

## Patient Safety Incident Response Plan (PSIRP)

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### Introduction

The NHS Patient Safety Strategy was published in 2019 and describes the Patient Safety Incident Response Framework (PSIRF) as a foundation for change and as such, it challenges us to think and respond differently when a patient safety incident occurs. It is a replacement for the NHS Serious Incident Framework. This document is the Patient Safety Incident Response Plan (PSIRP) and sets out how Fairlie Healthcare Group will respond to patient safety incidents.

PSIRF is designed to promote learning and systemic improvement, moving away from the previous Serious Incident Framework which focussed more on process than emphasising a culture of continuous improvement in patient safety.

This framework is designed to focus on doing investigations in a collaborative way, led by those who are trained to conduct them. It ensures the involvement of patients, carers, families, and staff in an embedded system that responds in the right way, appropriate to the type of incidents and associated factors. It recognises the need to provide a safe and supportive environment for those involved in any investigation, with an emphasis on systemic improvement.

Analysis of our current systems has improved our understanding of our patient safety processes and allowed us to use these insights to develop our PSIRP.

The Fairlie Healthcare Group supports a culture of safety and openness. All staff are required to report events so that steps can be taken to improve the safety of patients. The Patient Safety Incident Response Framework (PSIRF) sets out the Fairlie Healthcare Group's approach to developing and maintaining effective systems and processes for responding to patient safety incidents and issues for the purpose of learning and improving patient safety.

The Fairlie Healthcare Group intends to respond to patient safety incidents within agreed timeframes of between 20 (Duty of Candour/Complaints) to 30 days in agreement with stakeholders but no longer than a period of 12 to 18 months if being instructed not to investigate by the Police or because the investigation is extensive. The plan is not a permanent rule that cannot be changed. We will remain flexible and consider the specific circumstances in which patient safety issues and incidents occurred and the needs of those affected.

## Scope

There are many ways to respond to an incident. Our PSIRP covers responses conducted solely for the purposes of systems-based learning and improvement.

Patient safety incidents are any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare. Reporting safety events, however trivial they may appear enables greater risk identification of the operational and clinical risks that exist for patients. By better understanding the patterns and trends of events, Fairlie Healthcare Group can manage the underlying risks in a more effective way. Therefore, the nature of reporting events not only enables improved risk management, but also enables us to comply with statutory requirements and other regulatory frameworks in terms of standards and clinical governance.

There is no remit to apportion blame or determine liability, preventability, or cause of death in a response conducted for the purpose of learning and improvement.

Other types of response exist to deal with specific issues or concerns, and it is outside the scope of PSIRF to review matters to satisfy processes relating to these, examples of which may include complaints, HR matters, legal claims, and inquests.

## Resources, Support & Collaboration

The most appropriate investigator/s will be allocated to investigate the patient safety incident and support will be given by other senior colleagues whether within the Care Centre's senior management team or the Executive Director Team to enable the investigator/s to have the capacity within their working schedule to give the investigation their full attention.

All Care Centres will work closely, openly, and collaboratively with the staff, Patient(s), and their relatives as well as with all external agencies including the ICB, Safeguarding, Police, CQC, HSE, MHRA and Coroner.

The investigator, Care Centre Director, Clinical Services Manager or Executive Director must take the opportunity at the first interaction with the stakeholder to agree how any information will be shared with them including the preferred future method of communication for keeping Patients and relatives informed of the progress of the investigation, i.e., telephone, face to face (meeting), email or by letter. Then finally, the completed investigation, outcomes, and action plans including learning.

The importance of support for staff from line managers, and colleagues in the aftermath of a patient safety incident should not be underestimated. Being available for staff and hearing/acknowledging their story surrounding the event is crucial. Staff require a safe and confidential space in which to discuss the incident and can find this therapeutic.

The conduct of members of staff when supporting Patients, relatives, external stakeholders, and other members of staff especially following an incident, will be conducive to our values framework and include kindness, compassion, integrity, courage, empathy, honesty.

The organisation must offer support & resources that reflects the "Assist me" model.

