



**Health
Information
and Quality
Authority**

An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Guide to the Health Information and Quality Authority's Medication Safety Monitoring Programme in Public Acute Hospitals

October 2016

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.

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Purpose of this guide

This guide outlines the Health Information and Quality Authority (HIQA's) medication safety monitoring programme in public acute hospitals in Ireland. As part of the Business Plan for 2016,¹ HIQA set out that it would commence a programme of monitoring in public acute hospitals in the area of medication safety. HIQA plans to adopt a phased approach for monitoring medication safety in public acute hospitals in Ireland, with each phase building on the previous phase or phases.

This guide will focus on the first phase of the medication safety monitoring programme. Further guidance detailing the methodology for subsequent monitoring phases will be published in the future.

This guide also outlines why HIQA has decided to focus on medication safety in public acute hospitals in Ireland, how the medication safety monitoring programme will be conducted, and what the desired outcomes from this monitoring will be.

This guide is structured as follows:

Sections 1 and 2 gives background information on the role of HIQA, quality and safety in healthcare, and the role of standards and continuous monitoring in improving quality and safety in healthcare.

Section 3 outlines the aims of HIQA's medication safety monitoring programme in the long-term, and details the methodology and lines of enquiry for the first phase of this monitoring programme.

Section 4 provides details on HIQA's risk identification, assessment and notification process.

Section 5 describes HIQA's process for reporting the findings of medication safety inspections.

Section 6 summarises the response expected from hospitals regarding medication safety inspection findings.

1. Background

1.1 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 2007,² 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 2007,² 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.

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

The *National Standards for Safer Better Healthcare*³ (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 looks 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 service user. 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.^{4,5} 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 Standards³ at all times.

HIQA, through its monitoring programmes, aims to assure the public that hospitals are implementing and meeting the National Standards,³ and are making any necessary quality and safety improvements that are required to safeguard patients.

To achieve this, HIQA has designed an evidence-based monitoring programme targeted at medication safety and underpinned by the National Standards³ to examine if hospitals have the essential capacity and capability factors in place to improve patient safety related to medication usage.

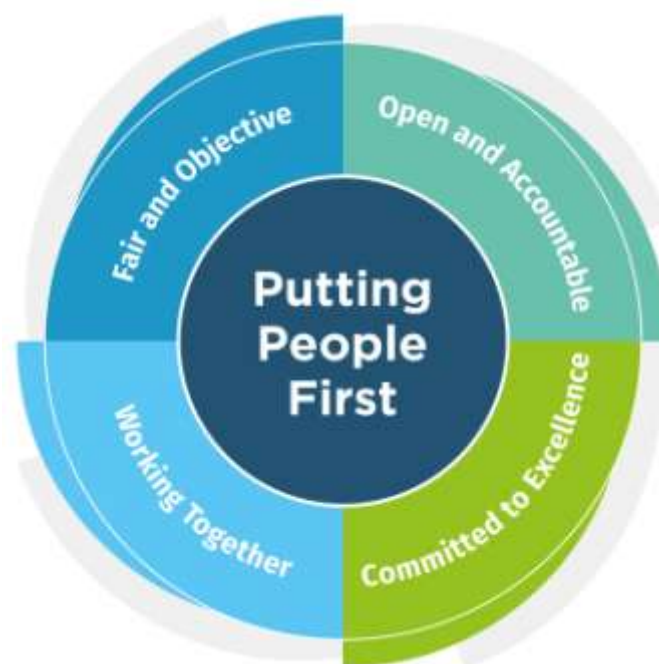
2. Monitoring and quality improvement programme

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 will operate within HIQA's core values.

2.1 Our mission

The mission of HIQA is derived from the statutory functions described in the Health Act 2007² and can be summarised as:

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



2.2 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.

3. Overview of the medication safety monitoring programme

3.1 Introduction to medication safety

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. Many of the advances in life expectancy and improved patient quality of life that have been experienced over the past few decades are thanks to advancements in medicines availability and usage. As modern medicine continues to advance, an ever-increasing list of medication treatment options are available for patients.⁶

With increased choice of medication treatments comes added treatment complexity.⁷ 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 patients may experience adverse effects from medication use due to expected or unexpected side-effects.⁸

In addition, where medicines are used, the potential for error in use also exists, for example in prescribing, administration, monitoring, or use in combination with other incompatible medicines. Indeed, because the use of medicine is so common in healthcare, extensive research internationally has identified medication usage as the leading cause of unintended harm for patients availing of hospital care.^{9,10}

