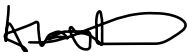


Patient Safety Incident Response Policy

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	NAME	TITLE	SIGNATURE	DATE
Author	Amanda Last	Deputy Director of Governance		30/08/2023
Reviewer	Quality and Safety Committee	N/A	N/A	26/09/2023
Authoriser	Trust Board	N/A	N/A	12/10/2023

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Purpose

This policy supports the requirements of the Patient Safety Incident Response Framework (PSIRF) and sets out The Dudley Group NHS Foundation Trust'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 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 supports development and maintenance of an effective patient safety incident response system that integrates the four key aims of the 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.

Scope

This policy is specific to patient safety incident responses conducted solely for the purpose of learning and improvement across The Dudley Group NHS Foundation Trust.

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. Other processes, such as claims handling, human resources investigations into employment concerns, professional standards investigations, coronial inquests and criminal investigations, exist for that purpose. The principle aims of each of these responses differ from those of a patient safety response and are outside the scope of this policy.

The following processes sit outside the scope of the Patient Safety Incident Response Plan:

- Complaints
- Disciplinary/human resources investigation (link policy)
- Coronial inquests,
- Claims management,
- Safeguarding concerns,
- Information governance concerns,

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

Our patient safety culture

The Trust is committed to:

- Promoting an open, inclusive and just culture that champions the belief that incidents cannot simply be attributed to the actions of individual staff but focuses on the system in which they were working, in order to learn lessons.
- Improving communication and the development of psychological safety, encouraging a positive approach to the reporting of and responding to patient safety incidents ([Incident management policy](#))
- Openness with patients and their families in the application of Duty of Candour and beyond ([Being open policy](#))
- Justifiable accountability and a zero tolerance for inappropriate blame.

The Trust has a strategic objective to be 'a brilliant workplace' this is supported by an improvement workplan which focuses on understanding the organisational culture, developing means of measurement as well as specific improvement approaches. The work is supported by a comprehensive and inclusive review of the Trust's behaviour framework and associated activities.

Patient safety partners

Patient Safety Partners (PSPs) have been actively involved in the development and implementation of this policy and will continue to play key roles in its application and development, providing a patient perspective to developments and innovations to drive continuous improvement.

PSPs will use their lived experience as a patient, carer, family member or a member of the local community to support and advise on activities, policies and procedures that will improve patient safety and help us to deliver high quality care.

PSPs will work alongside staff, volunteers and patients, attend meetings and be involved in projects to co-design developments of patient safety initiatives.

PSPs are integrated members of Trust Committees and Groups aligned to the quality governance framework joining key conversations and meetings focusing on patient safety.

Addressing health inequalities

As a provider of acute and community services, the Trust has a key role to play in tackling health inequalities in partnership with our local partner agencies and services.

Through the implementation of PSIRF, we will seek to improve our collection and use of data and learning from investigations to identify actual and potential health inequalities, making recommendations to our Trust Board and partner agencies on how to tackle these.

In preparation for PSIRF, we have reviewed and strengthened our incident reporting system to facilitate the collection of key data sets to inform our future improvement works. The tools we have designed to thematically review incidents have incorporated the collection of equalities data to enable us to review inequalities in our practices and design improvements accordingly.

The processes we have developed will work hand in hand with key equality and diversity leads across our organisation to ensure we have the appropriate skills and perspectives to inform wider improvement workstreams.

Engagement with patients, families, and carers following a patient safety response will recognise diverse needs and ensure inclusivity. This has been planned for in our investigative processes with the support of our PSPs.

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

The 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.

Involving Patients, Families and relevant persons:

This policy plans for engagement with patients and their relevant persons beyond the statutory requirements of the Duty of Candour. It is recognised from experience and research that patients and families often provide an invaluable perspective to the circumstances around patient safety incidents, and / or may have different questions or needs to that of the

organisation. This policy reinforces the need to notify patients and their relevant persons as soon as possible and to then plan their involvement throughout the planned incident response. The Trust acknowledges that one size does not fit all and that we need to be flexible to meet the needs of the people involved. Our response completion timeframes will aim to meet the needs of the patient and their relevant persons, noting that sometimes people may need a longer time period to process information and engage. Equally they may benefit from earlier feedback on their questions ahead of the closure of the incident response; which we will endeavour to meet.