- **Acknowledge** - with empathy the incident that has occurred and the impact on the member of staff.
- **Assess** - the impact of the incident on the member of staff and on their ability to continue normal work.
- **Sorry** - express regret for what has happened and for their experience.
- **Story** – allow time and space for the member of staff to talk about what happened and how they are feeling.
- Demonstrate understanding. Share experience, as appropriate.
- **Inquire** – encourage questions.
- **Information** – provide information.
- **Supports & Solutions** -
  - Informal Emotional Support: Demonstrate empathy and compassion. Be available and accessible to provide support, as required.
  - Formal Emotional Support: Assess any immediate needs and discuss supports available including referral process e.g., Employee Assistance Programme (EAP), Occupational Health and/or GP.
  - Practical Support: Discuss and agree immediate working arrangements e.g., ability of staff member to continue with normal duties – consider allocation to other duties, as appropriate. Provide contact details for staff liaison person.
- **Travel** – provide continued support and reassurance going forward and throughout the incident review/open disclosure process.
- **Maintain** - contact and ongoing communication.
- **Monitor progress** – check in regularly with the staff member.
- **Move** forward with guidance and support.
- **End** – close this support process when the staff member feels ready. Remain available.

- **Evaluate** - the staff members experience of the support process and use learning to benefit other staff.

### Defining our patient safety incident profile

In order to determine any priority areas to support the delivery of the new PSIRP, an understanding of the scale of patient related safety activity was required. The PSIRF advocates a co-ordinated and data-driven response to patient safety incidents. It embeds patient safety incident response within a wider system of improvement and prompts a significant cultural shift towards systematic patient safety management.

Data and information from a variety of sources has been gathered from **January 2018 to December 2023** across a wide range of data. The governance framework continuously seeks to identify the necessary “inputs” from which a wide variety of data is fed into the framework followed by the processing of such data and then finally the “outputs.” The input data is wide ranging and comes from multiple sources including Residents and their family members, & staff.

- Patient safety incidents
- Serious Incidents including a never event
- Complaints
- Freedom to Speak Up

Further data sources to be reviewed:

- Mortality / Learning from deaths
- Safeguarding - any event that constitutes abuse, where abuse is suspected, or an event/s highlights a safety concern
- Staff & Patient experience survey results
- Risk management
- CQC inspections and events
  - **An unexpected death caused by the potential actions of a staff member**
  - **Safeguarding event**
  - Any injury to a resident that results in:
    - Permanent impairment to sensory, motor, or intellectual functions
    - **Changes to the structure of a Patient’s body**
    - The Patient is experiencing prolonged pain or prolonged psychological harm
    - **The shortening of a Patient’s life expectancy**
  - **Any injury that requires treatment to prevent the death of a patient**
  - Any event which prevents the normal operation of the service
- To the Health and Safety Executive under RIDDOR
- To the police if they meet those criteria listed above

- To the Medicines and Healthcare Products Regulatory Agency (MHRA)
- Or, if a trend is identified in a similar category of events even if of low or no harm but highlights a potential developing safety concern

### Our patient safety incident response plan: national requirements

Some events in healthcare require a specific type of response as set out in national policies or regulations. These responses may include review by or referral to another body or team, depending on the nature of the event. Incidents meeting the Never Events criteria (2018) and deaths thought more likely than not due to problems in care (i.e., incidents meeting the Learning from Deaths criteria for PSII) require a locally led PSII.

Table 1 below sets out the local or national mandated responses.

	National priority	Response
1	Incidents that meet the criteria set in the Never Events list 2018	Locally led PSII
2	Deaths clinically assessed as more likely than not due to problems in care	Locally led
3	Maternity and neonatal incidents meeting the Healthcare Safety Investigation Branch (HSIB) criteria	Refer to HSIB for independent PSII
4	Child Deaths	Refer for Child Death Overview Panel review. Locally led-PSII (or other response) may be required alongside the Panel review - organisations should liaise with the panel
5	Death of persons with learning disabilities	Refer for Learning Disability Mortality Review (LeDeR) Locally led PSII (or other response) may be required alongside the LeDeR review