The Institute of Medicine's landmark report, 'To Err Is Human: Building a Safer Health System',¹¹ estimated that on average at least one medication error per hospital patient occurs each day. This figure would potentially equate to over three million medication errors in Irish public hospitals per year.¹² It is estimated that the majority of these errors could be potentially preventable.¹² However, the true incidence of medication errors is difficult to determine, as many errors are never discovered, acknowledged or reported.¹³ Most medication errors cause little to no actual harm to patients, and some are unavoidable through unforeseen

circumstances or unknown allergies.¹⁴ Nonetheless, medication errors have in some instances the potential to result in catastrophic harm or death to patients.¹⁵

Medication safety has been identified by a number of bodies in Ireland as a key focus for improvement.^{16,17,18,19,20,21} 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 a leadership level in the organisation, and through the introduction of systems and processes that prevent and or mitigate the impact of medication-related risk.²²

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.²³ 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.^{10,8,24} Programmes should be directed towards standardising practices to reduce unnecessary variation, along with effective use of resources to enhance knowledge and skills. In addition, programmes should strive to develop a safety culture that involves senior leadership support, continuous operational training and high-level organisational learning.⁸

Medication safety programmes, as with all patient safety programmes, should be underpinned by defined senior management accountability and governance arrangements to ensure effective oversight of medication use and safety within hospitals and hospitals should have a clear strategic vision for medication safety.¹⁶ Medicines related policies and procedures must be designed to ensure patients are not unduly exposed to clinical risk or harm.²⁵

3.2 The aim of HIQA's medication safety monitoring programme

HIQA's medication safety monitoring programme aims to examine and positively influence the adoption and implementation by hospitals of evidence-based practice in relation to medication safety.

To achieve this aim, HIQA has designed an evidence-based monitoring programme which will involve announced inspections of public acute hospitals in Ireland. This will enable HIQA to examine and analyse systems in place to support safe practice in relation to medication safety in line with international best practice and research.

HIQA plans to adopt a phased approach for monitoring medication safety in public acute hospitals in Ireland with each phase building on and including the monitoring approach of the previous phase(s). As part of its assessment, HIQA will include an opportunity for patients to provide insight into their experience at the centre of the medication use process to inform all involved of what worked well, and where scope for improvement lies.

3.3 Expert Advisory Group

An expert advisory group has been formed to assist with the development of this medication safety monitoring programme. This group has provided advice to HIQA in relation to the medication safety monitoring programme to date and this guidance will continue throughout the programme as it progresses.

