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ICT Patient Safety Risk Assessment

PSRA Guide for ICT Projects

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Contents

1 Introduction

The use of information and communications technology (ICT) in health care settings can deliver real benefits to patients in terms of timeliness, access, accuracy and efficiency. However, it can also introduce new risks and unintended consequences if the system fails, or is not designed, implemented or used properly.

Patient Safety Risk Assessments (PSRAs), undertaken throughout the system lifecycle, can help prevent some of these unintended consequences.

Examples of unintended consequences include[1]:

- New system leading to workflow changes that result in fewer checks and balances
- Extensive computer time leading to less time with the patient
- Some clinicians preferring paper based systems, creating multiple systems/records
- System failures leading to prescriptions being allocated to the wrong patient
- Users assuming the system will send key notifications and messages, leading to required actions not being undertaken
- Misuse of data fields leading to missed or misinterpreted information
- Negative user emotions due to difficulty to use systems and time required
- Overdependence on systems eg. leading to not remembering contraindications during system downtime.

As technology-induced errors have origins in requirements specification, design, development, programming, customisation, implementation and integrations, the PSRA process is embedded in the MP 0001/16 Information and Communications Technology (ICT) Governance Policy.

This Guide focuses on the **PSRA process for ICT Projects**, to help ensure sufficient consideration of clinical risk during the development or deployment of ICT applications.

It is important to note that errors are also introduced through maintenance and support phases, so a whole-of-life cycle approach needs to be taken with ongoing risk management of WA Health's applications and systems, after the system has been implemented.

The key policies and guidelines underpinning PSRAs are:

- MP 0001/16 ICT Governance Policy
- MP 0006/16 Risk Management Policy
- WA Health Clinical Risk Management Guidelines: A Best Practice Guide
- WA Health Integrated Corporate and Clinical Risk Analysis Tables and Evaluation Criteria

The PSRA process for ICT Projects will culminate in a Patient Safety Risk Report, which must be completed and approved during the Project Delivery Stage**,** and **handed over to operations as part of the approval to transition**. The Patient Safety Risk Report demonstrates to relevant stakeholders that a required minimum level of clinical governance has been undertaken throughout the course of the project.

[1] Examples from Health Informatics Society of Australia (HISA) 2016 "*Assuring Patient Safety in Relation to E-Health Systems and Applications Part A: Information Paper,* HISA Ltd.

2 Key Requirements

In accordance with MP 0001/16 ICT Governance Policy, patient safety risk assessments are "required throughout the system lifecycle, for any ICT system or application that impacts, directly or indirectly, on patients. For ICT projects, an ICT Patient Safety Risk Report must be completed and handed over to operations as part of the approval to transition."

The management of patient safety risks within ICT Projects should form part of the overall Project Risk Management Strategy. The process should include an assessment of:

- the likelihood of occurrence of harm to a patient
- the consequence of that harm
- existing controls (to reduce the likelihood of the event or severity of the consequence)
- treatment action plans (TAPs) to minimise the risk.

Regular review of the patient safety risks needs to be undertaken throughout the project, and these risks should be escalated to the Project Board / Project Control Group (PCG) as appropriate for ongoing oversight.

Stakeholder consultation must involve users and appropriate accredited clinicians, including the key or lead business user and any others identified by the Project's Senior User.

Following system implementation, the residual risks identified as part of the project must be transitioned to the appropriate operational areas (user or technical) to own and manage ongoing. This may involve review by local users, the local or state Business User Group, Application Portfolio Manager, Application Business Owner or Business Advisory Group.

All risk management in WA Health is to be conducted in accordance with the MP 0006/16 Risk Management Policy, using ratings and scores from the WA Health Integrated Corporate and Clinical Risk Analysis Tables and Evaluation Criteria. Patient safety risks are usually recorded under consequence category Clinical Care and Patient Safety (PS).

Where there is a potential impact to patient safety, employees should also refer to the WA Health Clinical Risk Management Guidelines for a comprehensive guide to risk management in a clinical context at WA Health.

