Patient Safety & Incident Response Policy

1. Purpose

This policy supports the requirements of the Patient Safety Incident Response Framework (PSIRF) and sets out CES Medical Ltd 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 should be read in conjunction with our current

- Risk Management Policy
- Health and Safety

- Complaints Policy
- Safeguarding
- Raising Concerns Policy (Freedom to Speak-up)

2. Scope

This policy is specific to patient safety incident responses conducted solely for the purpose of learning and improvement across CES Medical Ltd.

Outside of the scope of the PSIRF policy are:

- Complaints
- Human resources investigations
- Professional standards investigations
- Criminal investigations
- Claims management
- Financial investigations and audits
- Safeguarding concerns
- Information governance concerns

Refer to other incident reporting and response guidance as required.

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.

3. Oversight roles and responsibilities

The below describes our organisational roles and responsibilities in accordance with the Patient Safety Incident Response Framework B1465-4.-Oversight-roles-and-responsibilities-specification-v1-FINAL.pdf

Board/The Executive Group
The CES Medical Ltd Board is responsible for identifying executive lead(s) for PSIRF (Clinical Operations Manager) who will:

- Ensure the organisation meets national patient safety incident response standards
- Ensure PSIRF is central to overarching safety governance arrangements
- Quality assure learning response outputs with full PSIIs shared at Board

Executive Leads
The Managing Director is the designated executive lead to support PSIRF. The Director will provide direct leadership, advice, support in complex/ high profile cases, and liaise with external bodies, as required, in collaboration with the Clinical Lead.

Managing Director (CEO)
The Managing Director has overall responsibility, on behalf of the CES Medical Ltd, for ensuring the implementation of this policy throughout the organisation.

Clinical Governance
The Board has delegated responsibility for Clinical Governance to the Clinical Operations Manager. An assessment of governance arrangements and compliance with CQC standards is included in the annual business planning process.

This role is also responsible for;

- Overseeing changes in legislation and ensuring these are adopted within the organisation
- Receive and respond to safety alerts / patient safety incidents within the specified timescales, and disseminate where appropriate.
- Ensuring clinical audits are taken in accordance with the audit schedule, learning is identified and action plans are put in place (where required).
- Ensuring clinical governance meetings are held monthly and outcomes are fed into both the Board and into local staff meetings.
- First point of contact for department staff, corporate specialists, central governance departments, and organisation-wide specialist committees for governance communications covering multiple specialist roles or when the designated lead is absent.
- Ensure that healthcare governance communication is locally disseminated to relevant staff, and that they are consulted about changes to governance systems and documents.
- Ensure that serious departmental issues are rapidly brought to the attention of the relevant /department lead, corporate lead central department, and to any relevant colleagues.
- Ensure that agreed changes to governance systems, policies and protocols are implemented across the organisation and any issues are fed back.
- Participate in surveys, audits and inspections to test local governance processes and provide evidence of compliance with standards when required.
- Ensure that local systems are in place to review and update clinical guidelines and governance protocols produced by the organisation.

- Support and advise governance leads as appropriate and ensure relevant information and data is reported to the Clinical Governance Meeting and CES Oversight Committee.
- Provide assurance on the robustness of incident reporting frameworks and procedures, as well as improvement action plans into the Clinical Governance Meeting and CES Clinical Oversight Committee.
- Support local service improvement and quality improvement projects and apply appropriate governance processes e.g. risk assessment when required.

Clinical Lead

- Oversee investigations being undertaken, and ensure that action plans are produced (where required) and the recommendations enacted in practice.
- Advise on education and training for staff in response to incidents.
- Ensure that any risks identified through patient safety incidents are assessed and, where appropriate, entered onto the organisational Risk Register.
- Disseminate the results of incidents and investigations appropriately within the and in the wider organisation where appropriate.