6	<p>Safeguarding incidents in which: Babies, children, and young people are on a child protection plan; looked after plan or a victim of wilful neglect or domestic abuse/ violence.</p> <p>Adults (over 18 years old) are in receipt of care and support needs by their Local Authority</p> <p>The incident relates to FGM, Prevent (radicalisation to terrorism; modern slavery &amp; human trafficking or domestic abuse/violence.</p>	<p>Refer to local authority safeguarding lead.</p> <p>Healthcare providers must contribute towards domestic independent inquiries, joint targeted area inspections, domestic homicide reviews and any safeguarding reviews (and enquiries) as required to do so by the Local Safeguarding Partnership (for children) and local Safeguarding Adults Boards</p>
7	<p>Incidents in screening programmes</p>	<p>Refer to local Screening Quality Assurance Service for consideration or locally led learning response</p> <p>See : Guidance <a href="https://www.gov.uk/guidance/managing-safety-incidents-in-nhs-screening-programmes">Managing safety incidents in NHS screening programmes - GOV.UK (www.gov.uk)</a></p>
8	<p>Deaths in custody (e.g. police custody, in prison , etc ) where health provision is delivered by the NHS</p>	<p>In prison and police custody, any death will be referred (by the relevant organisation) to the Prison and Probation Ombudsman (PPO) or the independent Office for Police Conduct (IOPC) to carry out the relevant investigations.</p> <p>Healthcare providers must fully support these investigations where required to do so.</p>
9	<p>Deaths of patients detained under the Mental Health Act (1983), or where the Mental Capacity Act (2005) applies, where there is reason to think that the death may be linked to problems in care (incidents meeting the Learning from Deaths criteria)</p>	<p>Locally led PSII by the provide in which the event occurred with STG/ESTH participation if required</p>
10	<p>Mental health related homicides</p>	<p>Referred to the NHS England and NHS Improvement Regional Independent Investigation team for consideration for an independent PSII</p> <p>Locally led PSII may be required with mental health provider as lead and STG / ESTH participation</p>
11	<p>Domestic Homicide</p>	<p>A Domestic Homicide is identified by the police usually in partnership with the Community Safety Partnership (CSP) with whom the overall responsibility lies for establishing a review of the case. Where the CSP considers that the criteria for a Domestic Homicide Review (DHR) are met, they will utilise local contacts and request the establishment of a DHR Panel. The Domestic Violence, Crime and Victims Act 2004, sets out the statutory obligations and requirements of providers and commissioners of health services in relation to domestic homicide reviews.</p>

## Our patient safety incident response plan: local focus

The Fairlie Healthcare Group has implemented a System-based Analysis approach to safety investigations which is a well-recognised way of investigating safety incidents that has been adopted by the Health and Safety Executive. Analysis is used to identify areas for change and to develop recommendations which deliver safer care for Patients. The systems analysis model for investigations focuses on prevention, not blame or punishment.

Events classified as requiring a [patient safety incident investigation \(PSII\)](#) are those defined in our patient safety incident profile and below in reporting guidelines and indicators.

Fairlie Healthcare Group intends to respond to patient safety incidents within agreed timeframes of between 20 (Duty of candour/Complaints) to 30 days in agreement with stakeholders but no longer than a period of 12 to 18 months if being instructed not to investigate by the Police. The plan is not a permanent rule that cannot be changed. We will remain flexible and consider the specific circumstances in which patient safety issues and incidents occurred and the needs of those affected.

The organisation will plan and conduct systems-based investigations utilising the four Ps (people - stakeholders involved, paper – documentation relevant to the incident, parts – equipment involved and place – the environment where the incident occurred). During the systems-based analysis investigation, and when the key causal factors of the event have been established, it will be necessary to define the action points that need to be implemented to reduce the risk of a similar event occurring again. Not only will the action plan outline learning through safety alerts, safety hubs, staff meetings/supervision and handovers but will form part of each Care Centre's Service Improvement Plan which is reviewed and updated by the Senior Management Team in liaison with the Director of Clinical Services on a monthly basis as part of the Operational Board meeting and as required as part of the daily operations of each Care Centre. Ultimately, to be shared at the Quality, Clinical Governance quarterly meeting for each centre.

There are different forms of system-based learning that can be used depending on the incident and is at the discretion of the investigator and/or senior management team to support a system-based analysis:

### [Multidisciplinary team \(MDT\) review](#)

An MDT review supports health and social care teams to learn from patient safety incidents that occurred in the significant past and/or where it is more difficult to collect staff recollections of events either because of the passage of time or staff availability. The aim is, through open discussion (and other approaches such as observations and walk throughs undertaken in advance of the review meeting(s)), to agree the key contributory factors and system gaps that impact on safe patient care.

### [Swarm huddle](#)

The swarm huddle is designed to be initiated as soon as possible after an event and involves an MDT discussion. Staff 'swarm' to the site to gather information about what happened and why it happened as quickly as possible and (together with insight gathered from other sources wherever possible) decide what needs to be done to reduce the risk of the same thing happening in future.

### [After action review \(AAR\)](#)

AAR is a structured facilitated discussion of an event, the outcome of which gives individuals involved in the event understanding of why the outcome differed from that expected and the learning to assist improvement. AAR generates insight from the various perspectives of the MDT and can be used to discuss both positive outcomes as well as incidents.

It is based around four questions:

- What was the expected outcome/expected to happen?
- What was the actual outcome/what actually happened?
- What was the difference between the expected outcome and the event?
- What is the learning?