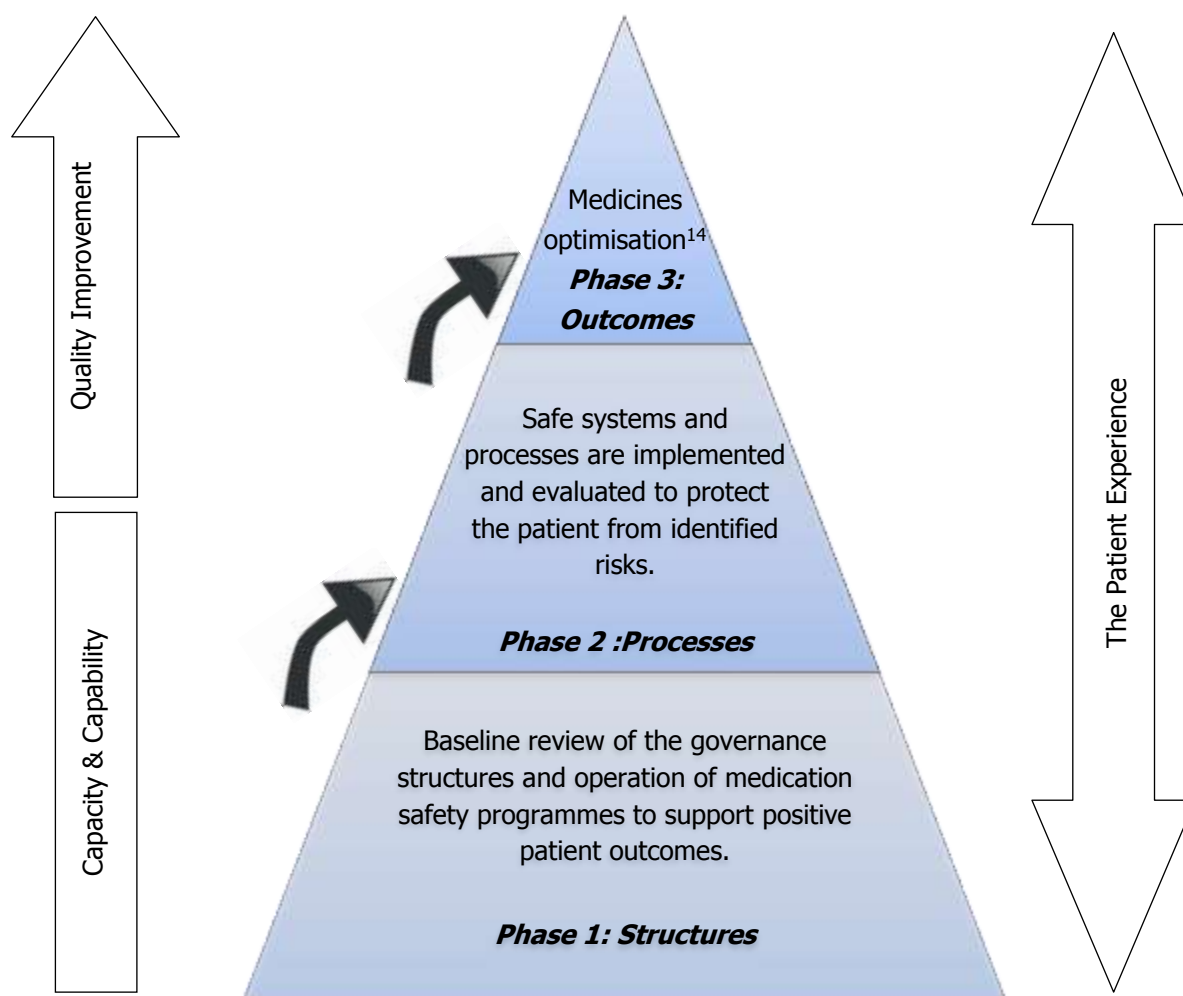
The advisory group membership includes patient representation, alongside members with relevant expertise from across the Irish health service.

3.4 Phased approach to the medication safety monitoring programme

This medication safety monitoring programme will broadly follow three distinct phases as outlined in Figure 2 below. The rationale for using a phased approach is to allow and encourage incremental improvement in the systems in place in public acute hospitals. This first phase will initially focus on the fundamental governance and structure requirements to support a medication safety programme.

Further monitoring in phase two and three will focus on specific structures and systems that have been proven to enhance the safety of medication use in healthcare.

Figure 2: Programme of Monitoring Medication Safety in Acute Hospitals



Phase One

In phase one of the medication safety monitoring programme HIQA aims to:

- **measure performance** by carrying out announced on-site inspections in order to assess the structures and systems in place for medication management and safety.
- **assess** if hospitals have 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.
- **establish** if hospitals have effective and safe medication management systems in place to ensure patient safety in line with international best practice and research.

- **provide hospitals with the findings** of the inspections to highlight examples of good practice and areas for improvement.
- **publish** the findings of inspections on our website www.hiqa.ie.

The aim of this phase is to support the establishment of medication safety programmes in acute hospitals in line with the National Standards.³ This initial phase will focus on the structure and management of medication safety programmes.

This will be a baseline review of the governance structures, accountability arrangements and the operation of medication safety programmes to support positive patient outcomes. Announced inspections will focus on clinical governance of medication safety programmes and systems.

Phase Two

During the second phase, HIQA will 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.

The focus will be on how the medication safety systems operate in practice to prevent latent failures contributing to medication error.

Phase Three

The final phase of the medication safety monitoring programme will expand upon previous phases, and aims to focus on medication optimisation.²⁶ 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'.²⁶

This phase 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.

Phase One: Lines of Enquiry

The focus for phase one of the medication safety monitoring programme is outlined below in seven lines of enquiry. These lines of enquiry were developed based on international best practice and research, and are aligned to the National Standards³ as illustrated in Table 1 below.

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

Area to be explored	Line of enquiry*	National Standards for Safer Better Healthcare ³
Clear lines of accountability and responsibility for medication safety	1. 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	2. 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	3. 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	4. 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	5. 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	6. 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	7. 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

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

3.5 Announced on-site inspections

The initial approach for this medication safety monitoring programme will be to conduct one day on-site announced inspections. Hospitals will be notified of an intention to inspect in writing 10 working days in advance.

