intrathecal and neuromuscular-blocking agents.

Appendix 3: Hierarchy of effectiveness of risk reduction strategies in medication safety



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https://www.ismp-canada.org/index.htm

Appendix 4: Pre-Inspection Information Request

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

HIQA's Medication Safety Monitoring Programme against the *National Standards for Safer, Better Healthcare* in acute healthcare services

Pre Inspection Information Request

Date of publication: January 2019

Hospital
Hospital Name:
Hospital Group:
No of inpatient beds in hospital:
Lead Respondent
Lead respondent's name:
Lead respondent's role:
Lead respondent's email address:
Lead respondent's contact phone number:

Contents

A. Please provide the names of staff in the roles outlined below	
Role	**Name**
Chief Executive Officer/General Manager	
Director of Nursing	
Director of Midwifery (as applicable)	
Chair of the Drugs and Therapeutics Committee	
Clinical Director	
Chief Pharmacist	
Medication Safety Officer (if in post)	
Lead Anaesthesiologist	
Quality and Risk Manager (or equivalent position)	

B. Leadership, governance and management

Line of enquiry 1: Patient safety is enhanced through an effective medication safety programme underpinned by formalised governance structures and clear accountability arrangements.

Essential elements:

1.1. Hospitals have formalised governance and accountability arrangements for medication management and safety that are clear and unambiguous.
1.2. Hospitals set clear objectives in a strategic plan for medication safety with evidence of implementation of identified quality improvements.
1.3. There is evidence of a functioning Drugs and Therapeutics Committee in operation.
1.4. Leaders at all levels promote medication safety to strengthen a culture of quality and safety

B.1	What is the name and role of the person with executive accountability, responsibility and authority for medication safety within your hospital?		
B.2	Is your Drugs and Therapeutics membership multidisciplinary, representing the service provided by the hospital?	Yes	No
B.3	Please list any representatives identified for inclusion in the membership of the Drugs and Therapeutics Committee membership that are currently vacant (for example directorate/speciality or community representative)?		
B.4	Outline how the Drugs and Therapeutics Committee escalate identified medication related risks.		
B.5	List any Drugs and Therapeutics Committee subgroups/subcommittees (if applicable)		

B.6	Does the hospital have a Medication Safety Committee?	Yes	No
B.7	Does the hospital have a strategic plan for medication safety?	Yes	No
	Include any additional comments for the section above, indicating related question e.g. B.3		

C. Risk management

Lines of enquiry 2: There are arrangements in place to proactively identify report and manage risks related to medication safety throughout the hospital.

Essential elements:

2.1. There is proactive identification, management, reduction and elimination of risks associated with medication use.
2.2. Hospitals monitor and learn from information regarding the risks associated with medication use and actively promote learning.
2.3. Hospitals act on standards and alerts and take into account recommendations and guidance as formally issued by relevant authorities and regulatory bodies as they apply to their service, e.g. HPRA.

C.1	Do you have a system in place for reporting of medication safety incidents and near misses?	Yes	No
C.2	Is the system for reporting of medication safety incidents and near misses outlined in a policy, procedure or guideline?	Yes	No
	If yes, please outline title below		
C.3	Have any medication safety related Serious Reportable Events (SRE) occurred in the hospital within the past two years?	Yes	No
	Number of medication safety related SREs in 2017		

	Number of medication safety related SREs in 2018		
	Have reviews been conducted or commenced in relation to these SREs?	Yes	No
C.4	What governing committee has oversight and responsibility for reviewing and addressing reported medication safety incidents?		
C.5	Does your hospital use an evidence based classification system to categorise medication safety incidents?	Yes	No
	Name the classification system(s) used		
C.6	Is hospital data from medication safety incidents routinely analysed to identify trends or patterns in relation to risk?	Yes	No
C.7	How often are medication safety incident analysis reports generated?		
	Monthly		
	Quarterly		
	Annually		
	Other		
C.8	To whom (individuals/ groups/committee) are the reports of analysis of medication safety incidents circulated? (tick as appropriate)		
	Drugs and Therapeutics Committee		
	Hospital Risk Management Committee (or equivalent)		
	Executive Management Team (or equivalent)		
	Doctors		
	Nurses		

	Pharmacists	
	Other (please detail)	
C.9	List any proactive medication safety risk assessments undertaken in the past two years	
C.10	What areas of medication safety have been identified as requiring targeted improvement based on incidents analysis and risk assessments in 2017/2018?	
	Include any additional comments for the section above, indicating related question e.g. C.3	

D. High-risk medications

Line of enquiry 3: Hospitals implement appropriate safety measures for high risk medications that reflect national and international evidence to protect patients from the risk of harm.