Initial engagement with patients and their relevant persons is the responsibility of the responsible clinician or allocated lead, in line with our Duty of Candour policy. Where a full Patient Safety Incident Investigation (PSII) is being conducted, an engagement lead will be assigned to the response team, to help support the process and ensure engagement opportunities and plans are acted upon. The allocated response leads for other response types (e.g., AAR, SWARM) will ensure patients are appropriately involved in line with their preferences and this will be overseen by the Patient Safety Team.

In order to support engagement, we have developed a support booklet which provides information and advice specific to the response planned. This resource allows for notes to be made specific to the case under review. This does not substitute engagement. The booklet will be offered to patients and/or their relevant person(s) at the start of the response process. This resource also serves as a library for signposting patients and families to various support agencies. We acknowledge that meaningful support for people involved in incidents is vital to the wellbeing of those involved.

Involving staff:

The impact incidents can have on staff wellbeing should not be underestimated. This policy acknowledges the importance of robust staff support and the value of meaningful involvement in the incident response; not only for the staff member's wellbeing but for the Trust's understanding of events and the success of subsequent improvement work.

We have worked closely with the Trust's Wellbeing Lead to ensure a coordinated approach to the staff wellbeing offer. Opportunities to offer support have been mapped out across the incident response pathway. The support offered to staff as part of the response does not replace that offered by the staff member's line manager or peers; it aims to offer additional or alternative approaches to meet the needs of the individual.

Where a full Patient Safety Incident Investigation (PSII) is being conducted, an engagement lead will be assigned to the response team to help support and ensure relevant staff are given the opportunity to engage, be heard and supported. The assigned response leads for other response types (e.g., Action After Review, SWARM) will ensure relevant staff are given the opportunity to be involved and this will be overseen by the Patient Safety Team.

Our staff are key to the development and implementation of effective improvement plans; their practical experience of 'work as done' is key to the understanding of how we can strengthen systems and processes to create safer practices and environments. Response approaches will include the staff involved in a patient's care; not through statement collection but through supportive conversations and group huddles. Action plans should not be developed without their input.

Patient safety incident response planning

PSIRF supports organisations 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. Beyond nationally set requirements, organisations can explore patient safety incidents relevant to their local context rather than only those that meet a certain defined threshold. The Trust has welcomed this more considered approach, where investigative resource can be directed to the local priority incidents that we need to understand further. Conversely, where the Trust has a good understanding of the improvements required to address safety incidents, investigative resource will be redirected to support improvement rather than repeated investigations.

In order to fully understand the Trust's priorities for investigation and improvement, we have utilised a multifactorial approach to formulate our patient safety incident /issue profile, namely:

- A series of thematic reviews across a three year period on a suite of workstreams (including complaints, incidents, legal claims, mortality reviews, freedom to speak up concerns)
- Analysis of current incident investigation activity
- Direct feedback through a programme of engagement with stakeholders
- A collation of existing quality improvement activity

Following this our Patient Safety Incident Response Plan (PSIRP) has been formulated with informed rationale for each of the responses planned in the context of the Trust resources available.

Resources and training to support patient safety incident response

PSIRF recognises that resources and capacity to investigate and learn effectively from incidents is finite. It is therefore essential that our PSIRP is achievable in the context of the resource available to deliver our plan.

Our Patient Safety Team has been resourced with a team of investigation leads which will be key to the success of our PSIRP. The team consists of four leads and a risk and quality facilitator who are supported by the Patient Safety Management Team. Collectively they will lead our approach to PSII teamed with an assigned Director and specialist lead. The team will also have assigned key responsibilities in the other planned responses e.g., Action After

Reviews, SWARM, Thematic Reviews. All members of this team have received the appropriate training in line with the PSIRF.