The aim of on-site inspections in each hospital is to gather evidence through interviews, observation in clinical areas, patient surveys and review of documentation. The process for the announced inspections is detailed below.

Authorised persons

- Announced on-site inspections will be conducted by authorised persons, employed by HIQA.
- Authorised persons are appointed in accordance with section 70 of the Health Act 2007² for the purposes of monitoring compliance with standards.
- All authorised persons will carry an authorisation card together with a form of personal identification.
- Authorised persons will work within the powers described in the Health Act 2007.
- All authorised persons must comply with the HIQA's Code of Conduct, which is available on HIQA's website, www.hiqa.ie.

Confidentiality

HIQA is subject to the Freedom of Information Acts²⁷ and the statutory Code of Practice regarding Freedom of Information.²⁸ As part of the pre-inspection information request, hospitals are requested to explain to HIQA if they regard any information submitted to be confidential.

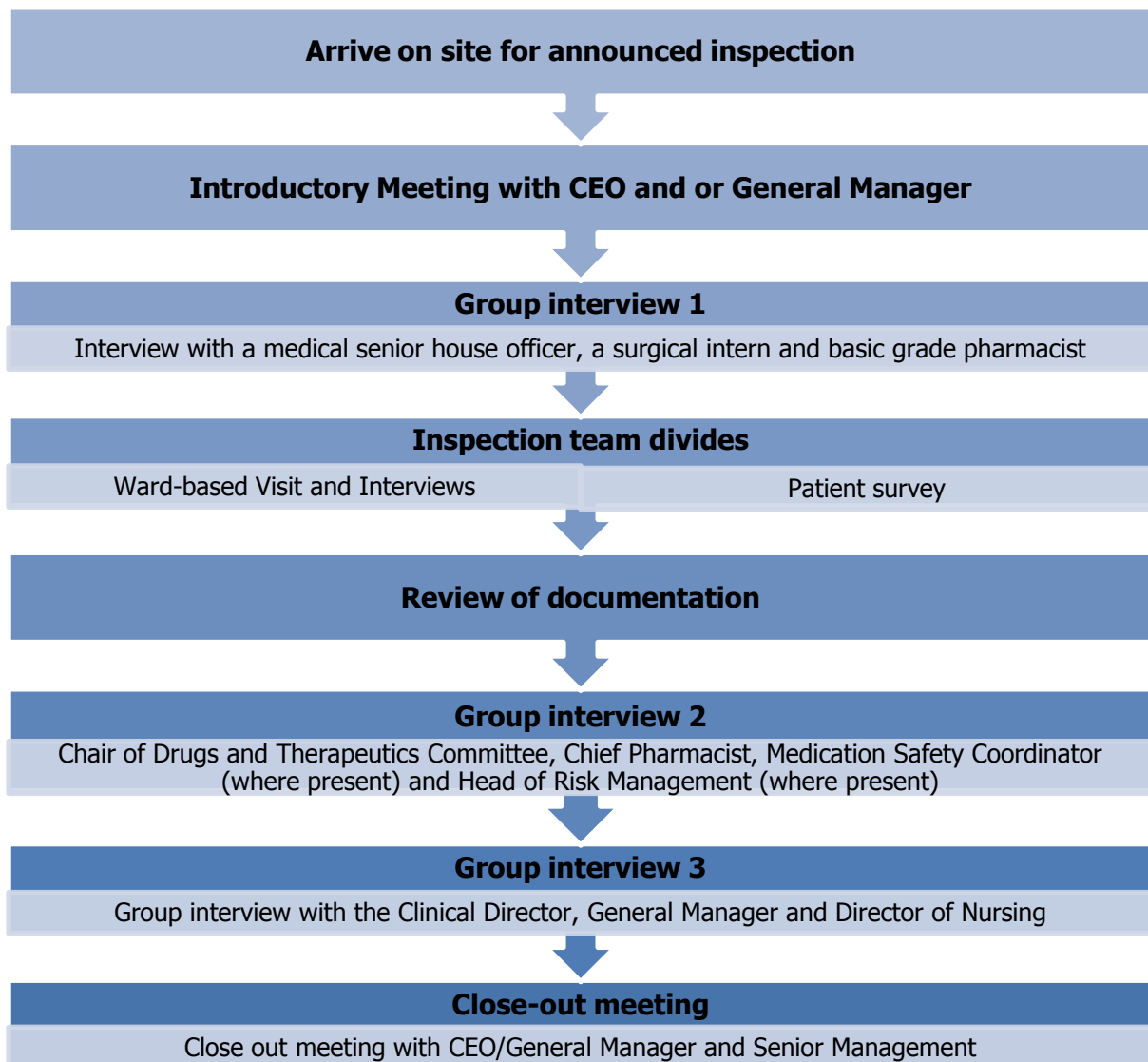
If HIQA receives a request for disclosure of information, HIQA will take full account of each hospital's explanation, but HIQA cannot give an assurance that confidentiality can be maintained in all circumstances. Hospitals must not return any information to HIQA that could be used to identify an individual patient.