Essential elements:

3.1. Hospitals have identified high-risk medications with associated risk-reduction strategies in place to reduce the associated risks.
3.2. Hospitals have identified Sound-alike look-alike drugs (SALADs) and implemented associated risk reduction strategies.
3.3. Hospitals have safe systems in place for antimicrobials which require therapeutic drug monitoring.
3.4. Hospitals have specific measures in place to prevent inadvertent administration of concentrated electrolytes.
3.5. Hospitals have systems in place to support safe medication management during the perioperative period.
3.6. Hospitals have systems in place to mitigate against the risks associated with the following classes/categories of medications:
- anticoagulants: heparin, direct oral anticoagulants and warfarin.
- intravenous paracetamol
- oral methotrexate
- insulin's, including high strength insulin.
- medications administered for procedural sedation

	• opioids.		
D.1	Is there a list of high-risk medications identified by the hospital?	Yes	No
D.2	List the **concentrated electrolytes** approved for use in the hospital.		
D.3	Are medications administered for **procedural sedation** in units/areas outside the Operating Theatre Department?	Yes	No
	If yes, list units/areas where **procedural sedation** is used		
	Include any additional comments for the section above, indicating related question e.g. D.3		

E. Person centred care and support

Line of enquiry 4: There is a person centred approach to safe and effective medication use to ensure patients obtain the best possible outcomes from their medications.

Essential elements:

4.1. There is a person centred approach in place to promote medication optimisation and reduce polypharmacy, particularly for high-risk patient groups.
4.2. There is a person centred approach in place to provide patients with clear, timely and relevant information in relation to medications.
4.3. Medication reconciliation is conducted by a suitably trained individual in accordance with hospital policy at admission/discharge and transitions in care.

E.1	List specific initiatives undertaken in your hospital to **promote medication optimisation** and reduce the risk of polypharmacy, especially for high-risk patient groups?

<table>
<tr><td rowspan="3">E.2</td><td colspan="6">Who provides patients with medication related information including information on side effects when a patient commences a new medication (tick as appropriate)</td></tr>
<tr><td colspan="2">Doctor</td><td colspan="2">Nurse</td><td colspan="2">Pharmacists</td></tr>
<tr><td colspan="2"></td><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td>E.3</td><td colspan="4">Are patients routinely given evidence based and up-to-date information leaflets when they commence on a new medication while in hospital or at discharge</td><td>Yes</td><td>No</td></tr>
<tr><td rowspan="3">E.4</td><td colspan="4">Is formal medication reconciliation undertaken by a suitably trained individual</td><td>Yes</td><td>No</td></tr>
<tr><td colspan="4">On patient admission?</td><td>Yes</td><td>No</td></tr>
<tr><td colspan="4">On patient discharge?</td><td>Yes</td><td>No</td></tr>
<tr><td rowspan="6">E.5</td><td colspan="6">If yes, which health care professional(s) undertakes medication reconciliation on admission and discharge for patients:</td></tr>
<tr><td rowspan="5">On admission
(tick as appropriate)</td><td>Nurse</td><td></td><td rowspan="5">On discharge
(tick as appropriate)</td><td>Nurse</td><td></td></tr>
<tr><td>NCHD</td><td></td><td>NCHD</td><td></td></tr>
<tr><td>Consultant</td><td></td><td>Consultant</td><td></td></tr>
<tr><td>Pharmacist</td><td></td><td>Pharmacists</td><td></td></tr>
<tr><td>Other</td><td></td><td>Other</td><td></td></tr>
<tr><td rowspan="4">E.6</td><td colspan="6">If yes to G.4
What percentage of patients (approximately) have medication reconciliation undertaken (tick as appropriate)</td></tr>
<tr><td colspan="2" rowspan="3">On patients admission?</td><td colspan="3">0 - 25%</td><td></td></tr>
<tr><td colspan="3">25 - 50%</td><td></td></tr>
<tr><td colspan="3">50- 75%</td><td></td></tr>
</table>

