Patient safety incident response policy

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Note – this policy is developed from the NHS England PSIRF mandated policy template – we have incorporated learning from NHS Organisations, including mental health early implementers and large NHS Mental Health Trusts.

Other Relevant Elysium Policies

- Accident Reporting (RIDDOR)
- Being Open and Duty of Candour
- Capability
- Carer involvement
- Clinical Governance
- Complaints
- Disciplinary
- Equality Impact Assessment
- Freedom to Speak Up: Raising Concerns
- Grievance
- Mortality prevention and review
- Incidents and untoward occurrences (including PSIRF)
- Information Governance
- Legal Claims
- Partnership with Service Users
- Safeguarding – Adults and children
- Staff Health and Wellbeing

Contents

1. Purpose

This policy supports the requirements of the NHS England Patient Safety Incident Response Framework (PSIRF) and sets out how Elysium Healthcare will approach the transition from the Serious Incident Framework (SIF) to ensure the introduction, development, and maintenance PSIRF from September 2023 onwards. The policy ensures effective systems and processes, across the transition and introduction of PSIRF for responding to patient safety incidents and issues for the purpose of learning and improving patient safety. This will be an iterative process and the policy will be reviewed regularly as we develop our learning.

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.

This policy applies to all Elysium services in England and Wales. NHS Wales supports the use of a consistent patient safety approach and Elysium has ensured that PSIRF will work within the safety processes expected of Health Inspectorate Wales. Elysium in the interests of a consistent and safe patient safety system also uses the principles, reporting functions and tools for reviewing patient safety incidents within all its' care homes.

This policy supports development and maintenance of an effective patient safety incident response system that integrates the four key aims of PSIRF:

- Compassionate engagement and involvement of those affected by patient safety incidents.
- Application of a range of system-based approaches to learning from patient safety incidents.
- Considered and proportionate responses to patient safety incidents and safety issues.
- Supportive oversight focused on strengthening response system functioning and improvement.

This policy should read in conjunction with our current Patient Safety Incident Response Plan (PSP), and CH23 Incidents and Untoward Occurrence (including PSIRF) Policy which are separate documents setting out how this policy will be implemented.

NOTE: Any response that seeks to find liability, accountability or causality is beyond the scope of this policy. This is all the response types that are outside the scope of patient safety incident response plan (e.g. complaints, human resources investigations, professional standards investigations, coronial inquests, criminal investigations, claims management, financial investigations, and audits, safeguarding concerns, information governance concerns, and estates and facilities issues).

2. Scope

This policy is specific to patient safety incident responses conducted solely for the purpose of learning and improvement across all services in Elysium Healthcare.

Responses under this policy follow a systems-based approach. This recognises that patient safety is an emergent property of the healthcare system: that is, safety is provided by interactions between components and not from a single component. Responses do not take a 'person-focused' approach where the actions or inactions of people, or 'human error,' are stated as the cause of an incident.

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. The principle aims of each of these responses differ from those of a patient safety response and are outside the scope of this policy, in particular:

- claims handling,
- human resources investigations into employment concerns,
- professional standards investigations,
- information governance concerns
- estates and facilities concern
- financial investigations and audits
- safeguarding concerns
- complaints (except where a significant patient safety concern is highlighted)
- coronial inquests
- criminal investigations

Important - *Information from a patient safety response process can be shared with those leading other types of responses or investigations, but other processes should not influence the remit of a patient safety incident response.*

3. Our patient safety culture

KITE - Kindness, Integrity, Teamwork, Excellence - A Just Culture

Elysium's KITE values influence all our processes in the management of staff. Elysium recognise that all our staff strive to do their best and when things do not occur as planned need support to ensure we learn to improve our service. Elysium supports the use of the ***Just Culture Guide*** (see appendix A) when there are queries about an individual staff members performance. This supports our commitment to a learning environment and a culture that does not blame but seeks to ensure practice improvement through detailed understanding and learning from patient safety incidents, and the measures we can take to improve patient safety. The fair treatment of staff supports a culture of fairness, openness and learning by making staff feel confident to speak up when things go wrong, to support learning, rather than fearing blame.

Elysium supports open and transparent reporting.

Supporting staff to be open about mistakes allows valuable lessons to be learnt so the same errors can be prevented from being repeated.

The Just Culture guide should not be used routinely. It should only be used when there is already suspicion that a member of staff requires some support or management to work safely, or as part of an individual practitioner performance/case investigation.

Example: An incident where a nurse in charge may have failed to look at the Section 17 forms and let a patient go on escorted leave to the shops when they had no authorised leave. This would be a HR/Professional practice investigation, using the Just culture Tool, and if an individual issue would not require a PSIRF approach.

You are outside of this Policy when investigating individual practitioner performance, when a single individual needs support to work safely (including training, supervision, reflective practice, or disciplinary action), as opposed to where a whole cohort of staff has been identified, which would be examined as part of a wider safety investigation.

What is being done to support the development of a just culture.

Elysium Human Resources during the implementation of PSIRF are developing practice changes and ongoing training to support the use of the Just Culture Tool across all staff disciplinary procedures and the training will be widened out to include all service management teams as part of basic management training.

The training for wider use of the principles of a just culture in how we support learning and managing services to be open, transparent, and able to discuss quality and patient safety is via a range of programmes that are led by both education, regions, and other parts of Elysium – e.g. Closed Culture training.

4. Patient safety partners

Lived experience is an important component of ensuring our patient safety plans and oversight has effective challenge. Ensuring involvement with the PSIRF oversight group is a part of ensuring service users have voice and that our practice is open and transparent.

It is within our duty of care to ensure involvement with patients and gain benefits for prevention by ensuring a wider and more experiential viewpoint. The following nine engagement principles are being used to develop Elysium's response to patient incidents and the development of patient safety partner roles/function.

1. Apologies are meaningful.
2. Approach is individualised.
3. Timing is sensitive.
4. Those affected are treated with respect and compassion.
5. Guidance and clarity are provided.
6. Those affected are "heard."
7. Approach is collaborative and open.
8. Subjectivity is accepted.
9. Strive for equity.

5. Addressing health inequalities

Elysium as an independent provider of NHS services has a core role to play in reducing inequalities in health by improving access to services and tailoring those services around the needs of our patients in an inclusive way. We will use data intelligently to assess for any disproportionate patient safety risk, to patients from across the range of protected characteristics.

Within our patient safety response toolkit, we will directly address if there are any particular features of an incident which indicate health inequalities may have contributed to harm or demonstrate a risk to a particular population group, including all protected characteristics. When constructing our safety actions in response to any incident we will consider inequalities, and this will be inbuilt into our documentation and governance processes.

Engagement of patient, families and staff following a patient safety incident is critical to the review of patient safety incidents and their response. We will ensure that we use available tools

such as easy read, translation and interpretation services and other methods as appropriate to meet the needs of those concerned and maximise their potential to be involved in our patient safety incident response.

6. Engaging and involving patients, families and staff following a patient safety incident

PSIRF recognises that learning and improvement following a patient safety incident can only be achieved if supportive systems and processes are in place. It supports the development of an effective patient safety incident response system that prioritises compassionate engagement and involvement of those affected by patient safety incidents (including patients, families, and staff). This involves working with those affected by patient safety incidents to understand and answer any questions they have in relation to the incident and signpost them to support as required.

We are committed to continuously improving the care and services we provide. We want to learn from any incident where care does not go as planned or expected by our patients, their families, or carers to prevent recurrence.

Our KITE values underpin the principle of being open and honest whenever there is a concern about care not being as planned or expected or when a mistake has been made. As well as meeting our regulatory and professional requirements for Duty of Candour, we want to be open and transparent with our patients, families, and carers because it is the right thing to do. This is regardless of the level of harm caused by an incident. As part of our new policy framework, we will be outlining procedures that support patients, families, and carers – based on our existing Duty of Candour Policy.

7. Patient safety incident response planning

PSIRF enables Elysium to respond to incidents and safety issues in a way that maximises learning and improvement, rather than basing responses on arbitrary and subjective definitions of harm. We manage incidents that have nationally set requirements and can also explore patient safety incidents relevant to their context and the populations they serve rather than only those that meet a certain defined threshold.

Elysium ensures the focus of response to patient safety incidents is on maximising improvement. To fulfil this, we will undertake planning of our current resource for patient safety response and our existing safety improvement workstreams. We will identify insight from our patient safety and other data sources both qualitative and quantitative to explore what we know about our safety position and culture.

Our patient safety incident response plan will detail how this has been achieved as well as how Elysium will meet both national and local focus for patient safety incident responses.

7.1 Resources and training to support patient safety incident response.

Elysium are ensuring that we fully embed PSIRF and meet the NHS England nationally set requirements. We have therefore used the NHS England patient safety response standards (2022) to frame the resources and training required to allow for this to happen.

We aim to ensure that staff are supported to participate in the improvement response and learning response, where appropriate, as the experience of staff is invaluable to learn from the incident. PSIRF level one (all staff) and two (Qualified, supervisory and HR staff) training is mandatory for Elysium staff to ensure they have a working understanding of the structure, meaning and learning responses (including investigative tools) available to use in PSIRF. The details of PSIRF which is an NHS England requirement are available at **NHS England » Patient Safety Incident Response Framework**

Our governance arrangements will ensure that PSIRF learning responses (particularly PSII and After-Action Review) are not led by staff who were involved in the patient safety incident itself or by those who directly manage those staff, but we ensure those staff are supported to participate in a review by an external (to that clinical area) Elysium investigator. There is a list of trained investigators associated to each clinical networks within Elysium to support expertise in that clinical area.

Responsibility for the proposal to designate leadership of any learning response sits within the senior leadership team of the service. The second sign off point of the IRIS reporting system will be used to notify which PSIRF response is being utilised (an improvement response, a learning response or null PSP response). A learning response lead will be identified and nominated by the service (from the network list for all PSII or after-action response or if they choose to seek network assistance) and the individual should have an appropriate level of training, seniority and influence– this may depend on the nature and complexity of the incident and response required. A PSII will have two assigned investigators.