To ensure that patient safety risk management is embedded in ICT management practice, **Health Service Providers** should consider establishing local policies or procedures that incorporate PSRA requirements, as described in this Guide, into local risk management and project management methodology, if no suitable arrangements currently exist.

3 Quick Guide to PSRAs

The following table summarises the key steps involved in undertaking PSRAs for **ICT projects**. This process is usually completed by the Project Manager but they can also be assigned to another team manager/ member. More information on these steps is provided in this Guide.

PROJECT PHASE	KEY STEPS
PRE-PROJECT STAGE	1. **Initiate Project** a. Read this Patient Safety Risk Assessment Guide. b. Identify the appropriate Risk Management Officer and arrange an initial meeting if required. c. Create an Electronic Document and Records Management System (EDRMS) file for this application/system's patient safety records. d. Consider any initial patient safety risks and benefits to be addressed by this System/Application and incorporate these into the Concept Approval Request (CAR), Project Brief or Business Case.
PROJECT INITIATION STAGE	2. **Establish risk register** a. Establish/identify the Patient Safety Risk Register for this application/system. b. Using a Fishbone Cause and Effect Diagram, or other mind mapping tool, begin to identify and record as many potential causes of patient harm as possible, from the implementation and use of the system. c. Record these as risks in the Risk Register, and attempt to assess the causes, likelihood, consequences and any controls that are already in place that would reduce the level of risk. Document any potential treatment actions. 3. **Conduct patient safety risk assessment workshop** a. Identify stakeholders and plan the workshop. b. Conduct the workshop to evaluate the risks identified at Step 2, considering any further risks, controls, Treatment Action Plans (TAPs) and TAP owners. 4. **Transfer to other project documentation** a. Incorporate any relevant controls and risk treatments into the Project Initiation Document (PID) and any other business requirements documents, including technical specifications and contractual documentation. b. Identify critical controls and incorporate these into the Project Work Breakdown and Resource Requirements. c. Incorporate any relevant patient safety requirements into testing scenarios.
PROJECT DELIVERY STAGE	5. **Assess and treat risks** a. Throughout the project, it will be necessary to **continuously review** and **update** the risk register, in accordance with Project Risk Management Strategy, and **report to the Project Board** on these risks as regularly as appropriate. b. Escalate any risks to appropriate officers where risk rankings are at unacceptable levels. 6. **Evaluate and accept risks** a. Review all residual risk rankings and send to relevant tiers to accept risks. b. Ensure ongoing risk acceptance in the appropriate operational area before implementation to production. c. Complete the Patient Safety Risk Report and circulate it with the final Risk Register to the Risk Management Officer for quality review.
PROJECT CLOSE	7. **Finalise the Patient Safety Risk Report** a. Transfer any residual risks to End Project Documentation, clarifying roles (eg Application Business User Group Chair) in managing ongoing controls within relevant HSPs' operational/corporate risk registers. b. Make any required changes to Patient Safety Risk Report and send it to the Executive (Project) Sponsor for final approval. c. The Patient Safety Risk Report and Risk Register must be handed over to operations as part of the approval to transition.