Before the on-site inspection

- All associated communication before and after the inspection will be communicated to the General Manager and or the Chief Executive Officer (CEO) of the hospital.

- HIQA will issue notification correspondence confirming the date of the on-site component of the announced inspection **10 working days prior to the inspection.**
- An agenda for the day outlining the schedule of the on-site component of the inspection will be provided with the notification letter (see Figure 3 below). This will include a schedule of meeting times with the service provider in order to ensure that the relevant staff are available.

Figure 3: Sample on-site inspection schedule



- 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 five working days. The purpose of this is to provide background information about the governance arrangements for medication safety in the hospital (see

Appendix 1). There is no requirement to submit other supplementary documentation or evidence in addition to what is requested.

During the on-site inspection

- 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.
- A list of documentation that needs to be reviewed during the inspection will be provided to the hospital at the beginning of the day on site. Other documentation may be required during the inspection. This will vary depending on the inspection and hospitals will be informed if additional documentation is required.
- It is likely that many of the guidelines and procedures required will be part of larger medication management guidelines. Hospitals do not need to remove or photocopy pertinent sections of these documents. Instead, hospitals can identify these sections using bookmarks, tabs or through the display of soft copy or electronic information.
- One staff member should briefly familiarise the inspection team with how the documents are organised.
- If any piece of documentation is not available on the day of the inspection, the inspection team may request that it be provided by the hospital after the inspection to inform the overall evaluation.
- A suitable room will be required by the inspection team during the on-site assessment to accommodate scheduled meetings, interviews and documentation review.
- Please note the pre-inspection request and document requirements have been developed with the understanding that these are already in existence. Service providers do not need to send supplementary information or supporting evidence.

Visits to clinical areas

The inspection team will visit clinical areas to speak with staff. Once the clinical area or areas have been selected, the inspection team will meet with the member of staff responsible for that area in relation to their role and practices within that area for medication safety.

During the course of the clinical area component, the inspection team will review documentation in the clinical area or areas selected for assessment. The service will be required to have the documentation expected to be located in a clinical area, for example, medication management policies, procedures, guidelines, drug monographs, results of medication safety related audit activities and related quality improvement plans for that clinical area.

The inspection team will also speak with medical, nursing and clinical pharmacy staff. These members of staff will be identified during the inspection.

Individual meetings and interviews

The inspection team will talk with relevant senior hospital managers, nurses, medical and pharmacy staff about medication safety practices in the hospital.

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.

Patient experience

The inspection team will distribute a short, anonymous paper questionnaire to a number of patients to gather key information about the advice and information they received in relation to their medication while in hospital and at the point of discharge.

This part of the on-site inspection will require the hospital to identify an area where patients who have been discharged from the hospital are returning for follow-up appointments, for example, an outpatient clinic in the hospital that is being conducted on the day of the inspection. A member of staff will identify these patients to the inspection team. The inspection team will introduce themselves to patients and invite them to complete a brief questionnaire as part of the inspection.

Patients are under no obligation to complete the questionnaire and participation is entirely on a voluntary and anonymous basis. The questionnaire will not request any identifiable patient information.

The hospital also needs to identify a member of staff for patients to contact should patients have any specific clinical concerns regarding their medication or any other matter.

The details of the patient experience component will be discussed and confirmed at the start of the on-site inspection.

Concluding the on-site inspection

When the inspection has been completed, the inspection team will conduct a close-out meeting with senior management and will inform them of the overall findings of the inspection. Senior management will also be informed if any high risks (see section 4 below for more detail) which require immediate action have been identified, to allow them to rapidly address such risks.

4. Risk identification, assessment and notification

During the course of the monitoring assessments, the inspection team may identify specific issues that they believe may present a risk to the health or welfare of patients. Please note that this is applicable to any risk identified - it may not be solely related to medication safety.