		75 - 100%	
	On patient discharge	0 - 25%	
		25 - 50%	
		50 - 75%	
		75 - 100%	
	Include any additional comments for the section above, indicating related question e.g. E.3		

F. Model of service and systems for medication management

Line of enquiry 5: The model of service and systems in place for medication management are designed to maximise safety and ensure patients' healthcare needs are met.

Essential elements:

5.1. Hospitals have a clinical pharmacy service in place which is led by a Chief Pharmacist.
5.2. Hospitals have an approved list of medications for use in the hospital (formulary).
5.3. Hospitals have effective processes, to promote medication safety including the use of technologies, that are implemented and supported by clear up-to-date policies, procedures, protocols and guidelines.

F.1	Is there a clinical pharmacy service available to all clinical units/wards?	Yes	No
	Please list units/wards where clinical pharmacy services are not provided		
F.2	Does the hospital have a list of medications approved for use in the hospital? (formulary)	Yes	No
F.3	Does the hospital have a system for the approval of new medications?	Yes	No

F.4	How often is a formal review undertaken of the medications approved for use within the hospital? *e.g. periodic review of formulary*		
F.5	Is there a system in place for the supply of medications out of hours?	Yes	No
F.6	Outline specific electronic technology used to support medication safety		
	Include any additional comments for the section above, indicating related question e.g. F.3		

G. Use of Information

Lines of enquiry 6: 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.

Essential elements:

6.1. Essential information for the safe use of medications are available to staff in the clinical area that have been locally developed / adapted and approved for use at the hospital and are available at the point of prescribing, preparing and administration.

G.1	Which medication information is available to guide the safe use of medications?			
	Medications guide	Medications guide available	Yes	No
		Locally developed/adapted	Yes	No
		Approved for use in the hospital	Yes	No
		Available to staff at the point of care and in clinical areas as required	Yes	No

	Medication protocols	Medication protocols available	Yes	No
		Locally developed/adapted	Yes	No
		Approved for use in the hospital	Yes	No
		Available to staff at the point of care and in clinical areas as required	Yes	No
	Intravenous medication administration guidance (monographs)	Intravenous medication administration guidance (monographs) available	Yes	No
		Locally developed/adapted	Yes	No
		Approved for use in the hospital	Yes	No
		Available to staff at the point of care and in clinical areas as required	Yes	No
	Antimicrobial Medicines Guide	Antimicrobial Medicines Guide available	Yes	No
		Locally developed/adapted	Yes	No
		Approved for use in the hospital	Yes	No
		Available to staff at the point of care and in clinical areas as required	Yes	No
	British National Formulary	British National Formulary available	Yes	No
		Approved for use in the hospital	Yes	No
		Available to staff at the point of care and in clinical areas as required	Yes	No

G.2	Outline any additional sources of **information** available to guide staff on the safe use of medications below:		
G.3	Are pharmacists available to provide medication information to front line staff?	Yes	No
G.4	If yes, please outline the availability of a pharmacist to provide information to front line staff		
G.5	During core hours		
	Out of hours		
	Include any additional comments for the section above, indicating related question e.g. G.3		

H. Monitoring and evaluations

Line of enquiry 7: Hospitals systematically monitor the arrangements in place for medication safety to identify and act on opportunities to continually improve medication safety.

Essential elements:

7.1. The hospital has systematic monitoring arrangements for identifying and acting on opportunities to continually improve the quality, safety and reliability of medication management to support medication safety.
7.2. The hospital conducts regular audits and implements recommendations from audit to evaluate the systems in place to support medication safety.