Operational Leads / Managers

- ensure that reporting procedures are complied with in the event of any incident affecting any service user, member of staff, or premises for which they are responsible
- offer support to staff as soon as possible after an incident has occurred
- ensure that staff are given the opportunity to access the Occupational Health Service for services such as support, physical investigation or counselling with reference to the Guidance on the Support of Staff Affected by Incidents, Complaints or Claims
- undertake initial review of the incident report, ensuring the grading is accurate, that the Duty of Candour has been considered and undertake any initial investigations and take remedial actions as required
- inform the team members when incidents occur involving people on their caseloads. Staff returning from long-term absence or a member of staff returning from extended leave should be informed when appropriate
- provide support and information to any investigation as required
- provide the opportunity for staff to receive feedback on specific incidents and ensure a system for the dissemination of lessons learned from incidents
- provide an opportunity for staff to meet to discuss incidents, soon after the event
- ensure that the outcomes and learning from all incidents are shared across their teams / services.
- Undertake any after action reviews agreed at the Incident Triage and Response Call, ensuring full engagement with patients, families and carers where appropriate

All staff

- are responsible for reporting incidents in accordance with this policy and co-operating where appropriate in any subsequent investigation. Staff should ensure any requests for information or additions to the incident form are completed as soon as possible to allow any investigations / triage to proceed without delay.
- to complete memory capture forms / Record of Post Incident Debrief where required
- who are concerned about the delivery of care/service to patients have a duty to express their concerns as outlined within the Freedom to Speak Up Policy (Whistleblowing) and complete an incident form
- take care of their own safety and that of people using Organisation services, colleagues and others on Organisation premises in line with organisation policies
- comply fully with the Duty of Candour requirements, ensuring all information is added appropriately to the Duty of Candour section of patient records

4. Our patient safety culture

Research into organisational safety has repeatedly found that an open and transparent culture, where colleagues feel able to report incidents and raise concerns without fear of blame, is essential to improving safety. Psychological safety underpins openness and transparency, and we actively encourage and support incident reporting and raising concerns where any member of staff feels something has happened, or may happen, which has led to, or may lead to, harm to patients (or staff).

At CES Medical Ltd, we promote an open culture, in line with the NHS Just Culture Guide to any work planned or underway to improve safety culture. Leadership is a key influencer of safety culture and leaders across CES Medical Ltd proactively embrace this approach. Support from trade union colleagues is instrumental in supporting the organisation transition to a just culture.

The goals of just culture include:

- A balance of fairness, learning and accountability (individual and organisational)
- Moral engagement
- Reintegration of the practitioner

We are clear that patient safety event responses should be conducted for the sole purpose of learning and identifying system wide improvements; they are not to apportion blame, liability or define preventability or cause of death.

The PSIRF will create stronger links between patient safety events and learning for improvement. We will work collaboratively with those affected including patients and their families, and our colleagues. This will continue to increase transparency and openness amongst our colleagues to report events and allow for wider engagement.

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.

5. Patient safety partners

Patient Safety Partners (PSP) have a vital role in supporting our response to incidents and service improvements by providing a patient perspective for developments and innovations to drive continuous improvement.

At CES Medical Ltd, we aim by January 2026 to have in place, PSPs who 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 with staff, volunteers and patients, attend meetings (face-to-face and online), be involved in future projects to co-design developments of patient safety initiatives, and join (and participate in) key conversations and meetings, focusing on patient safety. They will assist in the formulation of improvement outcomes, representing the patient, carer, family views.

PSPs will undertake the mandatory Patient Safety training modules accessible and will be supported by the Governance Lead. Each PSP will bring their own experience and expertise to contribute to patient safety responses and will be encouraged to present their ideas and solutions with equal merit.

PSPs will be invited to share their findings and views and have some oversight of recommendations and actions implemented following the conclusion of an incident response.

The PSP role will be reviewed annually to ensure the role is aligned to the patient safety agenda as it continues to develop and to ensure representation from the diverse communities we serve, including population groups who may sometimes experience challenges in accessing our services.

6. Addressing health inequalities

We have a duty to reduce inequalities in health by improving access to services and tailoring those around the needs of the local population in an inclusive way. CES Medical Ltd has a key role to play in tackling health inequalities in partnership with our local partner agencies and services.

However, most of the major factors driving inequalities in health are beyond the responsibility of the health care system alone and are driven by several socio-economic factors. We recognise there are areas within our region that have high levels ethnicity diversity and of deprivation. The all-inclusive, joined approach to patient safety under the PSIRF will require us to be more collaborative with the patient experience and inclusivity agenda and ensure investigations and learning do not overlook these important aspects of the wider health and society agenda.

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. We will use data captured by our Electronic Patient Care Records (EPcR) and the Mentor/HSE incident reporting system intelligently to assess actual and potential health inequalities and safety risks to patients from across the range of protected characteristics. We 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.

Additionally, CES Medical Ltd will record patient safety events on the National system 'The Learn from Patient Safety Events (LFPSE) NHS England » Learn from patient safety events (LFPSE) service from October 2025 once staff have completed training on the system. The policy will be revised to account for this practice.