4 Roles and Responsibilities

Role	Responsibilities
Risk Management Officer	Ensures that the processes defined by the clinical risk management policies and guidelines are followed. This can include providing guidance in the PSRA process and performing a quality review of the Patient Safety Risk Report in accordance with this Guide, WA Health Risk Management Policy and WA Health Clinical Risk Management Guidelines. Health Service Providers should ensure that risk management areas develop capability in ICT risk management and its application to clinical domains.
Executive Sponsor	Ultimately responsible for the project. Ensures that the project is focused on achieving its objectives and products achieve the forecasted benefits. Escalates risks to the appropriate Executive Management team if project tolerances are forecast to be exceeded. Approves the Patient Safety Risk Report. This approval certifies that the Report is delivered to the stated requirements and quality standards and that responsibility for ongoing management can be transferred to the relevant business area.
Project Board	Accountable to the appropriate Executive Management Team for the success of the project and has the authority to direct the project within the remit set out and documented within the Business Case. Ensures that risks are being tracked and managed as effectively as possible as per the project risk management strategy.
Project Manager	Ensures that the project produces the required products (including the Patient Safety Risk Assessment) in accordance with time, cost, quality, scope, risk and benefit performance goals. Undertakes or authorises work packages where necessary (eg. the PSRA work package may be assigned to another officer/team). Conducts risk and issues workshop/s, or assigns to another officer/team.
Risk Owner	Responsible for ensuring the assigned risk is managed so that it can ultimately be accepted based on the project or organisation's risk appetite. In the context of ICT, the risk owners are owners of components of the system or process. These components can be technical or business related. The Risk Owner's responsibilities include the following: • ensures risk treatment action plans are developed, actioned and available within the risk register for assigned risks; • ensures risk register entries and risk treatment action plans are reviewed on a monthly basis for assigned risks; • escalates any issues or difficulties with resolving the risk treatment action plans to the Project Manager.
Senior User	Accountable for ensuring that user needs are specified correctly and that the solution meets those needs. The Senior User(s) is responsible for: • specifying the needs of those who will use the project's products; • ensuring any user resources required for the project are made available; and • monitoring that the solution will meet end-user needs within the constraints of the Business Case in terms of quality, functionality and ease of use.

5 Identifying ICT Patient Safety Risks/Hazards

Patient Safety Risk Assessments involve the identification of hazards associated with the use and deployment of the health software product, under both normal and fault conditions, which may cause harm to patients.

Harm is defined as the "impairment of structure or function of the body and/or any deleterious effect arising there from, including disease, injury, suffering, disability and death, and may be physical, social or psychological."[2] A **hazard** is a source of potential harm to a patient.

In the context of ICT, clinical care and patient safety hazards are those that:

- result in **harm** to patients, i.e. not focused on damage to property, reputation etc
- occur in a **clinical** context, arising from or associated with the provision of healthcare
- are associated with the **implementation or use of ICT**.

It may be helpful to consider hazards as those that impact the ability of the system to provide the following critical success factors:

- the correct information
- about the correct patient
- to the correct health professional
- in the correct location
- at the correct time.

These potential hazards are expressed as **risks** in the Risk Register, and can be stated in the following terms (examples only):

- Inaccurate patient details
- Wrong patient record used
- Incorrect user/clinician details in system
- Incorrect patient location data
- Delay in data transmission.

These risks/hazards can be caused by both human and computer related factors, with examples listed below. A more comprehensive listing is provided at Appendix 2 for further assistance.

Human Factors

- Incorrect data entry
- Accessing the wrong record
- Lack of training
- Lack of attention to detail
- Inappropriate response to alerts (including due to poor interface design)
- Patient entered information is insufficient or incorrect
- Discharge summaries printed prior to treatment
- System printed prescriptions are

Computer Related Factors

- System interface design problems
- System configuration/software problems eg. unable to enter enough information into a screen
- Software function failures
- Malfunctioning devices/network issues (eg printers, monitors, slow networks)
- Incomplete monitoring/feedback systems (eg. GP does not receive alerts and no one is aware of it)
- System makes process longer

[2] WHO International, *Conceptual Framework for the International Classification for Patient Safety* Version 1.1, January 2009, https://www.who.int/publications/i/item/WHO-IER-PSP-2010.2.

later hand amended
- Poor data quality

- Poor useability causing confusion/frustration;
- Design interferes with implementation

A “Fishbone” Cause and Effect Diagram (also known as an Ishikawa Diagram), shown below, is an assessment tool that can be used to assist with analysing potential contributory factors or root causes of each of these patient hazards, either before or during the stakeholder workshop. A blank Visio fishbone diagram is available at Appendix 3. Examples of contributory factors or causes are provided at Appendix 3.] Other tools that can be used include Functional Failure Analysis (FFA), Hazard Identification (HAZID) and Structured What-IF Technique (SWIFT).