Our planned responses will recruit specialty leads to form part of our response teams; this pool of staff will receive the required training or support from the trained Patient Safety Team leads. Our PSII will also have an assigned Executive Director lead; they will have received the necessary PSIRF oversight training.

The number of planned responses has been formulated based on previous reporting data and the capacity of the staff aligned to this framework. This will be routinely monitored as the framework becomes embedded. The PSIRP will be reviewed every 12-18 months and amended accordingly to ensure the plan is achievable, is reflective of the Trust's risk profile and is effective.

Our PSIRP provides more specific details in relation to this including the anticipated number of responses, the response approach and how this will be resourced.

Our patient safety incident response plan

PSIRF enables organisations to explore local patient safety incidents rather than only those that meet a defined threshold. The framework provides flexibility regarding the investigative tools so that proportionate responses can be made reflective of the local understanding of the issues faced and the improvement work already underway; enabling time and resource to be directed accordingly.

Our Patient Safety Incident Response Plan (PSIRP) sets out how we intend to respond proportionally to patient safety incidents over a period of 12-18 months. Our plan is not permanent. We will work hard to remain flexible and consider the specific circumstances in which patient safety issues and incidents occurred and the needs of those affected. Our plan identifies how we will respond to national and local priorities; our responses are conducted solely for the purpose of systems-based learning and improvement.

A copy of our plan can be found here – [PSIRP](#)

Reviewing our patient safety incident response policy and plan

Our Patient Safety Incident Response Plan is a 'live document' that will be appropriately updated and strengthened 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; as we progress through our improvement programmes, 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. As well as remaining flexible, we will work hard to remain brave in our approach and changes to our PSIRP, either ahead of or during our formal planned review. This will be based on reliable data and robust engagement rather than making hasty decisions in response to small changes/natural variation in our incident/intelligence profile.

We will ensure our updated plans are published on our website, replacing the previous version.

We acknowledge that the effectiveness of our plan and the associated quality improvement work takes time; it often takes longer than 12 months to achieve and embed impactful change. Therefore, in addition to our annual review and reflection process, we will complete a more rigorous planning exercise every four years. This will 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 and wider stakeholder engagement.

Responding to patient safety incidents

Patient safety incident reporting arrangements

Patient safety incident reporting will remain in line with the Trusts Incident Management Policy – [Incident management policy](#)

As part of the implementation of PSIRF and the national Patient Safety Strategy, work has been undertaken and continues to take place to support staff to recognise and report incidents. Staff education coupled with engagement with teams and services to streamline our reporting systems form the basis of our approach. However we recognise that creating a psychologically safe culture is vital so that staff feel able to report without fear of retribution. Our People Plan hand in hand with our PSIRP aims to create and continuously reinforce a Just Culture.

Although our investigation process has changed, incident reporting and local incident management remains the same. There is still a requirement to report incidents regardless of whether they are incidents that feature on our PSIRP. PSIRF does not replace the routine incident management. The importance of daily incident reporting, review and local management remains. As a Trust, we recognise the value of local learning, ensuring an incident has been appropriately dealt with and that mitigating actions have been immediately instigated and shared as necessary to help prevent reoccurrence. Furthermore, reporting will enable the monitoring of trends and risks, review of the effectiveness of quality improvement workstreams and will inform our future PSIRPs.

The Patient Safety Team will work closely with relevant Trust departments to ensure we report incidents to external national bodies such as HSIB, HSE, and MHRA, in line with the Incident Management Policy which provides full details.