<b>ADVERSE CLINICAL EVENTS/ REPORTING GUIDELINES AND INDICATORS</b>					
<b>INDICATOR</b>	<b>REPORTING MECHANISM</b>	<b>INTERNAL THRESHOLD</b>	<b>ACTION</b>	<b>EXCEPTIONAL THRESHOLD</b>	<b>EXCEPTIONAL ACTION/PSIRF</b>
<b>Therapeutic processes and procedures</b>	ACE Form	0	Investigation	Harm	As per other indicators
<b>Pressure Sore (at the Home)</b>	ACE Form	0	Investigation	Grade 3 or above	Safeguarding CQC Notify
<b>Pressure Sore (externally)</b>	ACE Form	-	-	Grade 3 or above	Safeguarding CQC Notify
<b>Unplanned transfer to hospital</b>	ACE Form	-	Investigation		



<b>Medication Administration Error</b>	ACE Form	0	Investigation Reflection	Harm	CQC Notify
<b>Administration of medicine by the wrong route</b>		Never Event	Investigation	Never Event	CQC Notify ICB Notify Safeguarding
<b>Overdose of insulin due to abbreviations or incorrect device</b>		Never Event	Investigation	Never Event	CQC Notify ICB Notify Safeguarding
<b>Overdose of methotrexate for non-cancer treatment</b>		Never Event	Investigation	Never Event	CQC Notify ICB Notify Safeguarding
<b>Infection requiring antibiotics</b>	ACE Form	0			
<b>NEWs Protocol Activation</b>	ACE Form	-			
<b>Unexpected Death</b>	ACE Form	-		All	CQC Notify Police/ Coroner
<b>Expected Death</b>	ACE Form	-	-	All	CQC Notify only
<b>Adult Protection</b>	ACE Form	0	-	All	Safeguarding CQC Notify
<b>Event involving medical equipment</b>	ACE Form	0	Investigation	Device Failure	MHRA Notify
<b>Documentation Issues</b>	ACE Form	0		Harm	Investigation
<b>ADVERSE NON-CLINICAL EVENTS/ REPORTING GUIDELINES AND INDICATORS</b>					
<b>INDICATOR</b>	<b>REPORTING MECHANISM</b>	<b>INTERNAL THRESHOLD</b>	<b>ACTION</b>	<b>EXCEPTIONAL THRESHOLD</b>	<b>EXCEPTIONAL ACTION/PSIRF</b>
<b>Behaviour (inc violence and aggression)</b>	ANCE Form	0	Investigation	Serious	Police CQC Notify

<b>Security Breaches</b>	ANCE Form	0	Investigation	Serious	Police CQC Notify
<b>Information Governance Breaches</b>	ANCE Form	0	Investigation	Critical	Information Commissioner
<b>Devices, equipment, and supplies</b>	ANCE Form	0	Investigation	Critical	Manufacturer/ Supplier
<b>Events involving the Police</b>	ANCE Form	0	Investigation	Serious	Police CQC Notify
<b>Policy Failures</b>	ANCE Form	0	Investigation	Harm	
<b>Quality Issues</b>	ANCE Form	0	Investigation	Harm	
<b>Nutrition/ Food</b>	ANCE Form	0	Investigation	Harm	
<b>Administration Procedures</b>	ANCE Form	0	Investigation	Harm	
<b>Staff Shortages</b>	ANCE Form	0	Investigation	Harm	
<b>Other</b>	ANCE Form	0	Investigation	Harm	
<b>ACCIDENT/ REPORTING GUIDELINES AND INDICATORS</b>					
<b>INDICATOR</b>	<b>REPORTING MECHANISM</b>	<b>INTERNAL THRESHOLD</b>	<b>ACTION</b>	<b>EXCEPTIONAL THRESHOLD</b>	<b>EXCEPTIONAL ACTION/PSIRF</b>
<b>Slips/ trips/ falls</b>	AR Form	0	Investigation	Serious	RIDDOR
<b>Falls from poorly restricted windows</b>		Never Event	Investigation	Never Event	CQC Notify ICB Notify Safeguarding RIDDOR
<b>Injury due to equipment</b>	AR Form	0	Investigation	Serious	RIDDOR