- If risks are identified, the inspection team will use HIQA's Risk matrix (see Appendix 2) to assess the level, likelihood and the impact of the identified risks.
- High risks will be escalated in line with HIQA's escalation process (see Appendix 3).
- High risks which require **immediate** mitigation will be brought to the attention of senior management during the course of the on-site inspection to allow them to implement the actions necessary to mitigate such risks. Formal written notification of the identified risk will also be issued to the accountable person or persons* for the service within **two working days** of the inspection, with the requirement to formally report back to HIQA stating how the risk has been mitigated within **two working days** of receipt of the written notification.
- In the case of high risks which **do not** require immediate mitigation, formal written notification of the identified risk will be issued to the accountable person or persons within **two working days** of the risk being identified with the requirement to formally report back to HIQA with an action plan to reduce and effectively manage the risk within **five working days** of receipt of the written notification.
- Details of any risks identified will be included in the report of the monitoring assessment. This will include copies of notification of serious risks and the service provider's response.

* Identified individual or individuals with overall executive accountability, responsibility and authority for the delivery of high-quality, safe and reliable services.

5. The report

Each hospital will receive a written report following the announced inspection. The purpose of the reports are to provide assurances to the public that service providers are making the quality and safety improvements that prevent medication errors and safeguard patients. Reports will also provide service providers with the findings of the assessments. A single report will be generated for each hospital inspected.

A draft copy of the inspection report, together with a feedback form, will be sent to the accountable person or persons to allow them the opportunity to review the draft report and provide feedback regarding factual accuracy. The inspection team will review the feedback and may make changes to the report, if necessary, before issuing a final report to the accountable person or persons.

HIQA reports its findings publicly and each report will be published and made available on www.hiqa.ie to provide assurances to the public that service providers have implemented medication safety programmes and are making quality and safety improvements to help prevent medication errors and safeguard patients. Publication of the report will also enable the sharing of information across the hospital system, such as showing where there are areas of good practice and positive outcomes, and where a further focus for improvement should be concentrated.

6. Expected hospital response

In the event that the inspection team identifies serious risks to patients (either immediate or non-immediate), it is the responsibility of the hospital to respond as previously outlined in section 4.

Each service provider is accountable for the development of a quality improvement plan that prioritises the improvements necessary to comply with the National Standards.³ These 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.

The inspection team will also check during future inspections for evidence that hospitals have taken account of the findings of their individual inspection report and have appropriate plans in place to address any shortcomings that had been identified.

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.

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.

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.

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.

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.

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.

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.

Latent failure: an 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.

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 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 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.

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Appendices

Appendix 1: Pre-Inspection Information Request

A. Drugs and Therapeutics Committee			
A.1	Does the hospital have a multidisciplinary Drugs and Therapeutics Committee in place?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
A.2	Please insert the date of the last Drugs and Therapeutics meeting in the box below. Click here to enter a date.		
A.3	Please provide the job title of the Chair of the Drugs and Therapeutics Committee. <input type="text"/>		
A.4	How often does the hospital's Drugs and Therapeutics Committee meet? (Tick one option only) <input type="checkbox"/> Monthly <input type="checkbox"/> Every other month <input type="checkbox"/> Quarterly <input type="checkbox"/> Twice Yearly <input type="text"/> Other (please specify)		
A.5	Does your hospital hold any joint Drugs and Therapeutics meetings with any other hospital?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
A.6	If yes please list the hospitals:		

A.7	Please list the membership (by roles) of the Drugs and Therapeutics Committee		
A.8	Is there is a list of medications (formulary) stocked in the hospital or readily available from outside sources?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
A.9	Are decisions made to add or remove medications from the formulary guided by written criteria?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
A.10	Is there a system/process to monitor patient safety in use of newly added medications?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
A.11	How often is the hospital's approved list of medications (formulary) reviewed? <input type="text"/>		
A.12	Which member of the senior management team (by role) in your hospital is corporately responsible for oversight of medication safety? <input type="text"/>		
A.13	Does the hospital also have a Medication Safety Committee?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
A.14	(If yes) Please list the membership (by roles) of the Medication safety Committee		
A.15	Is there a defined medication safety programme in place at your hospital?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
A.16	Is there a named individual with a responsibility for co-ordinating medication safety within the hospital?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
A.17	Does an annual review of the medication safety programme take place?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