Patient safety incident response decision-making

A critical component for the success of our PSIRP is a robust governance framework which supports:

- the identification and oversight of incidents that meet the criteria for national and local response priorities
- ensuring each of the priority incidents are subject to the appropriate planned response

- the identification of incidents that fall outside of the plan but potentially pose significant safety concerns, need appropriate senior oversight and consideration for alternative response planning

We have structured our governance process around a weekly Executive Director-led Group referred to as Weekly Meeting of Harm and Learning. At this meeting incidents potentially fulfilling the criteria of our PSIRP will be reviewed. The core membership of this group enables a multi-disciplinary approach to incident review and decision making. The decision making process will be supported through the presentation of a Patient Safety Incident Initial Review (PSIIR); appendix 1 shares a copy of PSIIR report template. The Group will check that each incident meets the criteria set out in our plan and agree the response is appropriate; the response will then be commenced by the Patient Safety Team.

In addition, significant incidents that fall outside of the planned response will also receive the same review process at Weekly Meeting of Harm and Learning. The Group will assess the information available alongside any associated quality improvement work and immediate actions taken to mitigate risk. The Group then make a decision as to whether an unplanned response is required. Capacity has been built into our response planning to undertake 10 additional responses.

Incidents that require review at the Weekly Meeting of Harm and Learning (planned or unplanned significant) will be identified through the established process of daily incident review following reporting on Datix. This review is led by the Patient Safety Team in conjunction with the wider senior leadership team who receive daily incident reports through scheduled notifications and daily reporting summaries.

There are exceptions to this decision making process; namely the responses planned for falls and pressure ulcer incidents. These are managed through delegated group processes and forums.

A process map of the decision making processes is shared in appendix 2.

Responding to cross-system incidents/issues

Throughout the various stages of our PSIRP responses, we will actively look for opportunities for cross system learning, sharing practice concerns and excellence, working collectively to strengthen processes and pathways in a consistent manner.

Through our initial incident review processes, we will look to work with other system providers where a patient's care pathway involves multiple agencies. We will invite leads from our partner organisations to work with us to enable a more holistic review of care and to ensure safe and timely transitions for our patients.

Where relevant, we will work with system providers to review incident intelligence and address problems collectively in order to share ideas, resources and promote consistent working e.g. falls prevention task and finish group, mental health care support for patients in our hospital.

Through our Integrated Care Board (ICB) governance processes we will share our PSIRP process and outcome measures with system providers and look at trends in reporting and improvement on a larger scale.

Timeframes for learning responses

Timeframes for incident responses must consider a number of factors:

- The needs of the patient and their relevant person; a timely response will help them in processing what has happened
- The need to collect information whilst events are still fresh in the minds of those involved
- The need to undertake a thorough response in line with process and in the context of the complexity of the incident
- The dependence upon information that may not be readily available and is externally sourced

The timeframe assigned to a response must be agreed in conjunction with the affected patient and/or their relevant person (where applicable). It should be set at the beginning of a response and any variations or slippage on this must be communicated with those involved. This timeframe must be documented on Datix by the Response Lead to enable monitoring.

Approximate estimated timeframes for each response type are summarised below:

- Patient Safety Initial Incident Review (PSIIR) – as soon as possible, reviewed at Weekly Meeting of Harm within 9 working days of reporting
- Patient Safety Incident Investigations (PSII) – 3 months
- Action After Review (AAR) – 15 days
- SWARM huddle – 1 month

- Shortened Investigation Tool (SIT) – 5 days
- Thematic Review – 1 month

Safety action development, safety improvement plans and monitoring improvement

Safety actions arising from learning responses should follow the SMART (Specific, Measurable, Achievable, Realistic, Time-bound) principles and plan must incorporate means of monitoring completion and sustained effectiveness. All action plans must be developed with and agreed by the staff that will implement the change. The Dudley Improvement Practice Team can be recruited in at the improvement plan development stage to help support defining and implementing impactful and informed change ensuring the issues raised have been fully explored.

When defining safety actions is it essential that these are directly addressing the recommendations from a system-based incident response. Action plans should be concise, consisting of a small number of action points that have been prioritised based on impact, allowing staff to focus resource on those actions that are likely to result in sustained beneficial change. Actions reminding staff of policies or procedures or sharing reports in various forums should not be included in the plans generated under PSIRF.