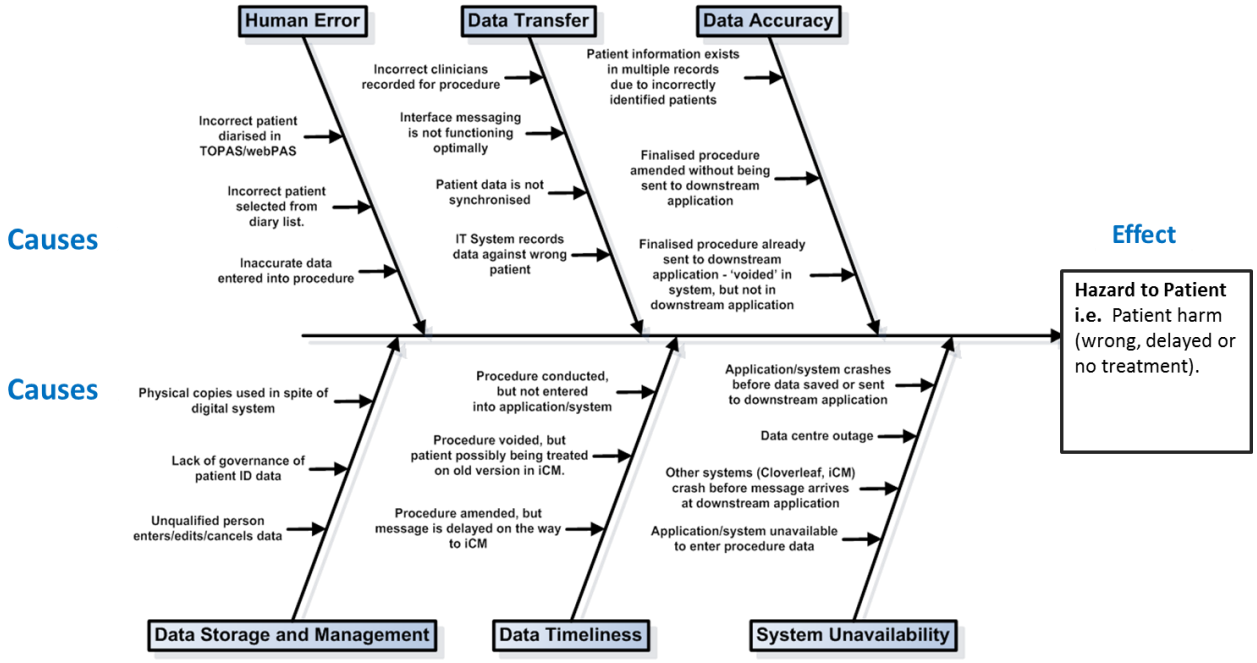

Figure 1. *Sample Fishbone Cause and Effect Diagram*

6 Key Stakeholder Consultation

The Project Manager is required to ensure appropriate clinical and technical consultation in conducting patient safety risk assessments and reviewing the patient safety risk register, and it is strongly recommended that this is obtained via PSRA Workshops.

PRSA Workshops are designed to bring together clinical and technical experts to collectively identify and analyse the clinical and technical hazards that may contribute to patient harm.

Workshop attendees therefore together must have knowledge of business workflows and/or the health ICT software product, its applications and the environment in which it will be used and should include:

1 Key or Lead Business User (Mandatory)
2 Appropriate Accredited Clinicians (Mandatory)
3 Subject Matter Experts/Specialists
4 Message Analysts

5 Technical Experts/Specialist
6 Health Care Professionals / Health and Social Care Professionals / End Users
7 Program Manager
8 Quality Assurance
9 Safety and Quality Resource/Function.

It is recommended that the patient safety risk register and fishbone diagrams (if relevant) be populated as much as possible, prior to the workshop to provide an initial basis of discussion.

For a comprehensive guide to conducting risk analysis, consult the WA Health Clinical Risk Management Guidelines: A Best Practice Guide.