Those staff affected by patient safety incidents will be afforded the necessary managerial support and be given time to participate in learning responses. Elysium will ensure that all staff are managed within our Just Culture principles and utilise other teams such as Health and Wellbeing to ensure that there is a dedicated staff resource to support such engagement and involvement. Services will have processes in place to ensure that managers work within this framework to ensure psychological safety.

7.2 PSIRF Roles

PSIRF is reliant on all staff recognising their individual responsibility to ensure that their practice, role, and environment is patient safety aware. Staff must contribute and participate in patient safety training and safety improvement work. Staff must raise patient safety incidents, or near misses to ensure learning.

Investigators – PSIRF learning Leads - We have identified 232 staff to undertake investigator training –and they will undertake a PSIRF leadership role to support the review of incidents and to undertake an investigation response when agreed.

Patient Safety Plans are the business of all staff and ensure that our practice is based on learning from past incidents and that we undertake proactive planning to avoid and/or reduce the likelihood of similar incidents recurring.

PSIRF is a mandatory part of our practice and is applicable across all our services. **Key Functions:**

- The Elysium Board has oversight and final accountability for all patients/residents' safety.
- Quality and Risk Committee acting as subcommittee of the board to be assured of the effective use of PSIRF.
- Patient Safety Meeting (PSM**) –** key Elysium wide oversight operational meeting to oversee PSIRF on a week-to-week basis.
- Members of the PSM will be called the patient safety team, with a core membership who attend all PSM and a rota for others who will attend at least once a month.
- Executive Medical Director has executive leadership for PSIRF across the whole company to ensure patient safety.
- Director of Clinical Services/ Chief Nurse function is to ensure practice is effective and safe.
- Group Director of Quality Assurance has an oversight role for learning responses and Chairs the Patient Safety Meeting.
- Regional Operational Directors must ensure PSIRF is effectively used within all services.

- Clinical Directors or leads have a quality assurance, quality improvement and clinical governance role to ensure patient safety.
- Registered managers must ensure effective patient safety procedures and practice within the requirements of the PSIRF policy.
- All staff have a responsibility to ensure patient safety.

7.3 Training

Elysium has implemented a patient safety training package to ensure that all staff are aware of their responsibilities in reporting and responding to patient safety incidents and to comply with the NHS England Health Education England Patient Safety Training Syllabus as follows.

- Induction – PSIRF introduction (Mandatory all staff)
- Level One - Health Education England patient safety syllabus module (Essentials for patient safety) (Mandatory all staff)
- Level Two - Health Education England patient safety syllabus module (Access to Practice) (Mandatory for key staff)
- Investigator
- Oversight
- Board Induction
- Patient Safety level one for boards and senior leadership
- Just Culture
- IRIS - Roles and responsibilities of reporting and recording incidents.
- IRIS - consistency of scoring to support PSIRF
- IRIS - Second sign off role in PSIRF
- Conducting a lower-level review (PSIRF)
- Duty of Candour
- Record Keeping

7.4 Our Patient Safety Plan (see appendix B for full plan)

Our plan sets out how Elysium Healthcare intends to respond to patient safety incidents over a period of 12 to 18 months. The plan is not a permanent set of rules that cannot be changed. We will remain flexible and consider the specific circumstances in which each patient safety incident occurred and the needs of those affected, as well as the plan. The approval process for changes to the PSP will be via the patient safety meeting, with governance oversight from the Quality and Risk committee. All proposed changes will have been presented and discussed at CCG for group wide engagement.

7.5 Reviewing our patient safety policy and plan.

Our patient safety plan is a ‘living document’ that will be appropriately amended and updated as we use it to respond to patient safety incidents. We will review the plan

every 12 to 18 months to ensure our focus remains up to date; with ongoing improvement work our patient safety incident profile is likely to change. This will also provide an opportunity to re-engage with stakeholders to discuss and agree any changes made in the previous 12 to 18 months.

Updated plans will be published on our website, replacing the previous version.

A rigorous planning exercise will be undertaken every four years and more frequently if appropriate to ensure efforts continue to be balanced between learning and improvement. This more in-depth review will include reviewing our response capacity, mapping our services, a wide review of organisational data (for example, patient safety incident investigation (PSII) reports, improvement plans, complaints, claims, staff survey results, inequalities data, and reporting data) and wider stakeholder engagement.

8. Responding to patient safety incidents

8.1 Patient safety incident reporting arrangements

All staff are responsible for reporting any potential or actual patient safety incident on the IRIS reporting system and will record the level of harm they know has been experienced by the person affected (see Appendix C IRIS Risk Matrix).

Hospital sites have daily Multi-Disciplinary Team (MDT) reviews in place, and Care Homes will have appropriate arrangements to review incidents to ensure that patient safety incidents can be responded to proportionately and in a timely fashion and will include the second sign off of IRIS. This should include consideration and prompting to service teams where Duty of Candour applies. Most incidents will only require local review within the service, however for some, where it is felt that the opportunity for learning and improvement is significant, these should be escalated (see Patient safety incident response decision-making below and see Form P1 appendix D).

Sites will highlight to the Patient Safety Meeting (PSM) any incident which meets the requirement for reporting externally. This will allow Elysium to work in a transparent and collaborative way with our commissioners if an incident meets the national criteria for PSII or if supportive co-ordination of a cross system learning response is required.

The services will be the link to their commissioners and will notify the Patient Safety Meeting (PSM) to ensure effective communication for Elysium.

8.2 Patient safety incident response decision-making

Elysium has arrangements in place to allow it to meet the requirements for review of patient safety incidents under PSIRF. Some incidents will require mandatory PSII, others will require review by, or referral to another body or team depending on the event. These are set out in our PSP.

PSIRF itself sets no further national rules or thresholds to determine what method of response should be used to support learning and improvement. Elysium has developed response mechanisms to balance the effort between learning through responding to incidents or exploring issues and improvement work. In the work to create our plan we have considered what our incident insight and engagement with key internal and external stakeholders has shown us about our patient safety profile. We have used this intelligence to build our local priorities for PSII and responding to other patient safety incidents NHS England » Patient safety learning response toolkit

We have established a process for our response to incidents which allows for a clear 'Ward to Board' set of mechanisms allowing for oversight of incident management and our PSIRF response within our clinical governance structures.

Regions will have escalation arrangements in place for the monitoring of patient safety incidents and this includes daily escalation of incidents which meet the need for further exploration as a rapid review due to possibly meeting the criteria as PSII or due to the potential for learning and improvement or an unexpected level of risk. Services and Regions will consider any such incidents for further escalation to the Patient Safety Meeting (PSM).

The Patient Safety Meeting (PSM) will have delegated responsibility for the consideration of incidents for PSII and for oversight of the outcomes of such reviews to ensure that recommendations are founded on a systems-based approach and safety actions are valid and contribute to existing safety improvement plans or the establishment of such plans where they are required.

The Elysium Quality and Risk Committee will have overall oversight of such processes and will challenge decision making of the Patient Safety Meeting to ensure that the Board can be assured that the true intent of PSIRF is being implemented within our organisation and we are meeting the national patient safety incident response standards.

Items that require escalation to the Patient Safety Meeting (PSM**)**:

i. Any safety incident that has required the individual to be escalated to acute hospital.
ii. Any safety incident that potentially there will be staff disciplinary action
iii. Any safety incident that the police are asked to respond to / a 999 call made.
iv. Missing service user
v. Any safeguarding incident going to a Section 42 England; Section 126 Wales; Section 47 Children.
vi. Any incident that triggers Duty of Candour
vii. Mental Health Act breach leading to illegal detention.
viii. Any incident that compromises the safety of the unit
ix. Any incident that has media interest
x. All deaths
xi. In addition - All incidents that are not included in the above where the service, region, network, or the board chooses to have a discretionary PSII.

Any incident escalated will follow the process outlined below which can be seen in diagram form in Appendix E Governance Flow Chart

Local level incidents – managers of all service areas must have arrangements in place to ensure that incidents can be reported and responded to within their area. Incident responses should include immediate actions taken to ensure safety of patients, public and staff, as well as indication of any measures needed to mitigate a problem until further review is possible. This may include for example, withdrawing equipment or monitoring a procedure. Any response to an incident should be fed back to those involved or affected and appropriate support offered. Where Duty of Candour applies this must be carried out according to Elysium guidance.

Regional Clinical Governance, Clinical Networks, or the Patient Safety Meeting (PSM) may commission thematic/index reviews of such incidents to consider and understand potential emerging risks. All such reviews should be notified to the PSM via Form P1 (see appendix D) to ensure learning is held across the organisation.

Incidents with positive or unclear potential for PSII – all staff (directly or through their line manager) must ensure notification of incidents that may require a higher level of response as soon as practicable after the event through Elysium escalation processes (including out of hours) and this must include the regional team. Duty of Candour disclosure should take place according to Elysium guidance. Where it is clear that a PSII is required (for example, for a Never Event) the site should notify the Region and the Patient Safety team as soon as practicable so that the incident can be shared to executive level staff. A rapid review will be undertaken by the service to inform decision making at the Region and PSM and onward escalation following this.

Services with a significant proportion of temporary staff (including agency workers) on duty at the time of the incident should always opt to undertake a learning response approach to an incident, especially where there is doubt an improvement response pathway/or local systems and polices would be known to the staff on duty in a meaningful way. The agency staff will be invited to attend.

Services that are new or undertaking a change in practice to a new client group will be supported by the relevant clinical network to establish a local patient safety plan but should ensure that all incidents are reviewed through a learning response process until assured practice is meeting the level of compliance to the planned patient safety plan in the improvement response.

Other incidents with unclear potential for PSII must also be reported to the central Patient Safety team. A rapid review will be undertaken by the service to inform this decision making. Significant incidents which may require consideration for ad-hoc PSII due to an unexpected level of risk and/or potential for learning should be included in this category.

The Patient Safety Meeting will meet weekly to discuss the nature of any escalated incident, immediate learning (which should be shared via the PSM email address) any mitigation identified by the rapid review or that is still required to prevent recurrence and whether the Duty of Candour requirement has been met. The PSM will define terms of reference for a PSII to be undertaken by an appropriately trained investigator. The PSM will also designate subject matter expert input required for any investigation or highlight any cross system working that may be necessary, as well as indicating how immediate learning is to be shared.