Our engagement with patients, families and carers following a patient safety investigation must also recognise diverse needs and ensure inclusivity for all. Any potential inclusivity or diversity issues will be identified through the investigation process and engagement with patients and families, for example, during the duty of candour / being open process. We will use easy read, translation, and interpretation services alongside any other method appropriate to meet their needs and maximise the potential of being involved.

We will continue to address health inequalities in our safety improvement work. We will include Patient Safety Specialists and Patient Safety Partners in future policy and plan development to ensure inequality identified from our patient safety data is considered as part of the development process. We will make recommendations to the Board and partner agencies to try and reduce the negative impacts on patients due to such inequalities.

We strive to improve the service we provide for our local community and provide better working environments, free of discrimination. We endorse zero tolerance of racism, discrimination, and unacceptable behaviours from and towards our people, our patients, carers, and families.

7. 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.

CES Medical Ltd are committed to continuous improvement for the services we provide, and we will be open and transparent regardless of the level of harm caused by an event as we endeavour to learn from any event where care does not go as planned or expected by our people, patients, their families, carers, and other organisations.

Patients and families involved in patient safety events will be treated with respect, compassion, and dignity at all times. Their needs will be prioritised and respected and the organisation will ensure full details of the patient safety incident are shared.

Support to patients and families will be led by a designated Service Lead who will be a single point of contact for the patient and/or family. Service Leads will understand that all patient safety incident responses are different, and will be flexible to adapt to individual needs.

We recognise colleagues can also be affected by their involvement in an incident, and that this can have an impact on staff retention and performance, and therefore patient care. We offer colleagues support when they are involved in a patient safety event. Colleagues are encouraged to access their dedicated mental wellbeing support where there are a range of guides and supportive resources via the mental help careline.

Staff members involved in patient safety events will be appropriately supported to share their experience without fear of retribution or blame being apportioned. Staff will also be provided with additional support such as access to the NHS Talking Therapies service and Benenden Healthcare Mental Health Helpline (as part of contractual benefits) and given opportunities to discuss and debrief following a patient safety incident.

If a staff member feels under-supported and that they have been treated unfairly, they should speak to their direct line manager in the first instance. If this does not resolve the issue, staff will be encouraged to contact the HR Team.

Our Clinical Operations Manager will support those involved in patient safety incident investigations (PSII) guiding our colleagues, patients, and their families through our patient safety learning responses to conclusion.

The investigation process should be a collaborative and open process with all those involved being provided with opportunity to be listened to and share their experience. Service Leads will support and guide patients, families and staff through the patient safety learning response process and ensure those involved are treated fairly with each person's contribution having equal importance.

6.1 Complaints

Patients and carers are also signposted to CES Medical Ltd Complaints and Concerns Procedure which is also available to patients and carers to report any concerns or issues.

The organisation will act on these concerns as outlined in our Complaints policy and make improvements where appropriate.

6.2 Support

CES Medical Ltd recognises that patients and families may require other forms of support that can offer assistance and guidance to those affected by patient safety incidents. A list of sources is provided below which patients and families can be signposted to. (This is not an exhaustive list, and other providers may be available that patients or families may prefer to contact).

Learning from Deaths Information: https://www.england.nhs.uk/publication/learning-from-deaths-information-for-families/ - Provides an explanation of what happens after a bereavement (including when a death is referred to the coroner) and how families and carers should comment on care received.

Bereavement following Suicide - www.supportaftersuicide.org.uk Specifically for those bereaved by suicide, the Help is at Hand booklet offers practical support and guidance who have suffered loss in this way.

Mental Health Support - Resource Hub | Useful Mental Health Resources | MN Essex Mind- Support for people struggling with mental health issues.

Child Death Support - Child Bereavement UK (www.childbereavementuk.org) and The Lullaby Trust (www.lullabytrust.org) offer support and practical guidance for those who have lost at a child at any age.

Complaints Advocacy - www.voiceability.org - The NHS Complaints Advocacy Service can help navigate the complaints process, attend meetings, and review information provided during the complaints process.

Healthwatch – www.healthwatch.org - An independent statutory body that provides information to help make a complaint. Local lists in each area can be found on their website.

Parliamentary and Health Service Ombudsman (PHSO) – www.ombudsman.org.uk - The PHSO makes final decisions on complaints for patients and families when the resolution provided by NHS in England has not been deemed to be fair.