Each planned response detailed in our PSIRP has defined improvement routes and oversight forums. Each priority incident type has a defined improvement plan that new actions arising from responses can be added to or considered. Improvement plans are centrally documented on a database and where actions are generated that sit outside these plan e.g. for local areas to action these are documented on Datix and are monitored through to completion through recognised governance processes.

It is important that the monitoring of completion of safety actions does not become an end in itself, but rather a means to improve safety and quality outcomes and reduce risk. Rather than reporting on action plan completion, we are more focussed on measuring and monitoring outcomes. The development of these outcome measures will be defined over the first 12 months of our plan. Key metrics will be reported to the Risk and Assurance Group (monthly) and Quality and Safety Committee (quarterly). These will be supported by scheduled reports from each PSIRP priority area on their overall service quality standards and safety improvement plans.

It is recognised that recommendations may be made following responses that may not be achievable at that time in the context of current finances or resources. It's important to still

consider and document these improvement ideas. Over time an evidence base may then build which in turn may influence future business cases, developments and financing options.

The Patient Safety Team will maintain an overview across the organisation to identify themes, trends and triangulation with other sources of information that may reflect improvements and reduction of risk as well as identify new priority areas which require further review and improvement.

Oversight roles and responsibilities

Our Trust Board has overall responsibility for the oversight of PSIRF. The framework defines 4 overarching areas of oversight:

1. Ensuring the organisation meets the national response standards

Our PSIRF Policy and Plan has been developed with and approved by the Quality and Safety Committee, a delegated committee of the Trust Board. The PSIRF standards are the foundation of our plan and policy and our monitoring approach incorporates reporting on compliance with each standard

- policy, planning and oversight
- competence and capacity
- engagement and involvement of those affected by patient safety incidents
- proportionate responses

2. Ensure PSIRF is central to overarching safety governance arrangements

In order to facilitate appropriate Board oversight of the implementation and effectiveness of our plan and policy, PSIRF is integrated into our Trust's governance framework and reporting schedules. Forums that are key to our oversight process include:

- The **Quality and Safety Committee** will receive high level quarterly reports detailing compliance with our PSIRP in terms of the number and types of responses commissioned, engagement with our staff and patients and their families and the Duty of Candour. The report will collate both quantitative and qualitative data to demonstrate the effectiveness of our plan in terms of process and outcome metrics. The Committee will play a key role in overseeing and challenging the effectiveness

of the plan as well as supporting the Trust to remain brave and on track with our proportionate and considered responses. The Committee will also play a key role in the annual and four yearly review of our plan.

The Quality and Safety Committee is chaired by a Non-executive Director and membership consists of Non-executive and Executive Trust Board Directors alongside the senior divisional leadership team. The Committee will report exceptions regarding PSIRF to Trust Board.

- The **Risk and Assurance Group** will receive detailed monthly reports on our incident reporting, harm levels, PSIRP responses and effectiveness measures. Improvement plan monitoring in terms of action plan completion will also be included in the report.

The Group will also serve as a sign off forum for PSII and SWARM reviews; challenging the quality of the system-based review, confirming engagement with those involved and agreeing improvement plans recommended.

The Group will also serve as an oversight forum for a number of our PSIRP priority improvement workstreams, namely the Deteriorating Patient Group, the Diabetes and Insulin management Group. The Group will oversee, support and challenge progress made in improvement programmes.

Risk and Assurance Group is chaired by an Executive Director of Trust Board; it will report exceptions accordingly to the Quality and Safety Committee.

- The **Weekly Meeting of Harm and Learning** is a sub-group of the Risk and Assurance Group co-chaired by the Chief Nurse and Medical Director. The Weekly Meeting of Harm and Learning is utilised as a platform for review of initial incident information and subsequent decision making on the response required, ensuring our PSIRP is followed and that incidents that fall outside of the plan that potentially pose significant safety concerns have appropriate oversight and consideration for alternative response planning.
 - The **Quality and Safety Group** are a sub-group to the Quality and Safety Committee. The Group serves as an oversight forum for a number of our PSIRP priority improvement workstreams, namely the Falls Prevention, Pressure Ulcer Prevention, Maternity Care, Gynaecology services, Paediatrics and Neonates and Imaging. The Group will oversee, support and challenge progress made in improvement programmes through scheduled reporting and presentation of quality metrics.
- The Group is chaired by an Executive Director of Trust Board. The Group will report exceptions accordingly to the Quality and Safety Committee.

