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Contents

1. Purpose

This policy supports the requirements of the Patient Safety Incident Response Framework (PSIRF) and sets out Herts & Essex Fertility Centre (HEFC) 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

This policy will be reviewed every three years as per our document control policy.

2. Scope

This policy is specific to patient safety incident responses conducted solely for the purpose of learning and improvement across Herts & Essex Fertility Centre.

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.

Where other processes exist with a remit of determining liability or to apportion blame, or cause of death, their principal aims differ from a patient safety response. Such processes as those listed below and are therefore outside of the scope this policy.

- complaints handling
- human resources investigations into employment concerns,
- professional standards investigations

- information governance concerns
- estates and facilities concern
- financial investigations and audits
- safeguarding concerns
- coronial inquests and criminal investigations

For clarity, HEFC considers these processes as separate from any patient safety investigation. 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.

3. Our patient safety culture

At HEFC we strive to ensure that our patient safety is upheld at all times. The systems we have in place to include staff training, patient questionnaires, Quality Management System (ISO9001:2015), incident reporting, continual improvement, key performance indicators and response to complaints will ensure a robust culture that keeps patient safety uppermost at all times.

The Senior Management team have been instrumental in supporting this policy in the transition to a restorative just culture, with guidance from the team at NHS England.

The main goals of restoration when an incident has happened is outlined as-:

- Moral engagement
- Emotional healing
- Reintegration of the Practioner
- Organisational learning
- Prevention

PSIRF will enhance these by creating much stronger links between a patient safety incident and learning and improvement, through our continual improvement mechanisms. We aim to work in collaboration with those affected by a patient safety incident – staff, patients, and service users to arrive at such learning and improvement within the culture we hope to foster. This will continue to increase transparency and openness amongst our staff in reporting of incidents and engagement in establishing learning and improvements that follow. This will include insight from when things have gone well and where things have not gone as planned.

We are clear that patient safety incident responses are conducted for the sole purpose of learning and identifying system improvements to reduce risk. Specifically, they are not to apportion blame, liability or define avoidability or cause of death.

To enhance our safety culture, we have introduced monthly departmental meetings to discuss risks emerging or known and the insight offered from incidents that have occurred and an opportunity to share learning.

We will utilise findings from our staff questionnaires based on specific patient (and staff) safety questions to assess if we are sustaining our ongoing progress in improving our safety culture.

4. Patient Safety Partners (PSPs)

The PSP is a new and evolving role developed by the NHS England to help improve patient safety. The main purpose of the role is to be a voice for the patients and customers who utilises our services and ensure that patient safety is at the forefront of all that we do.

At Herts & Essex we are committed to working with patients and their families. Three main reasons for this to enable PSIRF to work effectively are:-

- It is the best way to learn from a patient safety incident in which they are involved
- It recognises the vital role they play in improving the safety of care delivered by Herts & Essex. This will ensure that the patient voice is truly heard and that individuality and protected characteristics are taken into account during patient safety events
- This demonstrates a collaborative partnership where the patient is involved in their own safety

It is envisaged that the Patient Safety Partners roles will be developed further during 2024.

5. Addressing Health inequalities

HEFC recognises that the NHS has a core role to play in reducing inequalities in health by improving access to services and tailoring those services around the needs of the local population in an inclusive way.

HEFC is committed to delivering on its statutory obligations under the Equality Act (2010) and 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.

We will also address apparent health inequalities as part of our safety improvement work. We understand that our services provide care to those requiring fertility assessment and treatment in establishing our policy we will work to identify variations that signify potential inequalities by using our population data and our patient safety data to ensure that this is considered as part of the development process for future iterations of our patient safety incident response. We consider this as an integral part of the future development process.

Engagement of patient, service users and staff following a patient safety incident is critical to review any patient safety incidents and their response. We will ensure that we use available tools such as patient communication portal, SALVE, 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.

HEFC's commitment to transforming organisational culture to that of restorative justice has already been outlined. Further to this, HEFC has affirmed that it endorses a zero acceptance of racism, discrimination, and unacceptable behaviours from and toward our workforce and our patients/service users. As part of this, discrimination of any kind including racism will be dealt with by using a 'Support, Educate, Challenge' approach. With explicit role modelling led by the Senior Management Team, we will use these principles to underpin patient safety training and implement the system-based approach to patient safety responses which is at the heart of PSIRF best practice

6. Involving patients and service users 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, and service users). 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 firmly 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, and service users to prevent recurrence.

We recognise and acknowledge the significant impact patient safety incidents can have on patients and their families.

Getting involvement right with patients and service users in how we respond to incidents is crucial, particularly to support improving the services we provide.

Part of this involves our key 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, and service users 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, and service users – based on our existing Being Open & Duty of Candour Policy. This will be underpinned by our head of departments who are able to guide patients and service users through any investigation or learning review.