Workshop and attendees, plus any other individuals who have contributed to the assessment/ identification process, should be recorded in the Electronic Document and Records Management System (EDRMS) and Patient Safety Risk Report.

7 Risk Evaluation and Acceptance

The WA Health Integrated Corporate and Clinical Risk Analysis Tables and Evaluation Criteria shows four levels of risk rank, from low through to extreme, with associated risk acceptability / tolerance and conditions.

During the initial risk assessment/s, an initial risk ranking is obtained for each risk. Commensurate with this level of risk, an appropriately-tiered Risk Owner must be assigned to ensure risk Treatment Action Plans (TAPs) are actioned, risk register entries are reviewed regularly and issues are escalated as needed, so that the risk can ultimately be accepted based on the project and/or organisation's risk appetite.

Once TAPs have been completed, the risk ranking for each hazard should be reduced. This is the Residual Risk. A summary of these final risk rankings will need to be recorded in the Patient Safety Risk Report.

Each of the risks will need to be evaluated for final acceptance by the operational Risk Owner (in the appropriate technical or business area) before the system/application can go into operation.

Decisions concerning risk acceptability may be based on clinical, operational, technical, financial, legal, social, humanitarian or other criteria. These often depend on an organisation's internal policy, goals, objectives and the interests of stakeholders.

Some of the reasons why a clinical risk may be deemed as acceptable include:

- the likelihood and/or consequence of the risk are so low that specific treatment is inappropriate given the available resources.
- there is no treatment available for the risk and the level of risk associated with it is lower than the levels of risk for all the known alternative actions, including doing nothing.
- the opportunities presented outweigh the threats to such a degree that the risk is justified.

Where risks remain unacceptably high, information must be provided in the Patient Safety Risk Report to outline any further actions being undertaken to reduce these risks. This approved report is a requirement in the Project's Implementation Readiness Checklist (HSS Change Board) or other relevant change authority's requirements.

8 Quality Assurance and Approval

Risk Management Officer Review

The Risk Management Officer provides:

- guidance in the risk management and PSRA process and
- quality assurance of the Patient Safety Risk Report prior to final sign off.

A final draft of the Patient Safety Risk Report should be provided to the Risk Management Officer for review prior to final sign off. The Risk Management Officer must review the Patient Safety Risk Report in accordance with this Guide, WA Health Risk Management Policy and WA Health Clinical Risk Management Guidelines.

Health Service Providers should ensure that their risk management areas develop capability in the area of ICT risk management and its application to clinical domains.

Final Approval

The final Patient Safety Risk Report is to be approved by the Project's Executive Sponsor. This approval certifies that the Report is delivered to the stated requirements and quality standards and that responsibility for ongoing management can be transferred to the relevant business area.

9 Risk Transfer from Project to Operations

At Project Closure, responsibility and ownership of all final and ongoing patient safety risks must be reflected in End Project Documentation for transfer to Operations, along with the Patient Safety Risk Report and other PSRA records. "Operations" can include the relevant Application/System Support Team (technical) and Application Owner (business).

Following system implementation, ongoing patient safety risks are to be controlled and updated throughout the life of the application/system. This may involve regular review by local users, the local or state Business User Group, Application Portfolio Manager, Application Business Owner, or Business Advisory Group, in line with local risk management policies and procedures.

10 Document Control and Record Management

All PSRA documentation and supporting evidence must be recorded in the official Electronic Document and Records Management System (EDRMS) for this application/system, to provide traceability and an audit trail for all safety related activities. Documentation includes:

- Evidence of stakeholder consultation undertaken (eg via workshops and any other post workshop activities which were used to finalise the risk register)
- Patient Safety Risk Register
- Correspondence in relation to risk acceptance and TAPs
- Copy of the signed Patient Safety Risk Report.

The Patient Safety Risk Report should be clearly marked with document number and version number. The document should also be marked with any security/classification if appropriate.