3. Quality assure learning response outputs

All final reports for PSII and SWARM reviews will be reviewed and signed off by an assigned Executive Director of Trust Board in line with the national framework. Following this sign off process, PSII and SWARM reviews will be subject to a wider review process through their presentation at Risk and Assurance Group. This MDT senior leadership forum enables not only further supportive scrutiny and strengthening of the response but also serves as a platform for shared learning and opportunities for wider roll out of improvement plans.

The key members of the Group will receive appropriate PSIRF training in line with national recommendations.

Our plan also outlines how our other response types (AAR, thematic reviews, SIT) will have the appropriate oversight and approval through the delegated forum.

In addition to the monitoring and reporting processes outlined above which enable us to ensure that all safety actions are/have been implemented in response to learning, we will check these plans are delivering the required improvement utilising a number of methods:

- Audit programmes as part of improvement programmes
- Staff and patient feedback monitoring
- Quality and Safety reviews
- Board Walk arounds
- External quality reviews and inspections
- Focussed reviews
- Extended outcome metric monitoring

4. Develop, agree, maintain and review our PSIRP

The Trust recognises that it will take time to embed an effective PSIRP; training, response tools and processes are likely to need development and amendments in order to get the best learning outcomes for our patients and staff. Our staff also need time to build their confidence in this new framework however we are positive and committed to getting this right. Our scheduled monitoring of annual and four yearly formal reviews will enable flexibility in our approach to adapt to the risk profile the Trust encounters.

External Oversight

Integrated Care Board

The Trust is committed to close working, in partnership, with the Black Country Integrated Care Board (ICB) and other national commissioning bodies as required. This oversight under PSIRF focuses on engagement and empowerment rather than the more traditional command and control. There will no longer be a requirement to 'declare' an SI and have individual patient safety responses 'signed off' by commissioners. However, they will wish to seek assurance that improvements and priorities under PSIRF are progressing and delivering improvements in quality and safety.

There are 3 main elements to oversight at the system level:

- Oversee and support effectiveness of systems to achieve improvement following patient safety incident responses
- Support the co-ordination of cross system responses and improvement
- Share insights and information across organisations and services to improve safety

We will share our oversight and monitoring reports with our ICB colleagues to provide assurance on the effectiveness of our PSIRP. We will work closely to develop our process and improvement measures collectively as we embed and learn utilising our new response tools and standards.

We will invite our ICB colleagues to join us in our programmes of quality and safety reviews which will support our monitoring improvements in specific services. We will also support ICB-led assurance visits.

Care Quality Commission (CQC)

The CQC will close monitor and test the strength of our application of the PSIRF and associated patient safety incident response standards as part of its assessment approaches. We will work closely with the CQC to ensure timely notification of high profile and complex incidents, as well as providing all statutory notifications as required by the Health and Social Care Act (2008) and set out in CQC's guidance on statutory notifications. We will share our Patient Safety Initial Incident Review reports with the CQC as requested to provide the necessary assurance around immediate actions taken in response to incidents. We will also share our final PSII reports and welcome their oversight and constructive support in ensuring our responses are robust, meeting the national patient safety incident response standards.

Complaints and appeals

Any complaints relating to this guidance, or its implementation can be raised informally with the Trust's Patient Safety Specialist, initially, who will aim to resolve any concerns as appropriate.

Formal complaints from patients or families can be lodged through the Trust's complaints procedure at [Complaints and Concerns policy](#)

Appendices

Appendix 1: PSIR report template

Appendix 2: Response Decision Making