<b>Cuts, abrasions, burns, grazes, and sprains</b>	AR Form	0	Investigation	Serious	RIDDOR
<b>Scalding of patients during bathing and washing</b>		Never Event	Investigation	Never Event	CQC Notify ICB Notify Safeguarding RIDDOR
<b>Entrapment and crush injuries</b>	AR Form	0	Investigation	Serious	RIDDOR
<b>Chest or neck entrapment in bedrails</b>		Never Event	Investigation	Never Event	CQC Notify ICB Notify Safeguarding RIDDOR
<b>Other</b>	AR Form	0	Investigation	Serious	RIDDOR

#### CRITICAL EVENT/ REPORTING GUIDELINES AND INDICATORS

INDICATOR	REPORTING MECHANISM	INTERNAL THRESHOLD	ACTION	EXCEPTIONAL THRESHOLD	EXCEPTIONAL ACTION/PSIRF
<b>Failure of key services</b>	CE Form	0	Investigation	Serious	As per policy CQC Notify
<b>Fire</b>	CE Form	0	Investigation	Serious	As per policy
<b>Health and Safety breach</b>	CE Form	0	Investigation	Serious	As per policy HSE (Health and Safety Executive)
<b>Outbreak, infectious disease</b>	CE Form	0	Investigation	Serious	As per policy
<b>Serious staff shortages</b>	CE Form	0	Investigation	Serious	As per policy CQC Notify
<b>Other</b>	CE Form	0	Investigation	Serious	As per policy

COMPLAINTS/ REPORTING GUIDELINES AND LEVELS					
INDICATOR	REPORTING MECHANISM	INTERNAL THRESHOLD	ACTION	EXCEPTIONAL THRESHOLD	EXCEPTIONAL ACTION
Level I	Verbal	0	Investigation	Unresolved to Level 2	-
Level II	Written	0	Investigation	Unresolved to Level 3	Refer to Executive Board
Level III	Written	0	Investigation	Unresolved to Ombudsman	Refer to Executive Board
Ombudsman	External	0	-	-	Notify Insurance Company

This PSIRP will have the flexibility to manage emergent risks or new incidents that signify extreme levels of risk or incidents that don't fall into the outlines national or local categories, Fairlie Healthcare Group will take a pragmatic approach and a proportionate response to maximise learning.

Enhanced Governance and Investigation Training will be delivered by the Director of Quality, Clinical Governance & Risk to members of the senior management team including Executive Directors (Clinical), Care Centre Directors, Clinical Services Managers and Nursing Ward Managers.

These sessions will be supported by reading collateral and further follow up sessions will be available on the request of the individual. Training will include the Clinical Governance Framework, Complaint Management, Duty of Candour, Event Reporting and PSIRF, Health & Safety, System based Analysis Investigations, and Service improvement.

### Review of the Plan

**Fairlie Healthcare Group** will review this plan every 12-18 months in line with national guidance. If there is a change to the plan, **Fairlie Healthcare Group** will notify the ICB to agree sign off the change .

Where there is a cluster or unexpected significant number of incidents, ICB may ask for an earlier review of the plan as appropriate .

For more information, please refer to the following policies:

- Event Reporting & Patient Safety Incident Response Framework
- Quality & Governance Strategy

## **Annex 1 - Glossary**

### **PSII** - Patient Safety Incident Investigation

PSIIs are conducted to identify underlying system factors that contributed to an incident. These findings are then used to identify effective, sustainable improvements by combining learning across multiple patient safety incident investigations and other responses into a similar incident type. Recommendations and improvement plans are then designed to address those system factors and help deliver safer care for our patients effectively and sustainably.

### **PSIRP** - Patient Safety Incident Response plan

Our local plan sets out how we will carry out the PSIRF locally including our list of local priorities. These have been developed through a coproduction approach with the divisions and specialist risk leads supported by analysis of local data.

### **PSIRF** - Patient Safety Incident Response Framework

Building on evidence gathered and wider industry best-practice, the PSIRF is designed to enable a risk-based approach to responding to patient safety incidents, prioritising support for those affected, effectively analysing incidents, and sustainably reducing future risk.

### **AAR** – After action review

A method of evaluation that is used when outcomes of an activity or event have been particularly successful or unsuccessful. It aims to capture learning from these to identify the opportunities to improve and increase to occasions where success occurs.

### **Never Event**

Patient Safety Incident Response Plan

Patient safety incidents that are considered to be wholly preventable where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and have been implemented by healthcare providers.

#### **Deaths thought more likely than not due to problems in care**

Incidents that meet the 'Learning from Deaths' criteria. Deaths clinically assessed as more likely than not due to problems in care - using a recognised method of case note review, conducted by a clinical specialist not involved in the patient's care, and conducted either as part of a local LfD plan or following reported concerns about care or service delivery.