Appendix 1 – Definitions

Term	Definition
Accredited clinician	A suitably qualified and experienced clinician / health care professional
Clinical Hazard	A clinical (or patient safety) hazard is a source of potential harm to a patient. In the context of ICT development, deployment and use, clinical hazards are those that impact the ability of the system to provide the correct information about the correct patient, to the correct health professional, in the correct location at the correct time.
Consequence	A consequence is an outcome of an event affecting objectives. It refers to the outcome or impacts of an event expressed qualitatively or quantitatively, being a loss, injury, disadvantage or gain. There may be a range of possible outcomes associated with an event. In the context of clinical risk management, the consequence is ideally expressed as a clinical consequence, i.e. focusing on the possible harm to the patient.
Consequence category	Refer to the WA Health Integrated Corporate and Clinical Risk Analysis Tables and Evaluation Criteria to determine the relevant category. Patient safety risks are usually recorded under the category Clinical Care and Patient Safety (PS).
Consequence rating	The consequence rating is the degree of severity of harm to a patient. The consequence rating is calculated and ranked as **Insignificant, Minor, Moderate, Major or Catastrophic**. This rating should take into account any controls that are already in place to reduce the consequence to a patient.
Control	Control refers to any existing process, policy, device, practice or other action that acts to minimise negative risk or enhance positive opportunities. They can include mandatory policies, procedures, business continuity plan, functional specifications, business case, training plan, Request for Tender (RFT).
Control rating	Using the WA Health Integrated Corporate and Clinical Risk Analysis Tables and Evaluation Criteria, a Control Rating of: **Excellent**, **Satisfactory**, **Marginal**, **Weak** or **Unknown** is allocated using the Controls Adequacy Table. Controls are assessed using the following Control Assessment Questions: 1. **Documented**: is the control's documentation up to date? 2. **Awareness**: is the control well communicated to the relevant people? 3. **Compliance**: is the control impossible to by-pass? 4. **Effectiveness**: is the control effective (100% + all the time)?
Fishbone Cause and Effect diagram	The Fishbone (or Ishikawa) Cause and Effect diagram is a root cause analysis technique which uses the concept of a fishbone to capture the causes to a pre-defined hazard.
Likelihood	The likelihood is the chance of something happening that has the consequences assessed in the steps above. The initial (or inherent) likelihood should take into account any existing controls in place to reduce the likelihood of harm to a patient.
Likelihood rating	The likelihood rating is to be taken from the WA Health Integrated Corporate and Clinical Risk Analysis Tables and Evaluation Criteria.
Patient Safety Risk	A Patient Safety Risk is the chance of something happening that will impact on the health and safety of a patient or patients.

Patient Safety Risk Management	This is the reduction of the risk of unnecessary harm associated with healthcare to an acceptable minimum. An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the risk of non-treatment or other treatment.
Residual Risk Ranking	Once Treatment Action Plans have been implemented, the consequence and/or likelihood should be reduced. The Residual Risk Ranking is the level of risk that remains, based on the new consequence or likelihood rating. *Residual Risk Ranking = residual consequence rating x residual likelihood rating*
Risk	A risk is the chance of something happening that will have an impact upon values, goals or objectives.
Risk Acceptance	An informed decision to accept the likelihood and consequences of a particular risk. Clinical risk acceptability/ tolerance matters are to be determined by the Project Board in line with the project or organisation's risk appetite, and escalated as required to the Executive Sponsor/s. This evaluation should consider the degree of control that the organisation has over each risk and the potential cost impact, benefits and opportunities. Decisions may be based on clinical, operational, technical, financial, legal, social, humanitarian or other criteria. These often depend on an organisation's internal policy, goals, objectives and the interests of stakeholders.
Risk Ranking	Combination of the consequence (severity of harm to a patient) and the likelihood of occurrence of that harm. There are four levels of risk rank: low, medium, high and extreme. Refer to the WA Health Integrated Corporate and Clinical Risk Analysis Tables and Evaluation Criteria for guidance. *Risk ranking = consequence level x likelihood level*
Risk Register	A Patient Safety Risk Register template, outlining the minimum requirements, is available for use. A Risk Register can be any risk register that is defined in the project's risk management strategy, including an MS Excel or Word Document, or specific software, such as the Project and Portfolio Management Tool (PPM).
Patient Safety Risk Report	The Patient Safety Risk Report is the primary vehicle for presenting a statement of the clinical safety of the Health ICT system/application before it goes into operation. It summarises all the key elements of the Patient Safety Risk Assessment process undertaken for this project.
Treatment Action Plan (TAP)	This refers to the plan, that is developed and reviewed during the risk treatment process, of selecting and implementing the appropriate actions for dealing with identified risk. TAPs should include detail on the risk owner, proposed actions, resource requirements, timeframes and effect of the treatment on the risk. Examples of risk treatments include: user manual, training plan, testing strategy, system monitoring, appointment of staff, accreditation.