In addition, at HEFC we have a Complaints SOP whereby people with a concern, comment, complaint or compliment about care or any aspect of the HEFC services are encouraged to speak with a member of the management team and where appropriate, with other relevant organisations to negotiate immediate and prompt solutions.

We also use the services of Independent Sector Complaints Adjudicator Services (ISCAS) who act as an adjudicator for dealing with patient complaints.

6.1 Citizens Advice Bureau

https://www.citizensadvice.org.uk/ provides UK citizens with information about healthcare rights, including how to make a complaint about care received

6.2 Our patient safety incident response plan: national requirements

Patient safety incident type	Required response	Anticipated improvement route
Safeguarding concerns surrounding the Welfare of the Child	PSII	Create local organisational actions and feed these into the quality improvement strategy

Learning from our incident reporting such as ectopic pregnancy, severe ovarian hyperstimulation syndrome (OHSS) , becoming unwell after egg collection and being transferred to an NHS hospital	PSII	Create local organisational actions and feed these into the quality improvement strategy

6.3 Our patient safety incident response plan: local focus

Patient safety incident type or issue	**Planned response**	**Anticipated improvement route**
Wrong drug / person / route or dosage medication errors leading to incidents	Raise as an internal incident, reporting to SMT, RCA and revision of SOP	Create systems and actions to feed in to our Quality Management System
Patient safety incidents that identified poor record keeping in the learning response	Raise an internal incident, reporting to SMT, RCA and revision of SOP	Create systems and actions to feed in to our Quality Management System
Patient safety incidents resulting from errors or delays in clinical pathways or processes	Raise an internal incident, reporting to SMT, RCA and revision of SOP	Create systems and actions to feed in to our Quality Management System

Monitoring & Audit

There is a robust system of reporting, oversight and governance in place supporting the adoption of a proactive approach to the identification and management of incidents.

- Audits are agreed at the Quality Review meeting
- KPIs are identified at the Quality Review meeting
- QI are identified at the Quality Review meeting
- Audit logs are kept by our Quality Management team
- Ongoing Risk & Opportunities Register
- Robust Complaints Log

6.4 Multi-agency incidents

Where more than one organisation is involved in an incident requiring a formal and coordinated response, the relevant commissioner will be responsible for deciding who will act as the lead organisation for the purposes of the investigation and incident management and be responsible for reporting the incident. The Patient Safety Team will liaise with the ICB and advise accordingly.

7. Patient safety incident response planning

PSIRF supports HEFC 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 context and the populations they serve rather than only those that meet a certain defined threshold.

HEFC will take a proportionate approach to its response to patient safety incidents to ensure that the focus is on maximising improvement. To fulfil this, we will undertake planning of our current resource for patient safety response and our existing safety improvement work streams. 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. Resources and training to support patient safety incident response.

HEFC has committed to ensuring that we fully embed PSIRF and meet its 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

HEFC will have in place governance arrangements to ensure that learning responses are not led by staff who were involved in the patient safety incident itself or by those who directly manage those staff.

Responsibility for the proposal to designate leadership of any learning response sits within the senior management team. A learning response lead will be nominated by the Operations Director and the individual should have an appropriate level of seniority and influence within HEFC.

Those staff affected by patient safety incidents will be afforded the necessary managerial support and be given time to participate in learning responses. All HEFC managers will work within our just and restorative culture to ensure that there is a dedicated staff resource to support such engagement and involvement. Senior management will have processes in place to ensure that managers work within this framework to ensure psychological safety.

HEFC has identified Head of Departments as Freedom to Speak Up Guardians. Freedom to Speak Up is incorporated in yearly staff Performance Development Reviews (PDR) and in our Being Open & Duty of Candour Policy. The Staff Handbook provides guidance to staff regarding our Whistle Blowing Policy and is reported to the Operations Director.

All staff will have annual training to complete level 1 (essential of patient safety) and Senior Management Team and Heads of Departments will complete level 2 (access to practice) of the patient safety syllabus. Our nominated Complaints Officer will engage in training to look at the PSIRF and the Complaints Standards framework through real life content, bringing the human focus for the patients, loved ones, and indeed staff to the forefront. It will support to explore what compassionate engagement looks like, feels like and how to communicate it authentically and meaningfully. This will be undertaken by external trainers.

Quarterly Incident & Audit presentations will be held for all staff chaired by our Quality Manger to reflect on incidents in a learning and sharing exercise.HEFC will 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:-

7.1 Level 1

Internal – all staff will complete the patient safety eLearning module setting out the reporting and responding to incidents. This has been aligned to the national patient safety syllabus

All staff, clinical and non-clinical are expected to undertake these on induction and to repeat every year.

These modules are available on the eLearning portal.

Staff involved in NHS contracts will be required to take part in specific PSIRF training.

7.2 Level 2

National – Health Education England patient safety syllabus module (Access to Practice) – this is to be undertaken by all Head of departments and senior management with potential to support or lead patient safety incident management

These modules are available on the eLearning portal.