Where an incident does not meet the requirement for PSII, the PSM may request an MDT or lower-level review or closure of the incident at a local level, with due consideration of any Duty of Candour requirement being met. The PSM will also indicate how immediate learning is to be shared.

Services, networks and regions will ensure arrangements for learning will include the recording of safety action or other learning response and these details will be used to inform potential safety improvement plans and a learning log that will be shared from time to time for audit purposes and to ensure system wide review of the corporate patient safety plan. The learning log will be a standardised process across all services and is maintained at every site. A standardised excel spread sheet will be issued with an electronic collation system to be developed through learning about the functionality and audit of the logs.

The Patient Safety Team will work with the region/network/site to have effective processes in place to ensure that any incidents meeting external reporting needs are appropriately escalated.

Quality and Risk Board Committee

Elysium has an established Quality and Risk Board Sub-Committee to oversee the operation and decision-making of the Patient Safety Meeting and the incident responses it has delegated responsibility to commission. This will support the final sign off process for all PSIIs. Through this mechanism the Board will be assured that it meets expected oversight standards but also understands the ongoing and dynamic patient safety and improvement profile within the organisation.

8.3 Responding to cross-system incidents/issues.

The Patient Safety Team will forward those incidents identified as presenting potential for significant learning and improvement for another provider directly to that organisation's patient safety team or equivalent. Where required, summary reporting can be used to share insight with another provider about their patient safety profile.

Elysium will work with partner providers and the relevant ICBs/PC/NHSE/NHSW to establish and maintain robust procedures to facilitate the free flow of information and minimise delays to joint working on cross-system incidents. The Patient Safety Team will support local services with such working and will have supportive operating procedures to ensure that this is effectively managed.

Elysium will defer to the relevant ICB/PC/NHSE/NHSW for co-ordination where a cross-system incident is felt to be too complex to be managed as a single provider. We anticipate that this ICB or PC/NHSE/NHSW will give support with identifying suitable reviewers in such circumstances and will agree how the learning response will be led and managed, how safety actions will be developed, and how the implemented actions will be monitored for sustainable change and improvement.

8.4 Timeframes for learning responses

Timescales for patient safety PSII

Where a PSII for learning is indicated, the investigation must be started as soon as possible after the patient safety incident is identified and should ordinarily be completed within one to three months of their start date. No local PSII should take longer than six months.

The time frame for completion of a PSII will be agreed with those affected by the incident, as part of the setting of terms of reference, provided they are willing and able to be involved in that decision. A balance must be drawn between conducting a thorough PSII, the impact that extended timescales can have on those involved in the incident, and the risk that delayed findings may adversely affect safety or require further checks to ensure they remain relevant.

In exceptional circumstances (e.g., when a partner organisation requests an investigation is paused, or the processes of an external body delays access to information) Elysium can consider whether to progress the PSII and determine whether new information indicates the need for further investigative activity once this is received. This would require a decision by the PSM.

In exceptional circumstances, a longer time frame may be required for completion of the PSII. In this case, any extended time frame should be agreed between Elysium and those affected.

Timescales for other forms of learning response

All other learning response must be started as soon as possible after the patient safety incident is identified and should ordinarily be completed within one month of the start date.

No other learning response should take longer than two months to complete. The service senior team will be responsible for oversight over all local learning responses and will need to flag any delay through clinical governance.

8.5 Safety action development and monitoring improvement

Elysium acknowledges that any form of patient safety learning response (PSII or review) will allow the circumstances of an incident or set of incidents to be understood, but that this is only the beginning. To reliably reduce risk, better safety actions are needed.

Elysium will have systems and processes in place to design, implement and monitor safety actions using an integrated approach to reduce risk and limit the potential for future harm. This process follows on from the initial findings of any form of learning response which might result in identification of aspects of Elysium's working systems where change could reduce risk and potential for harm – areas for improvement. Elysium will generate safety actions in relation to each of these defined areas for improvement. Following this, Elysium will have measures to monitor any safety action and set out review steps. This will all be included within the Patient Safety Plan (PSP)

Learning response should not describe recommendations as this can lead to premature attempts to devise a solution - safety actions in response to a defined area for improvement depend on factors and constraints outside of the scope of a learning response. To achieve successful improvement safety action development will be completed in a collaborative way with a flexible approach from service/network/regions and the support of the Quality Improvement Team with their improvement expertise.

Safety Action development

Elysium will use the process for development of safety actions as outlined by NHS England in the Safety Action Development Guide (2022) as follows.

1. Agree areas for improvement – specify where improvement is needed, without defining solutions

2. Define the context – this will allow agreement on the approach to be taken to safety action development

3. Define safety actions to address areas of improvement – focussed on the system and in collaboration with teams involved

4. Prioritise safety actions to decide on testing for implementation

5. Define safety measures to demonstrate whether the safety action is influencing what is intended as well as setting out responsibility for any resultant metrics

6. Safety actions will be clearly written and follow SMART principles and have a designated owner

Safety Action Monitoring

Safety actions must continue to be monitored within the service/network/region clinical governance arrangements to ensure that any actions put in place remain impactful and sustainable. Regional reporting on the progress with safety actions including the outcomes of any measurements will be made to the Patient Safety Meeting and Corporate Clinical Governance.

8.6 Safety improvement plans

Safety improvement plans bring together findings from various responses to patient safety incidents and issues. Elysium has several overarching safety improvements plans in place which are adapted to respond to the outcomes of improvement efforts and other external influences such as national safety improvement programmes or Commissioning for Quality and Innovation (CQUINs).

Elysium PSP has outlined the range of local priorities for focus of investigation under PSIRF. These were developed due to the opportunity they offer for learning and improvement across areas where there is no existing plan or where improvement efforts have not been accompanied by reduction in apparent risk or harm.

Elysium will use the outcomes from existing patient safety incident reviews (Serious Untoward Incidents (SUI) Route Cause Analysis (RCA) reports), where present and any relevant learning response conducted under PSIRF to create related safety improvement plans to help to focus our improvement work. The Clinical networks will work collaboratively with the services/regions and Patient Safety Team and others to ensure there is an aligned approach to development of plans and resultant improvement efforts.

Where overarching systems issues are identified by learning responses outside of the Elysium local priorities, a safety improvement plan will be developed. These will be identified through regional governance processes and reporting to the Patient Safety

Meeting who may commission a safety improvement plan. The Clinical networks will work collaboratively with the services/regions and Patient Safety Team and others to ensure there is an aligned approach to development of plans and resultant improvement efforts.

Monitoring of progress with regard to safety improvement plans will be overseen by reporting by the designated lead to corporate clinical governance on a scheduled basis.

9. Oversight roles and responsibilities

Principles of oversight

Working under PSIRF, organisations are advised to design oversight systems to allow an organisation to demonstrate improvement rather than compliance with centrally mandated measures.

- Improvement is the focus.
- Blame restricts insight.
- Learning from patient safety incidents is a proactive step towards improvement.
- Collaboration is key.
- Psychological safety allows learning to occur.
- Curiosity is powerful.

Responsibilities

Alongside our NHS England, NHS Wales and local NHS ICB/PC structures and our regulators, the Care Quality Commission and Health Inspectorate Wales, we have specific organisational responsibilities with the Framework.

In order to meet these responsibilities, Elysium has designated the Executive Medical Director to support PSIRF as the executive lead with the following specific responsibilities:

1. **Ensuring that the organisation meets the national patient safety standards**

The Executive Medical Director will oversee the development, review and approval of Elysium's policy and plan ensuring that they meet the expectations set out in the patient safety incident response standards. The policy and plan will promote the just working culture that Elysium aspires to.

To achieve the development of the plan and policy the Executive Medical Director will be supported by Director of Quality Assurance.

To define its patient safety and safety improvement profile, Elysium will undertake a thorough review of available patient safety incident insight and engagement with internal and external stakeholders.

2. **Ensuring that PSIRF is central to overarching safety governance arrangements**

The Elysium Board will receive assurance regarding the implementation of PSIRF and associated standards via existing reporting mechanisms such as the Quality and Risk Committee. Quality and Risk Committee bi-monthly safety reporting will comprise oversight question responses to ensure that the Elysium Board has a formative and continuous understanding of organisational safety.

The PSM will provide assurance to the Quality and Risk Committee that PSIRF and related workstreams have been implemented to the highest standards. Regions will be expected to report on their patient safety incident learning responses and outcomes. This will include reporting on ongoing monitoring and review of the patient safety incident response plan and delivery of safety actions and improvement.

Services, Networks and Regions will have arrangements in place to manage the local response to patient safety incidents and ensure that escalation procedures as described in the patient safety incident response section of this policy are effective. They will maintain a learning log that will be available for audit purposes.

Elysium will source necessary training such as the Health Education England patient safety syllabus and other patient safety training across the organisation as appropriate to the roles and responsibilities of its staff in supporting an effective organisational response to incidents.

Updates will be made to this policy and associated plan as part of regular oversight. A review of this policy and associated plan will be actively monitored during the implementation of PSIRF with the ambition for a review to be undertaken at least every 4 years to comply with Elysium's guidance on policy development alongside a review of all safety actions.