A.18	Are adverse medication incident reports fed back to the Drugs and Therapeutics Committee?	<input type="checkbox"/> Yes	<input type="checkbox"/> No						
B. Risk Management									
B.1	Are medication management risks included on the hospital's risk register?	<input type="checkbox"/> Yes	<input type="checkbox"/> No						
B.2	Is risk grading carried out on all medication incidents?	<input type="checkbox"/> Yes	<input type="checkbox"/> No						
B.3	<p>How does the hospital identify strengths and weaknesses in medication management systems and inform development of medication safety improvement plans (tick all that apply)?</p> <table border="1" data-bbox="272 680 780 1021"> <tr> <td data-bbox="272 680 780 734"><input type="checkbox"/> Retrospective Chart Review</td> </tr> <tr> <td data-bbox="272 734 780 788"><input type="checkbox"/> Direct observation/ audit</td> </tr> <tr> <td data-bbox="272 788 780 842"><input type="checkbox"/> Trigger tools</td> </tr> <tr> <td data-bbox="272 842 780 896"><input type="checkbox"/> Risk assessments</td> </tr> <tr> <td data-bbox="272 896 780 949"><input type="checkbox"/> Voluntary reporting of adverse drug events</td> </tr> <tr> <td data-bbox="272 949 780 1021"><input type="checkbox"/> Other (please specify)</td> </tr> </table>			<input type="checkbox"/> Retrospective Chart Review	<input type="checkbox"/> Direct observation/ audit	<input type="checkbox"/> Trigger tools	<input type="checkbox"/> Risk assessments	<input type="checkbox"/> Voluntary reporting of adverse drug events	<input type="checkbox"/> Other (please specify)
<input type="checkbox"/> Retrospective Chart Review									
<input type="checkbox"/> Direct observation/ audit									
<input type="checkbox"/> Trigger tools									
<input type="checkbox"/> Risk assessments									
<input type="checkbox"/> Voluntary reporting of adverse drug events									
<input type="checkbox"/> Other (please specify)									
B.4	Does the hospital have a list of medications identified as high risk?	<input type="checkbox"/> Yes	<input type="checkbox"/> No						
B.5	If yes please list:								

C. Education			
C.1	Is there an ongoing education programme for medication safety for each of the following categories of staff (tick all that apply)?		
	<input type="checkbox"/> Non Consultant Hospital Doctors		
	<input type="checkbox"/> Medical Consultants		
	<input type="checkbox"/> Nurse Prescribers		
	<input type="checkbox"/> Non Prescribing Nurses		
	<input type="checkbox"/> Clinical Pharmacists		
	<input type="checkbox"/> Other (please specify)		
	<input type="text"/>		
D. Access to Information			
D.1	What decision support resources are available to the clinical workforce with medication management responsibilities (tick all that apply)?		
	<input type="checkbox"/> Drug monographs		
	<input type="checkbox"/> Local medicines usage guide/ app		
	<input type="checkbox"/> Other (please specify)		
	<input type="text"/>		
D.2	How often are local medication usage guidelines reviewed?		
	<input type="text"/>		
D.3	Can staff electronically access laboratory results in all clinical areas?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
D.4	Are directions for use/administration of emergency medications (antidotes, reversal agents, and rescue agents) readily available in all clinical areas where they are used?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
D.5	Do all wards have access to intravenous drugs monographs?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

E. Clinical Audit	
E.1	With respect to clinical audit over the past 12 months please list all of the medication related audits which have been conducted.
E.2	Please describe how the results of audits are fed back to staff (either individually, or to relevant teams, departments or directorates).
E.3	Please list any medication related quality improvement initiatives that have been conducted/completed in the last two years.
E.4	What measures does the organisation use to monitor the safety of medication usage within the hospital?

F. Policies, procedures/ protocols

F.1

In what format(s) are your policies, procedures guidelines available (tick all that apply):

Printed Booklet

Online Document

App

Intranet

Other (pleaes specify)

F.2

Please list the policies, procedures and/or protocols that have been developed and implemented for medication safety.

F.3. Please list all the key performance indicators you use to evaluate your medication safety programme.

Indicator	Fed back to prescribers?	Reported to Drugs and Therapeutics Committee?	Reported to Hospital Senior Management?
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
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	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No

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 document.