Appendix 2 – Contributory Factors / Causes

The following list provides examples to consider when identifying contributory factors or root causes of patient safety hazards in the risk register (HP category). The categories align to the categories in the Fishbone Cause and Effect diagram. This is not an exhaustive list and should not replace proper analysis and discussion on the nature of the specific system or application. Note that causes can belong in more than one category.

Human Error:

- Inaccurate data entered
- Incorrect patient selected
- Duplicate record created
- Data entered not saved
- Incorrect patient location
- Failure to record vital details
- Administrator makes changes without approval
- Wearables are not worn properly on body
- ID cards are not brought to work

Data Transfer:

- Incorrect patient demographics entered in feeder system
- Different Patient ID systems used in WA Health
- Connectivity with feeder system server
- HE number/password not available
- Health Information Hub (HIH) crashes
- Organisation tree not up to date
- Requestors copying incorrect patient information from webPAS or EBM
- Failure to integrate with the other systems

Data Accuracy

- Unable to produce meaningful reports
- Insufficient training to use system
- Inaccurate data entered
- Recommendations made without supporting evidence
- Failure to save record
- Development of workaround by staff regard to alerts/notification/timelines
- Failure to comply with new Business process
- Unauthorised person enters/edits/cancels incident
- Patient ID not recognised by system
- Paper form not transferred to system
- Incorrectly named location in source data
- Out of date location data

Data Storage and Management

- Misuse of generic logins
- Wrong access provided to users
- Inappropriate data migration in relation to integrated system

Data Timeliness

- Failure to meet Health Service Provider, System Manager, State or National data requirements
- Time out functionality
- Failure to integrate with the other systems
- Wi-Fi network performance is reduced
- Remote internet coverage speed
- Slow performance (or backlog of messages) from feeder system interfaces.

System Unavailable

- System not responding
- Remote internet coverage unavailable
- Alerts and email notifications not issued due to system failure
- Availability of network access
- Server/database failure
- Unplanned application outage
- Wearables not charged – battery is flat
- Wearables are faulty
- No Wi-Fi coverage
- Integrated system is down

Appendix 3 – Risk Register Template

This sample risk register template provides the minimum recommended fields for undertaking patient safety risk assessments.
An **MS Excel** version with in-built formulae and selection fields is available. Please visit the PSRA page at HealthPoint.

RISK REF	CATEGORY	RISK	CAUSES	CONSEQUENCES	EXISTING CONTROLS	CONTROLS RATING	CONSEQUENCE CATEGORY	INITIAL RISK CONSEQUENCE RATING	INITIAL RISK LIKELIHOOD RATING	INITIAL LEVEL OF RISK	INITIAL RISK RANKING	TREATMENT ACTION PLAN (TAP)	TAP OWNER	RESIDUAL CONSEQUENCE RATING	RESIDUAL LIKELIHOOD RATING	RESIDUAL LEVEL OF RISK	RESIDUAL RISK RANKING	RISK ACCEPTANCE TIER	RISK OWNER / ACCEPTANCE OFFICER	NOTES
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Appendix 4 – Fishbone Diagram Template