3. **Quality assuring learning response outputs**

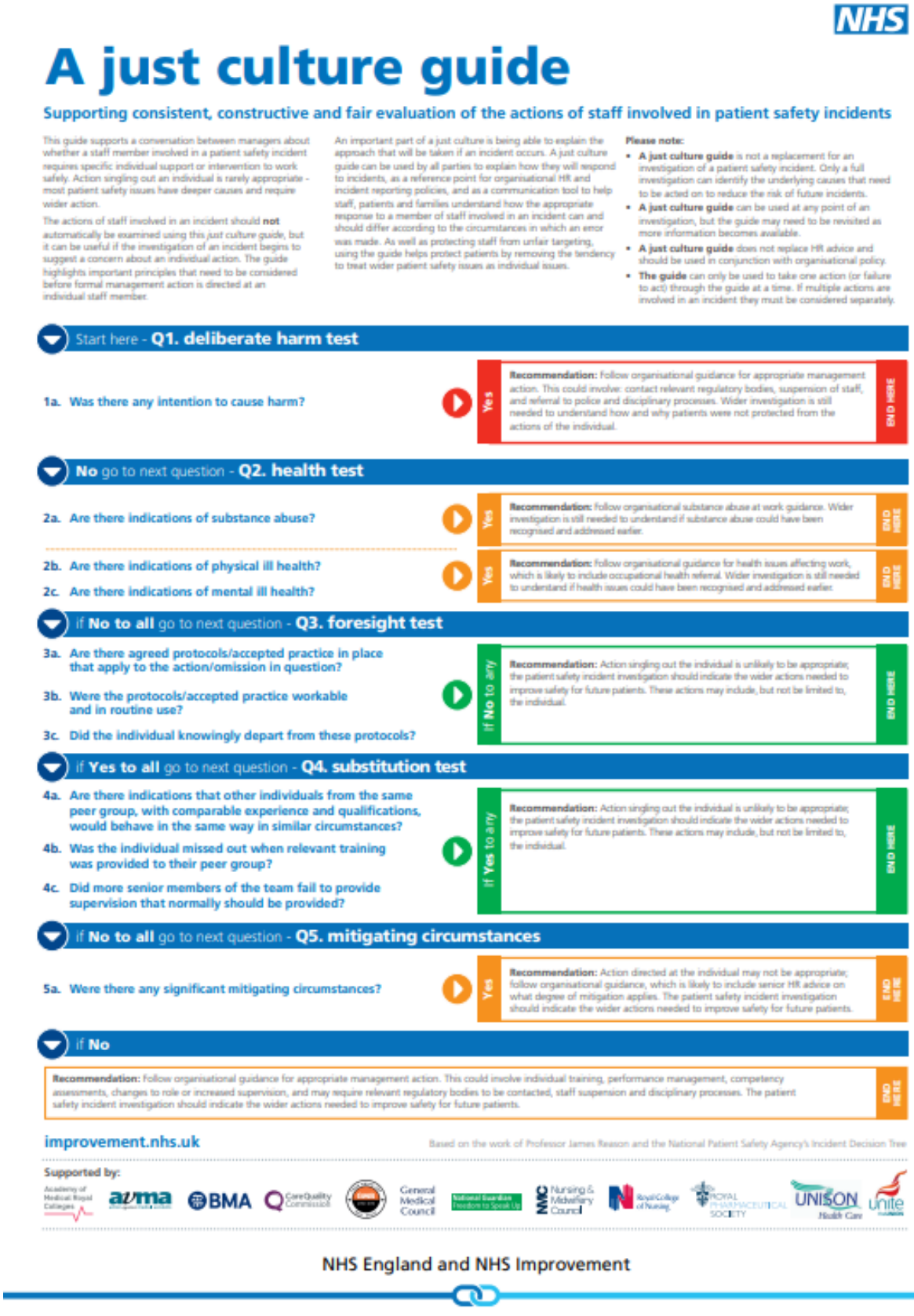
Elysium will implement a Patient Safety Meeting (PSM) review to ensure that PSIIs are conducted to the highest standards and to support the executive sign off process and ensure that learning is shared, and safety improvement work is adequately directed.

10. Complaints and appeals.

Elysium Healthcare recognises that there will be occasions when patients, service users or carers are dissatisfied with aspects of the care and services provided by Elysium.

Please note - See Elysium complaint policy.

Appendix A



NHS

A just culture guide

Supporting consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents

This guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. Action singling out an individual is rarely appropriate - most patient safety issues have deeper causes and require wider action.

The actions of staff involved in an incident should **not** automatically be examined using this *just culture guide*, but it can be useful if the investigation of an incident begins to suggest a concern about an individual action. The guide highlights important principles that need to be considered before formal management action is directed at an individual staff member.

An important part of a just culture is being able to explain the approach that will be taken if an incident occurs. A just culture guide can be used by all parties to explain how they will respond to incidents, as a reference point for organisational HR and incident reporting policies, and as a communication tool to help staff, patients and families understand how the appropriate response to a member of staff involved in an incident can and should differ according to the circumstances in which an error was made. As well as protecting staff from unfair targeting, using the guide helps protect patients by removing the tendency to treat wider patient safety issues as individual issues.

Please note:

- **A just culture guide** is not a replacement for an investigation of a patient safety incident. Only a full investigation can identify the underlying causes that need to be acted on to reduce the risk of future incidents.
- **A just culture guide** can be used at any point of an investigation, but the guide may need to be revisited as more information becomes available.
- **A just culture guide** does not replace HR advice and should be used in conjunction with organisational policy.
- **The guide** can only be used to take one action (or failure to act) through the guide at a time. If multiple actions are involved in an incident they must be considered separately.

Start here - Q1. deliberate harm test

1a. **Was there any intention to cause harm?**

Yes → **Recommendation:** Follow organisational guidance for appropriate management action. This could involve: contact relevant regulatory bodies, suspension of staff, and referral to police and disciplinary processes. Wider investigation is still needed to understand how and why patients were not protected from the actions of the individual. **END HERE**

No go to next question - **Q2. health test**

2a. **Are there indications of substance abuse?**

Yes → **Recommendation:** follow organisational substance abuse at work guidance. Wider investigation is still needed to understand if substance abuse could have been recognised and addressed earlier. **END HERE**

2b. **Are there indications of physical ill health?**

2c. **Are there indications of mental ill health?**

Yes → **Recommendation:** follow organisational guidance for health issues affecting work, which is likely to include occupational health referral. Wider investigation is still needed to understand if health issues could have been recognised and addressed earlier. **END HERE**

if **No to all** go to next question - **Q3. foresight test**

3a. **Are there agreed protocols/accepted practice in place that apply to the action/omission in question?**

3b. **Were the protocols/accepted practice workable and in routine use?**

3c. **Did the individual knowingly depart from these protocols?**

if **No** to any → **Recommendation:** Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. **END HERE**

if **Yes to all** go to next question - **Q4. substitution test**

4a. **Are there indications that other individuals from the same peer group, with comparable experience and qualifications, would behave in the same way in similar circumstances?**

4b. **Was the individual missed out when relevant training was provided to their peer group?**

4c. **Did more senior members of the team fail to provide supervision that normally should be provided?**

if **Yes** to any → **Recommendation:** Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. **END HERE**

if **No to all** go to next question - **Q5. mitigating circumstances**

5a. **Were there any significant mitigating circumstances?**

Yes → **Recommendation:** Action directed at the individual may not be appropriate; follow organisational guidance, which is likely to include senior HR advice on what degree of mitigation applies. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. **END HERE**

if **No**

Recommendation: Follow organisational guidance for appropriate management action. This could involve individual training, performance management, competency assessments, changes to role or increased supervision, and may require relevant regulatory bodies to be contacted, staff suspension and disciplinary processes. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. **END HERE**

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Based on the work of Professor James Reason and the National Patient Safety Agency's Incident Decision Tree

Supported by:

NHS England and NHS Improvement

Appendix B

Patient Safety Plan

Effective date: September 2023

Estimated refresh date: March 2025

	NAME	TITLE	SIGNATURE	DATE
Author (s)	**Jo Scott** **Patrick Neville**	**Group Director QA & PSIRF Project Manager** **Strategic Development Director**		
Reviewer	**Prof. Quazi Haque**	**Chief Medical Officer & Exec project lead PSIRF**		
Authoriser	**Quality & Risk Committee**			

Contents

Introduction

This patient safety incident response plan sets out how Elysium Healthcare intends to respond to patient safety incidents over a period of 12 to 18 months. 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.

This plan should be read in conjunction with the Patient Safety Incident Response Framework (PSIRF) Policy and Ch23 Incidents and Untoward Occurrences (inc. PSIRF) Policy.

Our services

Elysium Healthcare is an Independent Healthcare Provider it is comprised of the following services:

- Eighty-eight sites with over 2600 beds across England and Wales
- Hosted Services in majority of ICBs across England with service users from all areas of England and Wales

PSIRF methodology will be used across all our services, including our services in Wales and Local Authority funded services, to ensure a consistent and safe system providing one patient safety system across the Elysium Group.

In providing a range of services we work with partner organisations across health and social care, as part of these partnership arrangements we may be in local networks or wider Provider Collaboratives. No matter what types of relationships we have it is always important that we as a company maintain our own clinical leadership and support our services to provide safe and good quality care. In ensuring we maintain corporate oversight of quality and safety we group our services within Clinical Networks, to ensure that we maintain through clinical governance good assurance and oversight that all our services are operating within their sector to establish best practice. Our services within Clinical Networks work together to ensure the support necessary to provide innovative care, quality assurance, patient safety, and inter-service peer support. The following are our Clinical Networks:

- Secure
- Acute
- CAMHS
- Neurological
- Rehabilitation Hospitals (Male)
- Rehabilitation Hospitals (Women)
- LD/ABI Hospitals and wards (secure and non-secure)
- Care Homes (Qualified Nurse)

- Care Homes (No Qualified Nurse)

The range and types of services that fall within these networks reflects all different types of services that Elysium provides across the country. In developing the structure of the Clinical Networks, we mapped out all of our services, linked to key stakeholders and sought the views of our senior clinicians and members of the Corporate Clinical Governance (CCG) meeting to test out the meaningfulness of the Clinical Network grouping. In establishing the nine networks we used the following principles:

- Natural clinical alignment either to national specifications or agreed service types.
- Meaningful number of services able to support a peer support network.
- Established Elysium networks (CAMHS, LD & Acute) supported to continue.
- Leadership and Peer support able to undertake task and finish functions for CCG.
- Networks chaired by senior clinicians from services.

The make-up, structure and utility of the Clinical Networks will be monitored through CCG to ensure their functionality within their defined role. It is of note that the type and range of inpatient services provided by Elysium is far wider than an NHS Trust and geographically distanced from each other. Secondary to the complexities of range and distances between services is that the individual services are separately registered to the CQC / HIW. This separation of registration between individual services means that an NHS Trust divisional approach to setting patient safety plans is more complicated within the independent sector. To ameliorate the risk of services with similar functions developing separate patient safety plans we chose to bring services together within a network model to ensure learning, the sharing of learning and the ability to effectively review the patient safety plans within a meaningful professional and service user grouping.