List of documents required prior to announced inspection (if available)		
Copy of the most recent medication safety programme annual report.	<input type="checkbox"/> Yes	<input type="checkbox"/> Not available
Copy of the most recent medication safety programme plan.	<input type="checkbox"/> Yes	<input type="checkbox"/> Not available
Drugs and Therapeutics Committee Terms of Reference.	<input type="checkbox"/> Yes	<input type="checkbox"/> Not available
Minutes of Drugs and Therapeutics Committee from the previous 12 months.	<input type="checkbox"/> Yes	<input type="checkbox"/> Not available
A copy of an organogram clearly showing the lines of communication and cooperation between your hospital's Drugs and Therapeutics Committee/Medication Safety Committee, the Pharmacy Department, the Risk Management Team/Department and your hospital's senior Management Team.	<input type="checkbox"/> Yes	<input type="checkbox"/> Not available

Appendix 2: 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.

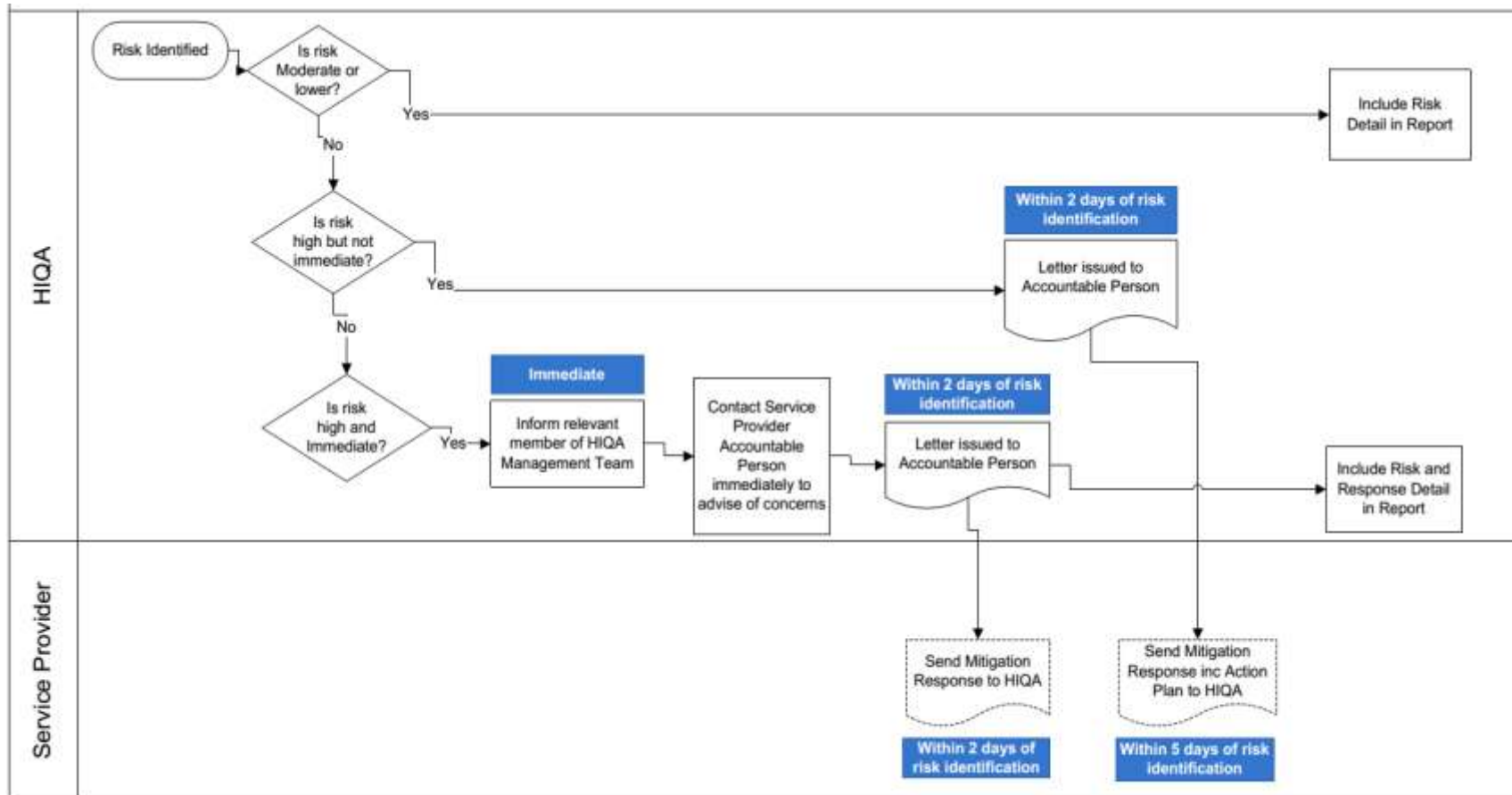
Risk Matrix

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 3: 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.

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