H.1	Indicate specific measures used to monitor **medication safety** within the hospital (tick as appropriate)			
	Analysis of medication		Patient experience surveys	

	incidents			
	Benchmarking		Patient focus groups	
	Chart Review		Safety Culture Surveys	
	Clinical Audit		Self-assessment tools	
	Direct observation		Staff Surveys	
	Key performance indicators/metrics		Trigger tools	
	Other (please Specify)			

H.2	List medication safety key performance indicators/metrics and outline to whom they are reported to.	
	Key performance indicators	**Reported to**

H.3	List **any trigger tools** used in the past two years to monitor medication safety e.g. use of naloxone		
H.4	List **medication safety audits** completed in **2017/2018**, including **role/department** involved and **date** of completion?		
	Medication safety audit	**Completed by role/department**	**Date audit completed**

H.5	Briefly outline how medication safety audits are selected.

H.6	Are medication safety audits results and recommendations communicated to staff listed below (tick as appropriate)	Yes	No	Method used for feedback
	Nurses			
	Doctors			
	Pharmacists			
	Drugs and Therapeutics Committee			
	Hospital Senior Management			
	Other prescribers			
	Other (please list)			

H.7	List medication safety related **quality improvements** implemented in 2017/2018 based on your monitoring and evaluation and outline what prompted the quality improvement (*e.g. analysis of local incidents, recommendation from audit etc. and indicate if a re-audit had been done to measure compliance with recommendations implemented.)*	
	Quality improvement initiative	**Prompted by**

	Include any additional comments for the section above, indicating related question e.g. H.3

I. Education and training

Line of enquiry 8: Safe prescribing and drug administration practices are supported by mandatory and practical training on medication management for relevant staff.

Essential elements:

8.1. Training on medication safety is provided by the appropriate person during orientation of new medical, nursing and pharmacy workforce.
8.2. Staff involved in medication use are provided with on-going education that includes education on medication error prevention and the safe use of medication.

I.1	Does the hospital have a **structured, targeted programme of education** for medication safety for new staff **on induction** for the following staff (tick as appropriate):				
	Nurses	Doctors	Pharmacists	Other	
I.2	Does the hospital have an **on-going structured, targeted programme of education** for medication safety for the following staff (tick as appropriate):				
	Nurses	Doctors	Pharmacists	Other	
I.3	Which methods are used to provide information and education sessions on medication safety for medical, nursing, pharmacy and other staff (tick as appropriate).				
	Induction programme				

	Class room based education sessions			
	Ward based education sessions			
	E-learning programmes			
	Medication safety awareness days			
	Grand rounds			
	Alerts			
	Other			
I.4	Does the hospital have a system in place to maintain and manage medication safety staff training records (tick as applicable)			
	Nurses	Doctors	Pharmacists	Other
I.5	Can managers identify which staff have or have not attended required medication safety training for:			
	Nurses	Doctors	Pharmacists	Other
	Include any additional comments for the section above, indicating related question e.g. I.3			

I.6 Pharmacy staff

Please provide the number of staff employed in roles outlined below

Position	Approved whole time equivalent	Approved posts filled (permanent contract)	Approved posts filled by agency staff/temporary contract (specify)	Approved posts unfilled (not filled by agency staff)
Chief Pharmacist I				
Chief Pharmacist II				
Senior Pharmacist				
Basic Grade Pharmacist				
Senior Pharmaceutical Technician				
Staff Grade Pharmaceutical Technician				
Others specify:				

Include any additional comments for the section above, including if any posts are located in other sites or services

I.7 Pharmacy Service

Please list services provided by the Pharmacy Department external to the hospital (e.g. clinical pharmacy, service dispensing, medication reconciliation, medicine information, antimicrobial pharmacist, compounding, clinical trials etc.)

Service	Location of service provided	Which role and number of staff provide this service (e.g. 2.5 WTE Senior Pharmacists/ 0.8 WTE Pharmacy Technician etc.)

Include any additional comments for the section above, including if any posts are located in other sites or services

Required Documentation

Please provide the following additional documentary information alongside this completed self-assessment tool in electronic format to HIQA at qualityandsafety@hiqa.ie

Please tick 'yes' if document available and supplied or 'not available' if the hospital does not have the document. If the document requested does not apply to the hospital please indicate by ticking 'not applicable' and explain in the text box at the end of this section giving further information.