Defining our patient safety incident profile

Elysium has always maintained central corporate oversight of incidents both in the reporting (via IRIS) and the management of incidents using the Serious Incident Framework (SIF). The data that is available to us is extensive as it derives from such a large and complex organisation, therefore, to understand the whole organisation requires a detailed PSP to reflect the range of services provided by Elysium Healthcare. We decided as a mapping exercise that we would review three years' worth of IRIS (our incident recording system) and SIF data to extract themes and cross reference this with three years' worth of Safeguarding, Health and Safety, Human Resources (disciplinary), duty of candour, complaints, and claims information. This gave us a rich but complex data source. It should be noted by the very nature of the reporting systems used under the SIF system patient safety incidents involving

significant harm will have been shared externally for oversight with NHS and Social care partners.

With this large data set the working group agreed a set of key priorities to form an indicative patient safety incident profile that was used to map the data available on all our electronic systems to triangulate the key themes that derive from all incident reporting.

The key themes (fig 1.) for the full detail please see appendix:

Direct - Patient safety issues that are well known to services and the company with associated data though reports and historic action plans	**Indirect -** Suspected or known patient safety issues, such as contributory factors with or without wider knowledge that are not always supported by direct correlation or specific mention in reports	**Unique -** One-off events are important as they will always require investigation and by their very nature cannot be covered in a patient safety plan, beyond the need to know that a response will be required.
1. Patient Supervision and Observations 2. Medication Management Errors 3. Self-Harm 4. Patient Violence towards others 5. Restrictive Practices 6. Accessing, granting, or breaching leave 7. Environmental factors 8. Physical Healthcare 9. Mental Health Act – process breaches of all types	10. Workforce 11. Patient Mix on ward/care home 12. Inappropriately placed Patients 13. Delayed Discharge 14. IT and BCP issues in care delivery 15. Care Planning Quality – or failure to follow. 16. Communication issues	17. Unexpected death will always fall into this category. 18. Random unique incidents that we would be negligent if we did not review/ investigate

These key patient safety themes were shared across CCG (and thereby to Regions and Services), Senior Clinicians who were part of the working group, senior managers, and service user representatives. The intention of sharing the key themes was to test validity of themes that were emerging from the mapping and to seek the wider company view on both the appropriateness of individual items inclusion and to check if any concerns or incident types had been missed. Feedback from this process supported by the data mapping of the volume and types of incidents have been used to set out our key patient safety priorities.

The key themes were also shared with NHS commissioner organisations through their participation in our working group and stakeholder events. It should be noted that as a large multi-site provider Elysium is a significant provider of NHS and Social care services but from

the point of view of the individual NHS and Social care commissioner it is more relevant for them looking at individual service user experience rather than a view of us as a large multi-site provider. This conflict in perception means that the NHS / Social Care view of the range and type of our patient safety incidents is wholly dependent on their use of our services, which may not include the wide spectrum of services that we provide and indeed mostly reflects an individual's care. Therefore, their ability to confirm or validate the range of patient safety incidents can be limited / biased on a companywide view. Although it is worth noting that from their wider system experience of all providers none of the NHS commissioners noted anything abnormal or missing from the key themes list.

We have therefore decided that the key themes list shall be the basis of the Elysium corporate patient safety plan and the profile that it will be based upon.

The process following the development of the corporate wide safety plan is as follows:

1) We will identify and undertake index case reviews (using PSII) to develop benchmark safety action plans that will form the basis of high-level quality improvement plans specific to each patient safety priority. These Patient Safety Priorities with their associated quality improvement plans will be the basis of specific clinical network and patient safety plans.

2) The clinical networks will identify key themes from the wider corporate list applicable to their services. They will then develop patient safety plans for their individual key patient safety issues in a collaborative way across all their member services.

3) The networks will produce their PSP's for sharing and ratification with the overarching corporate PSP at the quality and risk committee, having been first considered at CCG.

4) Inter-network learning and sharing will be encouraged where similar patient safety concerns (e.g. self-harm) are being considered across different networks. This is an enrichment process where learning may support multiple networks to develop best practice but does not impede the unique nature and presentation of those incidents within separate network populations e.g., the difference between severity, risk, frequency, options of treatment and management within the specific care environment.

5) Services with a significant proportion of temporary staff (including agency workers) on duty at the time of the incident should always opt to undertake a learning response approach to an incident, especially where there is doubt an improvement response pathway/or local systems and polices would be known to the staff on duty in a meaningful way. The agency staff will be invited to attend.

6) Services that are new or undertaking a change in practice to a new client group will be supported by the relevant clinical network to establish a local patient safety plan

but should ensure that all incidents are reviewed through a learning response process until assured practice is meeting the level of compliance to the planned patient safety plan in the improvement response.

7) Individual services within those networks will utilise the output to develop specific plans to implement the PSP within their service. This is particularly pertinent for some of our multi-service campus sites. This site level PSP will be shared through clinical governance to the region and CCG as well as for the opportunity to share best practice and learning back to the network.

8) The Patient Safety Meeting (PSM) will maintain a register of the corporate, network and service PSPs including date of implementation and all subsequent reviews. The purpose of which is to support the oversight function in relation to reported incidents and subsequent decisions on enacting either a learning response or the improvement response pathways.

9) The Patient Safety Meeting (PSM) will maintain a PSII (Patient Safety Incident Investigation) – database system centrally run and assign reference numbers to any incident being investigated using the PSII methodology and paperwork.

10) As part of the regularly reviewed patient safety profile information, the Patient Safety Meeting (PSM) will receive reports detailing:

    i. The safety plan for those individual's collecting significant numbers of incidents (out of kilter with the usual presentation within service) – those falling into this category will be identified through the mapping reports.
    ii. Those within our services escalating beyond the services expertise – where notice has been served to commissioners. The Patient Safety Meeting (PSM) should on a regular basis review the plan and actions being taken to resolve (see Form P2 in appendix).
    iii. All delayed discharges and on a regular basis review the plan and actions being taken. (see Form P2 in appendix).
    iv. Finishing the SIF system removes the harm threshold as the key driver for investigating but the Patient Safety Meeting (PSM) should still be aware of the harm happening within services. The Patient Safety Meeting (PSM) will be notified of any incidents that fall into the following categories, within the network / service PSP there is a pre-agreed response to some of these which will include to enact a learning response or confirm supported by the improvement response pathway (see Form P1 in appendix):

        i. Any safety incident that has required the individual to be escalated to acute hospital.
        ii. Any safety incident that potentially there will be staff disciplinary action undertaken.
        iii. Any safety incident that the police are asked to respond to / a 999 call made.
        iv. Missing service user.

v. Any safeguarding incident going to a Section 42 England; Section 126 Wales; Section 47 Children.
vi. Any incident that triggers Duty of Candour.
vii. Mental Health Act breach leading to illegal detention.
viii. Any incident that compromises the safety of the unit.
ix. Any incident that has media interest.
x. All deaths.
xi. In addition - All incidents that are not included in the above where the service, region, network, or the board chooses to have a discretionary PSII.

11) The Patient Safety Meeting (PSM) will maintain a register of all safety actions identified through PSII reviews demonstrating:
    i. A need to improve existing systems.
    ii. Identified missing systems.

    This will also include the recording of decisions taken to prioritise actions to address / mitigate to ensure that themes and trends of findings are clearly understood and support future thinking within refreshed PSP.

12) There is an on-going constant review requirement to maintain effective relevant and up to date PSP. This review process will occur every 18 – 24 months no matter how many times individual service, network or corporate PSP has been amended. The reason for this is to ensure a whole refresh of the entire patient safety system to give assurance at board level that all patient safety processes are maintained to a high level of PSIRF compliance. This 18 – 24 month review process will be shared with all our stakeholders both statutory, staff and service user related.

Defining our patient safety improvement profile

Elysium developed its governance processes to continually gain insight from patient safety incidents and this feeds into quality improvement activity. We continue to draw on guidance and feedback from national and regional level NHS bodies, regulators, commissioners, partner providers and other key stakeholders to identify and define the quality improvement work we undertake. The governance architecture supporting PSIRF, including the new networks, are being reported through Corporate Clinical Governance (CCG) to ensure there is timely engagement with the operational side of Elysium. Patient safety is the responsibility of the whole organisation and should never be seen solely as a clinical issue.

The Quality and Risk committee provides assurance to the Elysium Operational Board that quality improvement measures, including any safety improvement plans drawn up from the SIF system (completed and outstanding), or which require development and implementation in the future, continue to be of the highest standard. CCG will be responsible for the oversight of this quality improvement work including the robust use of quality improvement methodology

such as Qi (Quality Improvement) which is supported by the Quality Improvement Team. Services and regions also report through CCG on all types of improvement work and developments undertaken, that will also include patient safety actions. This process will continue through PSIRF and the new governance structure. *See PSIRF governance structure below fig 2.*