7.3 Learning response leads

Learning response leads must have completed level 1 & 2 of the national patient safety syllabus

7.4 Competencies

HEFC will expect all senior staff who will act as engagement leads to be able to

a. Communicate and engage with patients, service users and external agencies in a positive and compassionate way.
b. Listen and hear the distress of others in a measured and supportive way.
c. Maintain clear records of information gathered and contact those affected.
d. Identify key risks and issues that may affect the involvement of patients, and service users, including any measures needed to reduce inequalities of access to participation.

Recognise when those affected by patient safety incidents require onward signposting or referral to support services

8 Responding to patient safety incidents

All staff are responsible for reporting any potential or actual patient safety incident on the HEFC incident reporting system and will record the level of harm they know has been experienced by the person affected

Level of Harm

Levels of harm were previously set out in the National Reporting and Learning Service guidance on reporting patient safety incidents.

In summary harm is defined as follows

No harm

This has two sub-categories:

No harm (Impact prevented) – Any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care. This may be locally termed a 'near miss'.

No harm (impact not prevented) - Any patient safety incident that ran to completion, but no harm occurred to people receiving NHS funded care. Ensure that the

Low harm - Any unexpected or unintended incident that required extra observation or minor treatment and caused minimal harm to one or more persons receiving NHS-funded care.

Moderate harm - Any unexpected or unintended incident that resulted in a moderate increase in treatment, possible surgical intervention, cancelling of treatment, or transfer to another area, and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.

Severe harm - Any unexpected or unintended incident that appears to have resulted in permanent harm to one or more persons.

Death – Any unexpected or unintended incident that directly resulted in the death of one or more persons

The persons involved in the incident will complete the details of the complaint/incident/non conformance and record the proposed corrective action otherwise known as a quick fix, this will be followed by evaluation of the corrective/preventative action (how do we prevent it happening again). The Quality Manager will review the incident to ensure that patient safety incidents can be responded to proportionately and in a timely fashion. 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 to the Medical Director.

The Quality Manager and Medical Director will decide if the incident needs reporting externally to regulatory bodies.

9 Patient Safety incident response decision- making

HEFC will have 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.

PSIRF itself sets no further national rules or thresholds to determine what method of response should be used to support learning and improvement. HEFC has developed it's own response mechanisms to balance the effort between learning through responding to incidents or exploring issues for continual improvement.

Any patient safety incident highlighted will follow the process as indicated in our Incident SOP. \\Mail01\iso\The I Drive\Quality Management\Incidents\Managing Incidents SOP.doc \\Mail01\iso\The I Drive\Quality Management\Incidents\Reporting an incident and accident internally SOP.doc

10 Safety action development and improvement

HEFC 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 HEFC's working systems where change could reduce risk and potential for harm – which will then be highlighted on our continual improvement log.

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 actions must continue to be monitored via our continual improvement process at the monthly quality meetings.

11 Safety improvement plans

Safety improvement plans bring together findings from various responses to patient safety incidents and issues. HEFC incident reporting and response has a robust mechanism to support improvement plans and continual improvement.

HEFC will use the outcomes from existing patient safety incident reviews where present and any relevant learning response conducted under PSIRF to create related safety improvement plans to help to focus our continual improvement.

We aim to bring on board Patient Safety Partners (PSP) to help support and learn from incidents. We will encourage and engagement through our Patient Support Group and patient feedback questionnaires. We will also reach out through the NHS Futures platform to join groups.

12 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.

HEFC followed the principles to underpin the processes we have put in place to allow us to implement PSIRF as set out in the supporting document (NHS England (2022), p 3).

In order to meet these responsibilities, HEFC has designated the Operations Director to support PSIRF as the executive lead.

Ensuring that the organisation meets the national patient safety standards

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

Where more than one organisation is involved in an incident requiring a formal and coordinate response, the relevant commissioner will be responsible for deciding who will act as the lead organisation for the purposes of the investigation and incident management and be responsible for reporting the incident. The Patient Safety Team will liaise with the ICB and advise accordingly.

Ensuring that PSIRF is central to overarching safety governance arrangements

HEFC ensures that PSIRF will be central to our incident reporting practice to ensure that our patient's safety is uppermost at all times. All incidents are discussed at monthly departmental meetings. All incident outcomes are reported through our continual improvement log and monitored via our Quality Management System to ensure outcomes and actions are discussed.

13 References

NHS England (2021) Core20PLUS5: An Approach to Reducing Health Inequalities

core20plus5-online-engage-survey-supporting-document-v1.pdf (england.nhs.uk)

NHS England (2022) Patient safety incident response standards

B1465-5.-Patient-Safety-Incident-Response-standards-v1-FINAL.pdf (england.nhs.uk)

NHS England (2022) Safety action development guide

https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-Safety-action-development-v1.1.pdf