Please include the **related number** in the **title of each file submitted**
e.g. J.1 Organogram, J.2 Minutes of D&T.

J. Pre inspection document request.				
		Yes	Not available	Not applicable
J.1	A copy of organogram(s) outlining lines of communication between the Drugs and Therapeutics Committee/Medication Safety Committee, the Pharmacy Department, Risk Management and Executive Management Team			
J.2	The Drugs and Therapeutics Committee terms of reference *Please include the names and roles of the members outlining the Directorate/speciality area they represent*			
J.3	Minutes of the Drugs and Therapeutics Committee for the previous 12 months			
J.4	The Medication Safety Committee terms of reference *Please include the names and roles of members outlining the Directorate/speciality area they represent*			

J.5	Minutes of the Medication Safety Committee for the previous 12 months			
J.6	Strategic Plan for Medication Safety			
J.7	Medication Safety Annual Report for 2017/2018			
J.8	Copy of the Medication Prescribing and Administration Record			
J.9	Copy of any other records where medications are prescribed e.g. Insulin charts			
J.10	Reports of tracking, trending and analysis of medication safety incidents for 2017/2018			
J.11	List of high-risk medications and documentation outlining risk reduction strategies employed			
Documentation outlining the systems and or risk reduction strategies for the following classes/categories of medications (for example policies, procedures, protocols or guidelines)				
J.12	▪ Antimicrobials that require therapeutic drug monitoring			
J.13	▪ Anticoagulants (heparin, direct oral anticoagulants, warfarin)			
J.14	▪ Intravenous paracetamol			
J.15	▪ Insulins			
J.16	▪ Oral Methotrexate			
J.17	▪ Opioids			

J.18	▪ Sound-alike look- alike drugs (SALADs)			
J.19	▪ Medications administered for procedural sedation outside the Operating Theatre Department.			
J.20	▪ Concentrated electrolytes			
J.21	▪ Medications used in the perioperative setting			
J.22	Medication safety audit plan 2017/2018			
J.23	Medication safety key performance indicator compliance reports for 2017 and 2018			
J.24	Evidence of implementation of time-bound quality improvements related to medication safety undertaken in response to the **National Patient Experience Survey** e.g. Question 45 and 46.			
J.25	Evidence of implementation of time-bound quality improvements related to medication safety in response to the **Previous HIQA Medication Safety inspection.**			
Please briefly outline below the reason why any documents requested do not apply:				

K. Declaration

To be completed by the Chief Executive Officer/General Manager

I declare, that to the best of my knowledge and belief, all of the information that I have given in connection with this **Pre inspection information request**, is full and correct. I am aware that under the Health Act 2007 it is an offence to provide false or misleading information.

In the event that a digital signature cannot be provided please date and type your name below.

Type name:

Title:

Date:

Appendix 5: 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/reoccur
2	Unlikely	Do not expect it to happen/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.