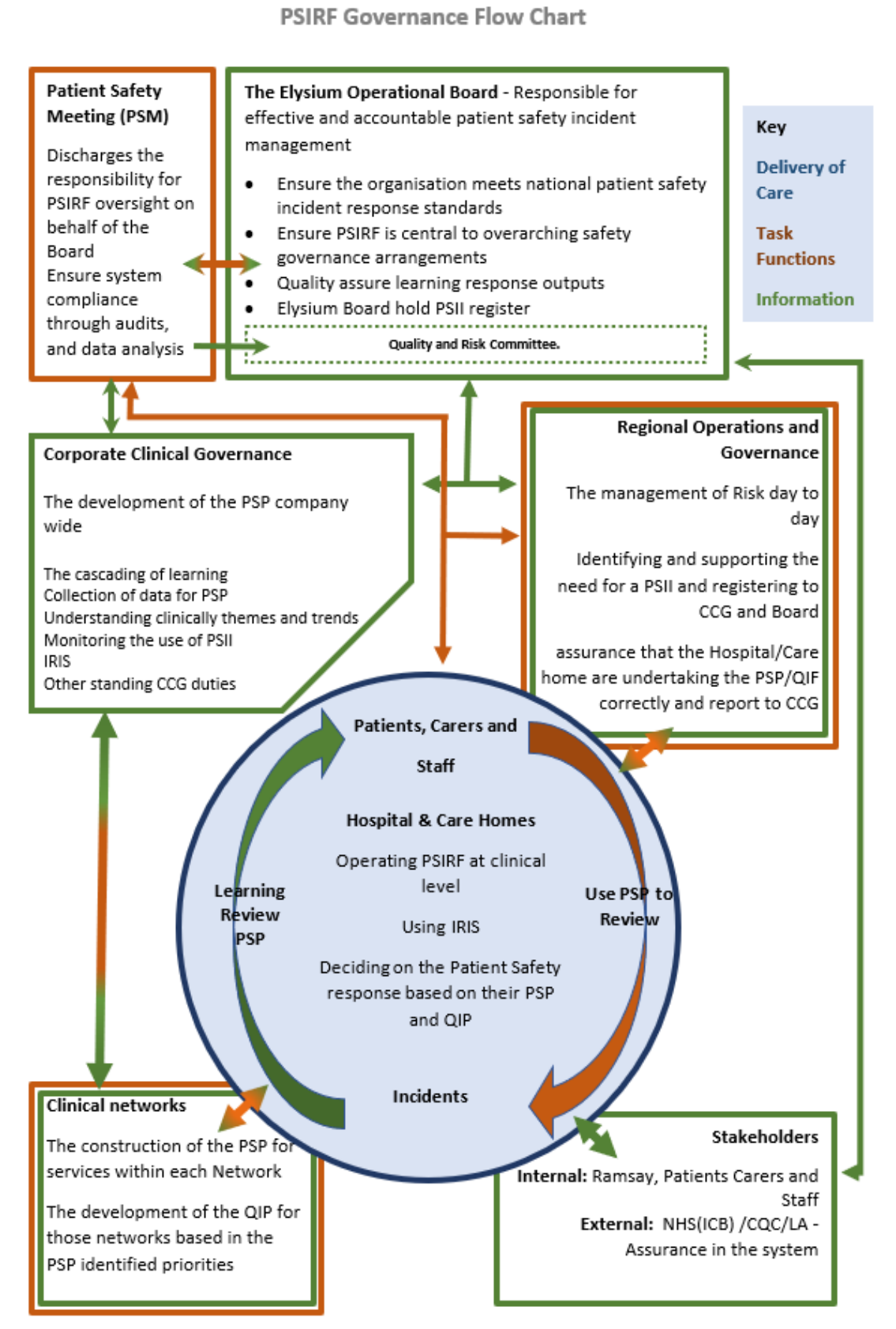
Our clinical networks and regions are required to report to our CCG in order to monitor and measure improvement activity across the organisation. This provides assurance during the development of new safety improvement plans following reviews undertaken within PSIRF to ensure they have followed robust processes during development and fulfil SMART (Specific, Measurable, Attainable, Relevant and Time Bound) requirements and are sufficient to support Elysium to improve patient safety in the future.

We have identified in the local patient safety priorities plans (see below) to index review four key patient priority areas to ensure that we develop quality improvement plans and agree safety actions for these high-level priorities.

A list of Qi improvement work and outstanding incident action plans currently underway can be found in the Qi Hub. Not all the Qi projects will be linked or derived from a patient safety incident, but the developmental nature of practice development and improvement includes a range of service specific projects.

It is important to note that flexibility to consider improvements as required, where a patient safety issue emerges from ongoing internal review or external information, remains supported.

PSIRF Governance Structure fig 2.



Our patient safety incident response plan: national requirements

Elysium, as with all healthcare providers resourced through the public sector, has finite resources for patient safety incident response. We intend to use those resources to maximise improvement. PSIRF allows us to do this, rather than repeatedly responding to patient safety incidents based on subjective thresholds and definitions of harm, from which new learning will be limited.

Some patient safety incidents, such as Never Events and deaths thought more likely than not due to problems in care will always require a Patient Safety Incident investigation (PSII) to learn and improve. For other types of incidents which may affect certain groups of our patients, a PSII will also be required. These have been determined nationally, but Elysium fully supports this approach as it fits with our aim to learn and improve within a just culture.

As well as PSII, some incident types require specific reporting and/or review processes to be followed. For clarity, all types of incidents that have been nationally defined as requiring a specific response will be reviewed according to the suggested methods and are detailed in the table below.

Patient Safety Event Occurs	Patient Safety Incident Investigation	National Priorities	Event	Approach	Improvement
			Maternity and neonatal incidents meeting HSIB and Special Healthcare Authority referral criteria	Work with partners to ensure cases are referred to Healthcare Safety Investigation Branch (HSIB)	Respond to recommendations from external referred agency/organisation as required and feed actions into the quality improvement strategy
			Child death	Refer for Child Death Overview Panel (CDOP) and liaise with panel as locally led PSII may be required	
			Death of a person who has lived with a Learning Disability or autism.	Refer for Learning Disabilities Mortality Review (LeDeR) liaise with ICB (LeDeR Local Area Co-ordinator) as locally led PSII may be required	
			Safeguarding incidents in which: Babies, children, or young people are on a child protection plan; looked after plan or a victim of wilful neglect or domestic abuse/violence. Adults over 18 years old are in receipt of care and support needs from their local authority. The incident relates to FGM, Prevent (radicalisation to terrorism), modern slavery and human trafficking or domestic	Refer to local authority safeguarding lead and notify Elysium named safeguarding lead. Elysium will contribute to domestic independent inquiries, joint targeted area inspections, child safeguarding practice reviews, domestic homicide reviews and any other safeguarding reviews (and inquiries) as required to do so by the local safeguarding partnership (for children) and the local safeguarding adults boards	

			abuse/violence.	
			Domestic homicide	Identified by the police usually in partnership with the local community safety partnership with whom the overall responsibility lies for establishing review of the case. Where the CSP considers that the criteria for a domestic homicide review are met and establishment of a DHR panel, Elysium will contribute as required by the DHR panel.
			Death of patients in custody/prison/probation	Refer to Prison and Probation Ombudsman (PPO) or the Independent Office for Police Conduct (IOPC)
			Mental health-related homicides	Refer to the NHS England Regional Independent Investigation Team for consideration for an independent PSII, locally led PSII may be required
			Patient Safety incidents meeting the Never Event criteria 2018 or its replacement	Patient Safety Incident Investigation
			Deaths of patients detained under the MHA (1983) or where the MCA (2005) applies, where there is reason to think that the death may be linked to problems in care	Patient Safety Incident Investigation
			Patient Safety incidents resulting in death where the death is thought more likely than not to be due to problems in care	Patient Safety Incident Investigation

Our patient safety incident response plan: local focus

PSIRF allows organisations to explore patient safety incidents relevant to their context and the populations served. Through our analysis of our patient safety insights, based on the review of incidents and engagement meetings and workshops we have determined that Elysium requires four patient safety priorities as local focus. We have selected this number due to the breadth of services that Elysium provides. We will undertake index case reviews (PSII) to develop benchmark safety action plans that will form the basis of high-level quality improvement plans specific to each patient safety priority. These Patient Safety Priorities with their associated quality improvement plans will be the basis of specific clinical network and

site patient safety plans. This will allow us to apply a systems-based approach to learning from these incidents, exploring multiple interacting contributory factors.

The following vignette is to demonstrate how this process will work:

A worked through example looking at self-harm patient safety incidents.

We will undertake for the self-harm patient safety priority a series of index PSII reviews across a range of self-harm incidents. The investigators for each PSII will receive supervision from the Patient Safety team to ensure that the process of the PSII ensures an outcome that we can use as a benchmark patient safety action plan. The selected incidents will be a variety of forms of self-harm which have been identified through the data as high frequency incidents (ingestion, insertion, ligature and one "other" incident type depending on occurrence such as cutting or headbanging). We will use incidents from both our adult and children's services to review applicability across all types of services.

The patient safety action plans will then be collated and with the support of a range of clinicians and service users reviewed to highlight the following:

- Similarity of themes in relation to systems and processes used to manage self-harm.
- Similarity in safety issues identified (work as done vs work as prescribed).
- Similarity in prevention and incident management themes.
- Significant differences in the presentation and management that would indicate a separate safety action plan to address system issues identified.

We will use the outcomes of PSII and the thematic MDT review to inform and develop our patient safety improvement planning and work.

Key Patient Safety Priorities

The following table lists our patient safety incidents against type, and this is based on the mapping of all incidents reported from 2020 -2023.

As PSIRF is being introduced we cannot prioritise all types of safety incident, as we develop skills and knowledge, we will be able to review our PSP over time. The previous system was not aligned to achieve symmetry between the practice of patient safety and the identification of the themes that needed to be addressed. PSIRF is more aligned to learning and using data to formulate PSPs. We will aim to reprioritise the management of a wider range of incidents going forwards. It is worth noting that the management of patient risk is not solely a PSIRF issue, as the need to develop systems and models of care will always include practice development and learning from research and best practice. Patient safety incidents and their outcome with the subsequent learning will always be used to improve the planning to manage incidents.

There are two PSIRF responses that feature in the decision pathway[1]

1. **Improvement Response Pathway** – defined improvement plans in place.
2. **Learning Response Pathway** – a range of proportionate learning responses (such as PSII or other tools).

The following table is the key priorities analysed by the data from IRIS and is different from the original key working priorities. See appendix for the Working Assumptions (Key Priorities Document) for reference and record.

Patient Safety Priorities (IRIS Data) with PSIRF decision Response

Event[2]	Approach	Improvement
Patient Violence towards others		
Abuse Aggression Physical	**PSII Index Review and full thematic review to develop PSP**	**Create recommendations to develop Network and site improvement strategy**
Abuse Aggression Verbal (including Hate incidents)	Not prioritised in PSP this year	Managed by Safeguarding
Hostage Taking and disturbance	A learning response will always be required	Create recommendations to develop Network and site improvement strategy
Sexual safety	Not prioritised in PSP this year	Managed by Safeguarding
Weapons	A learning response will always be required	Create recommendations to develop Network and site improvement strategy
Abuse – Neglect and Omission	Not prioritised in PSP this year	Managed by Safeguarding
Self-Harm		
All categories of self-harm are being reviewed through and INDEX PSII process	**PSII Index Review and full thematic review to develop PSP**	**Create recommendations to develop Network and site improvement strategy**

[1] *Decision Chart following patient safety event – see flow chart below Fig 3.*

[2] These are the general rules for managing incidents with PSIRF – although it must be understood that any incident can be investigated as requested by the Patient Safety Meeting (PSM), the service, or external stakeholders request.