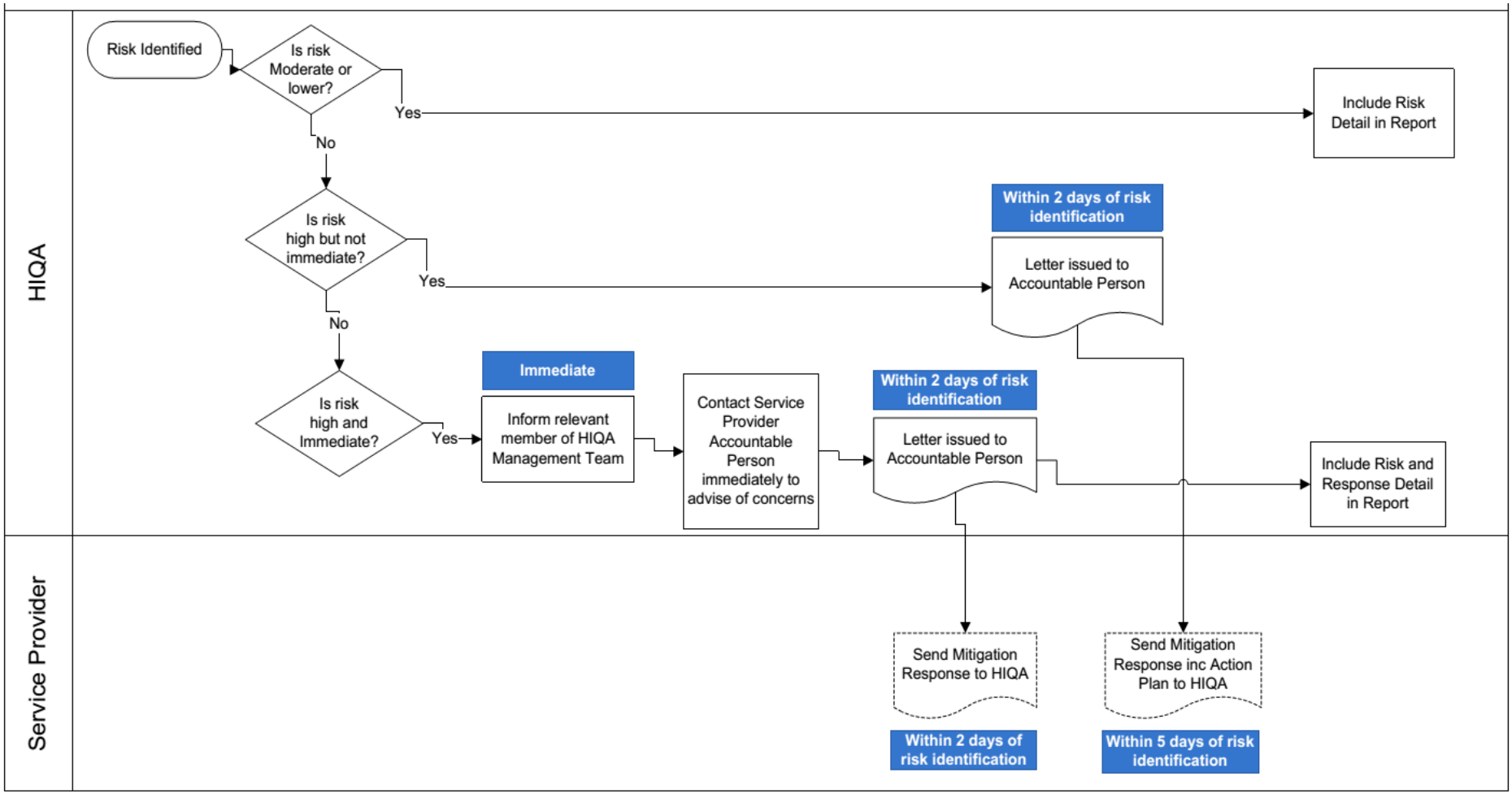
Risk Matrix

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 6: HIQA's 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.

13. Glossary of terms and abbreviations

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.

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.

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.

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.

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 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 clinical settings.

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

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.

Formulary: A formulary is a managed list of preferred medications 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 medications in practice at the hospital, and in doing so ensures an appropriate level of management control over medications use, in the interest of both patient safety and financial management.

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.

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: medications that bear a heightened risk of causing significant patient harm when they are used in error.

High-risk situations: a term used by the World Health Organization to describe situations where there is an increased risk of error with medication use. These situations could include high risks associated with the people involved within the medication management process (such as staff or patients), the environment (such as higher risk units within a hospital or community) or the medication. High-risk situations require risk reduction strategies to reduce avoidable errors.

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

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

Legislation: the set of laws of the Oireachtas (Ireland's national parliament) and statutory instruments or secondary legislation that have the force of law.

Medication error: 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: patient-centred care to optimize safe, effective and appropriate drug therapy. Care is provided through collaboration with patients and their health care teams.

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 reconciliation: is the process of creating and maintaining the most accurate list possible of all medications a person is taking including drug name, dosage, frequency and route in order to identify any discrepancies and to ensure any changes are documented and communicated, thus resulting in a complete list of medications.

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.

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.

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

Patient safety: the identification, analysis and management of patient-related risks and incidents, in order to make patient care safer and minimise harm to patients.

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.

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

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.

Safety culture: the product of the individual and group values, attitudes, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation's health and safety.

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.

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.

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