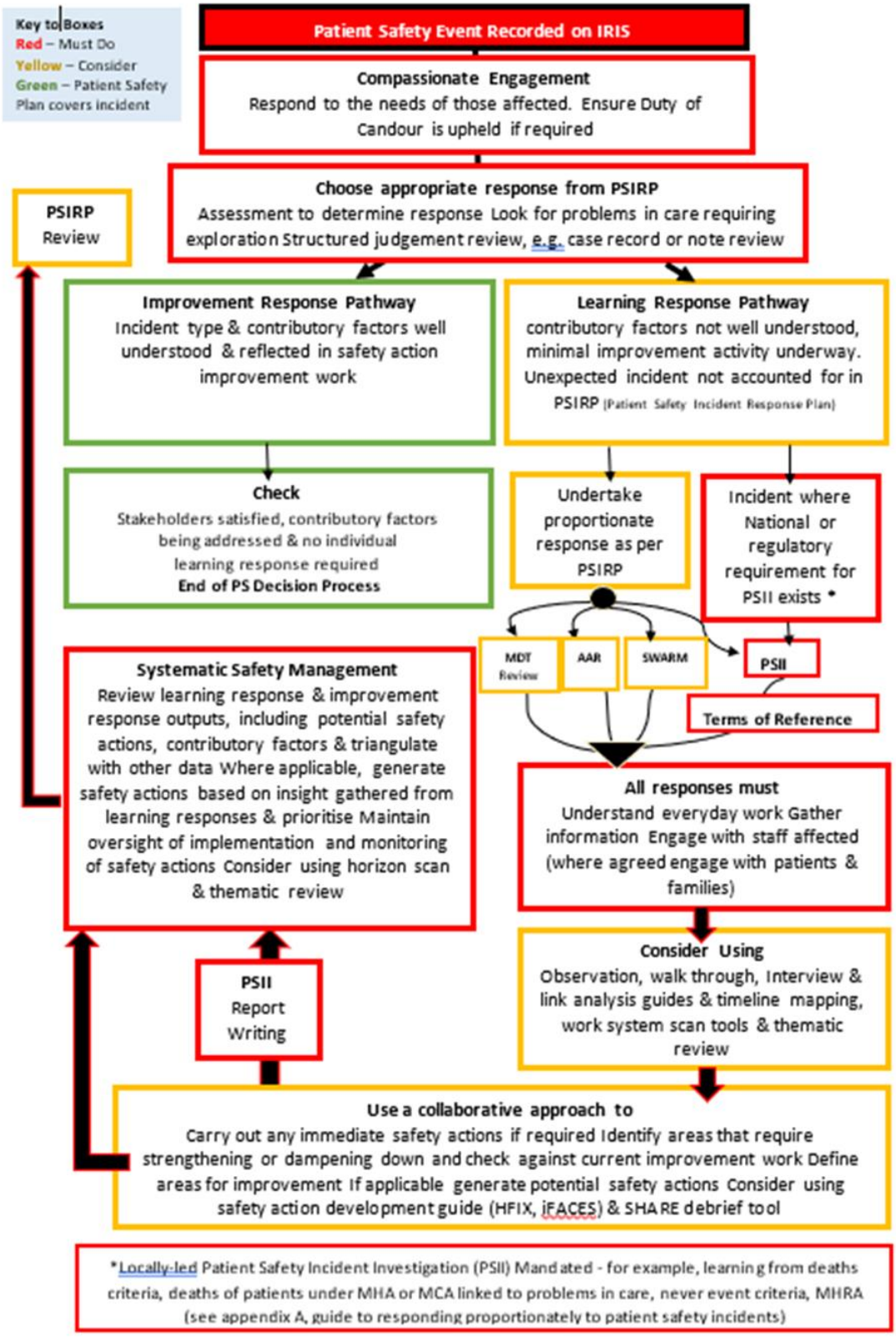
Suicide including those incidents with the potential to cause death	A learning response will always be required	Create recommendations to develop Network and site improvement strategy.
Physical Health Care - Neurological services Only		
Pressure Ulcers	A learning response will always be required	Create recommendations to develop Network and site improvement strategy
Falls	A learning response will always be required	Create recommendations to develop Network and site improvement strategy
All other Patient Safety Physical Health Incident Types	**PSII Index Review and full thematic review to develop PSP**	**Create recommendations to develop Network and site improvement strategy**
Physical Health Care - All other services		
Injury sustained during restraint (may reflect learning from a restraint itself)	A learning response will always be required	Create recommendations to develop Network and site improvement strategy
Accidents and Falls	Not prioritised in PSP this year	Managed by care plan review
Choking and Poisoning	Consider a learning response – if contributory factors not well understood and learning is indicated	To review care plan and potentially to create recommendations to develop Network and site improvement strategy
Substance Use	Not prioritised in PSP this year	Managed by care plan review
Infection Control	Not prioritised in PSP this year	Managed by referring to Policy
Failure to ensure safe use of equipment	Not prioritised in PSP this year	Managed by referring to Health and Safety
Urgent transfer to Acute setting (when not self-harm related)	Not prioritised in PSP this year	Managed by care plan review
Other Physical health patient safety incidents	Not prioritised in PSP this year	Managed by care plan review
Medication Management		

Administration and Dispensing Errors	**PSII Index Review and full thematic review to develop PSP**	**Create recommendations to develop Network and site improvement strategy**
All other medication incidents	Not prioritised in PSP this year	Managed by referring to Policy
Environmental		
Fire	Consider a learning response – if contributory factors not well understood and learning is indicated	Potentially to create recommendations to develop Network and site improvement strategy
Property and Equipment	Review as part of Violence to others	Managed by referring to Health and Safety
Cyber Breaches	Not prioritised in PSP this year	Managed by referring to Policy
Loss of service	Not prioritised in PSP this year	Managed by referring to Business Continuity Plan (BCP)
System Outage	Not prioritised in PSP this year	Managed by referring to BCP
Absent without Leave		
Escape from Secure Unit – from within the secure perimeter or whilst on escorted leave	A learning response will always be required	Create recommendations to develop Network and site improvement strategy
All other leave issues	Not prioritised in PSP this year	Managed by referring to Policy and a care plan review
Mental Health Act		
All mental health act issues including errors in administration, illegal detention, breaches in leave reporting etc	Not prioritised in PSP this year	Managed by referring to Policy

The above was agreed at the Quality and Risk Committee meeting on 7th July 2023 and has been verified by the Elysium Operational Board.

Fig 3

PSIRF- Patient Safety Response Decision Process



Assurance of the mapping process – ensuring validity

Reviewing large data sets will without doubt present a challenge on many fronts, both from ensuring inclusivity and relevance through to accuracy. The systems at Elysium have a series of checks and balances to maintain an oversight of compliance to the company policy and wider system expectations. These checks include a range of second step checks and oversight from other parts of the company and are integral to the clinical governance system. Historically and up to the point the Serious Incident Framework was closed NHS commissioners also had a direct scrutiny role over all RCA (Root Cause Analysis) reports and action plans. The data we used for the process of prioritisation has been through this historical review process. In the future the Patient Safety Meeting (PSM) will maintain a process of quality control and oversight to ensure compliance to our high-quality expectations for the patient safety system, this will be overseen by the Quality and Risk Committee as a standing subgroup of the Elysium Operational Board.

The volume of incidents is large, but the following table sets out our key priorities in relation to the number of incidents.

Fig 4

Event Category	Events Recorded				
	2020	**2021**	**2022**	**2023 (6 mths)**	**Average**
All Violence & Aggression (Physical Violence)	16,541 (10,858)	18,839 (12,009)	18,555 (11,698)	8,485 (4,932)	17,834 (11,285)
Self-Harm	7[3]	8,148	13,470	5,946	11,026
Physical Health (Neuro)	17,915[3] (1104)	12,742 (789)	7,303 (1034)	4,177 (664)	9,689 (1026)
Environmental	1,279	1,632	1,624	701	1,496
Medication	741	1,398	1,550	652	1,240
Breaching Leave	161	242	224	95	206
Mental Health Act	41	87	86	20	67

Assurance of Patient safety planning effectiveness

PSIRF was created to address the well understood problem with SIF, namely that immediate actions were usually implemented well (as achieving safety was an immediate goal) and long-

[3] Data excluded from the average as abnormal.

term action planning was strife with difficulties as the nature of monotonous repetition of the same action plans yet again being developed made evident. PSIRF encourages the retention of immediate safety actions as this is an effective tool. It moves away from disjointed repetitive action planning and builds on the need to invest in a learning culture, where the process of learning maintains momentum supported by oversight, skills and learning to ensure that the review of PSPs and the development of new PSP is evidence and learning based.

The safety plans developed through the improvement response pathway will include the intended aim and the agreed measurement of change. This will enable audit of the system to maintain an awareness of effectiveness of the system. It is recognised that the developed safety actions will take time to embed and see measurable change. The Patient Safety Meeting (PSM) will pre-agree the review and testing period prior to the review of the success and failure of any plan, sustaining change is the goal of patient safety, the iterations of the plan must build on that improvement. Each safety action plan will be subject to formal recording, audit, and scrutiny to ensure effective records of the plans, so that we have a library to review change against any shift in safety profile. This is in effect organisational memory to avoid repeat learning of known issues.

Appendix

P1 – The PSIRF Escalation Form

P1 - PSIRF ESCALATION FORM

P2 - The PSIRF Delayed Discharge and Notice Served Form

P2 - PSIRF delayed discharge and notic

Working assumption – Key Priorities

Working Assumption of Key F

Key Priorities reference to Operational Policies

PSIRF Key Priorities Referenced to OPS F

Appendix C

Level 1 - No Harm	Level 2 - Low	Level 3 - Moderate	Level 4 - High	Level 5 - Severe
Potential to cause harm, damage, or loss, with none resulting. Includes: impact prevented - e.g. attempted events, intervening actions prevented harm occurring impact not prevented - e.g. event ran to completion but no harm caused	Minimal harm, damage, or loss i.e. may require first aid. Damage to an individual's or team's reputation; possible local media interest	Moderate harm i.e. requiring medical attention or precautionary visit to GP / general hospital (e.g. for stitches); non-emergency hospital admission that may be care planned. Moderate damage or loss. Damage to Service's reputation; possible local media interest	Severe or permanent injury or harm i.e. requires emergency medical treatment in A&E or hospitalisation which is unpredicted/not care planned. High level of damage or loss. Damage to Elysium's reputation; local media interest	Serious events resulting in life threatening harm or death, substantial service disruption, damage, or loss. Damage to Elysium's reputation; national media coverage. Never events.

Appendix D

PSIRF ESCALATION FORM (P1)

This form will be completed for all patient safety incidents where an escalation is required to the Elysium Patient Safety Meeting (PSM)
A copy of the form will also be sent to the responsible commissioner and host commissioning body after PSM approval by the site management team

Send form to: PSIRF@Elysiumhealthcare.co.uk

Save form as: P1-UNITNAME-IRISINCIDENTNUMBER-00.00.0000 (e.g.: P1-COPSE-IR987654-25.12.2022)

Service / Unit / Hospital	
Ward Name	
Security Level	
IRIS Incident Number	
Patient NHS Number & Elysium Identifier	
Patient Initials	
Patient DOB	
Gender	
Ethnicity	
Diagnosis	
Responsible Clinician	
Responsible ICB/LA for Patient	
MHA Status	
Date of Incident	
Time of Incident	
Location of Incident	
Brief description what happened (including dates / times)	

Escalation Reasons	**Options–** mark with X all applicable	**Mark with X Below**
IRIS RISK SCORE [ ] **All incidents in this list must have scored 3 or more**	Any safety incident that has required the individual to be escalated to acute hospital	
	Any safety incident that potentially there will be staff disciplinary action	
	Any safety incident that the police are asked to respond to / a 999 call made	
	Missing service user	
	Any safeguarding incident going to a Section 42 England; Section 126 Wales; Section 47 Children.	
	Any incident that triggers Duty of Candour	
	Mental Health Act breach leading to illegal detention	
	Any incident that compromises the safety of the unit	
	Any incident that has media interest	
	All deaths	
	All incidents that are not included in the above where the service, region, network or the board chooses to have a discretionary PSII	

Police involved / informed	
Coroner involved / informed	
Known press / media involvement	
Next of kin informed	
Safeguarding procedures implemented	
Are HR Actions being undertaken with any staff member	

PSIRF response at second IRIS sign off		
Option (choose one)	Choose either Improvement or learning Response	Mark with X
Improvement Response Pathway	Please note above if a Duty of Candour also applies	
Learning Response Pathway	Type of Response	Mark with X
	Multidisciplinary Review	
	After Action Review	
	SWARM Huddle	
	Patient Safety Incident Investigation (PSII)	
	Other approach: describe	
Not Prioritised in PSP	Confirm action taken (describe below)	Mark with X

Name (s) of learning response lead/ Reviewer(s)/Investigator(s) if known	

Current location of Service User	
Details of immediate actions taken to prevent recurrence	

Name of staff member completing PSIRF Escalation Form	
Job Title	

Contact name for Responsible Commissioners contacted	
Job Title	
Name of Organisation	
Email Address	
Telephone Number	

PSIRF: Delayed Discharge and Noticed Served FORM (P2)

This form will be completed for all patients who meet the criteria for delayed discharge or the commissioning contracting body has been given notice where action to move patient is with the commissioning body. Sites will notify the contracting team of all patients who fall within this definition. The form is completed by the Contracting Team and sent to the Elysium Patient Safety Meeting (PSM)

A copy of the form will also be sent to the responsible commissioner and host commissioning body after PSM approval by the Contracting Team

Send form to: PSIRF@Elysiumhealthcare.co.uk

Save form as: P2-UNITNAME-ElysiumIdentifier-00.00.0000 (e.g.: P2-COPSE-15-99-85-25.12.2022)

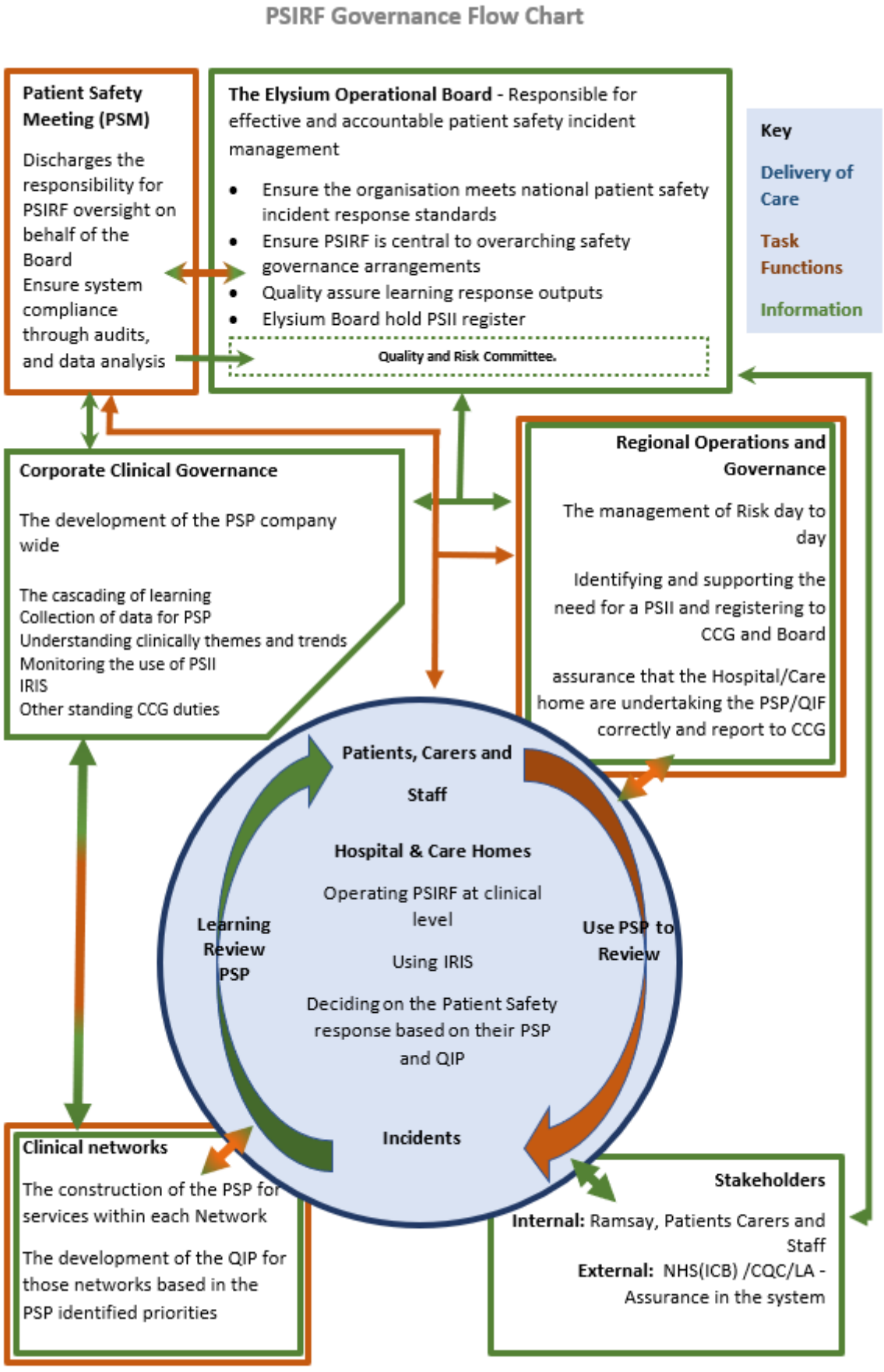
Service / Unit / Hospital	
Ward Name	
Date of Admission	
Patient NHS Number & Elysium identifier	
Patient Initials	
Patient DOB	
Gender	
Ethnicity	
Responsible ICB/PC/LA for Patient	
MHA Status	
Date of notification	
Brief description of communication to commissioner to date	

Notification Reason	**Options–** mark with X all applicable	**Mark with X Below**
	Delayed Discharge	
	Notice Served as service user escalating beyond the management capacity of the service and therefore causing safety concerns	

Patient Safety – for the individual and others	
Interim safety Management plan	

Name of staff member completing PSIRF P2 Form	
Job Title	
Contact name for Responsible Commissioners contacted	
Job Title	
Name of Organisation	
Email Address	
Telephone Number	

Appendix E


PSIRF Governance Flow Chart
Patient Safety Meeting (PSM)
Discharges the responsibility for PSIRF oversight on behalf of the Board
Ensure system compliance through audits, and data analysis
The Elysium Operational Board - Responsible for effective and accountable patient safety incident management
Ensure the organisation meets national patient safety incident response standards
Ensure PSIRF is central to overarching safety governance arrangements
Quality assure learning response outputs
Elysium Board hold PSII register
Quality and Risk Committee.
Key
Delivery of Care
Task Functions
Information
Corporate Clinical Governance
The development of the PSP company wide
The cascading of learning
Collection of data for PSP
Understanding clinically themes and trends
Monitoring the use of PSII
IRIS
Other standing CCG duties
Regional Operations and Governance
The management of Risk day to day
Identifying and supporting the need for a PSII and registering to CCG and Board
assurance that the Hospital/Care home are undertaking the PSP/QIF correctly and report to CCG
Patients, Carers and Staff
Hospital & Care Homes
Operating PSIRF at clinical level
Using IRIS
Deciding on the Patient Safety response based on their PSP and QIP
Learning Review PSP
Use PSP to Review
Incidents
Clinical networks
The construction of the PSP for services within each Network
The development of the QIP for those networks based in the PSP identified priorities
Stakeholders
Internal: Ramsay, Patients Carers and Staff
External: NHS(ICB) /CQC/LA - Assurance in the system