Citizens Advice Bureau – www.citizenadvice.org.uk - Provides UK citizens with information about healthcare rights, including how to make a complaint about care received.

8. 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.

We will explore all safety incidents, not just those that meet a defined threshold to determine a proportionate and compassionate response.

We will explore the insights from our safety data as well as the information available from the 'Learn from Patient Safety Events (LFPSE) system, to feed into our clinical governance forums to identify and act on areas requiring improvement.

Additionally, CES Medical Ltd are committed to ensuring our staff are appropriately trained in line with the PSIRF training standards.

Our leadership team are currently undergoing PSIRF training by a recognised provider as part of our transition period we will continue to provide training and clearly define what training should be carried out by which member of staff. This currently includes staff being trained in the system, The Learn from Patient Safety Events (LFPSE), which CES Medical Ltd intend to implement in October 2025.

Staff that are responsible for leading learning responses will have completed level 1 (essentials of patient safety **for all staff**) and level 2 (access to practice) of the patient safety syllabus and will contribute to a minimum of two learning responses per year.

The Patient Safety Team will support patient safety learning responses (including investigations and after actions reviews) and will provide advice on cross-system and cross-area working where this is required. We will utilise both internal and (where necessary) external subject matter experts with relevant experience, knowledge, and skills as well as information available such as reports and insight from the LFPSE system.

Responsibility for patient safety learning responses from our locally agreed priorities sits with the Clinical Operations Manager and Director who have an appropriate level of seniority to influence within the Company, this may depend on the nature and complexity of the patient safety event and the learning response required.

8.1 Our patient safety incident response plan

Our plan sets out how CES Medical Ltd intends to respond to patient safety incidents over a period of 12 to 24 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 PSIRP is based on a thorough analysis of themes and trends (including low harm, no harm and near misses), complaints and concerns, learning and recommendations from Serious Incidents (conducted under the previous framework), legal claims and inquests, risks and risk registers, Getting It Right First Time (GIRFT) outcomes and feedback from staff and patients.

The priorities identified in the PSIRP will be regularly reviewed against quality governance reports and surveillance to ensure they are responsive to unforeseen or emerging risks.

8.2 Reviewing our patient safety incident response policy and plan

Our patient safety incident response 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 (as agreed with our integrated care board (ICB)) 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

9. Responding to patient safety incidents

9.1 Patient safety incident reporting arrangements

It is recognised that staff must continue to feel supported and able to report any incidents, or concerns in relation to patient safety, to promote a system of continuous improvement and a just and open culture. We will continue to promote, support and encourage our colleagues and partners to report any incident or near-misses, with a shift in focus to incidents, or groups of incidents, which provide the greatest opportunities for learning and improvement.

9.2 Reporting of Incidents

All incidents should be reported in the Accident and Incident Log immediately or as soon as safe to do so, and from October 2025, patient safety events should be recorded on the The Learn from Patient Safety Events (LFPSE) system NHS England » Learn from patient safety events (LFPSE) service.

The reporter will record the level of harm (relating to physical and psychological) they believe to have been experienced by those affected, in accordance with the new PSIRF harm definitions referenced below.

Previous harm grades	New physical harm grades	New psychological harm grades

No Harm	No physical harm	No psychological harm
Low harm	Low physical harm	Low psychological harm
Moderate harm	Moderate physical harm	Moderate psychological harm
Severe harm	Severe physical harm	Severe psychological harm

Incident Report forms are the first step in reflection and learning that can lead to improvements in safety within the organisation. Details from these forms will be used to support safeguarding concerns, learning and investigations under the Patient Safety Incident Response Framework (PSIRF). Patient Safety Incident Response Framework.

The information reported on the incident form must be factual and accurate and should not include personal opinion or subjective judgement. This is a legal document and is disclosable in external processed i.e. coroners court, legal actions.

Incident forms must, wherever possible, be completed by the member of staff who first becomes aware of the incident and the incident number reference on the patient's record if appropriate.

There are times when a particularly sensitive incident regarding staff will need to be reported, in these cases the incident must be escalated immediately to the HR & Governance Lead.

Incident reporting is not intended to apportion blame but to enable understanding and learning to enable improvements in practice. Please also refer to the Freedom to Speak up (Whistleblowing) policy.

In rare cases disciplinary action may be required either within CES Medical Ltd processes or external bodies. These include instances of serious professional misconduct (as defined by the GMC, NMC and other professional bodies), reckless acts, criminal acts and repeated misdemeanours.

Staff who intentionally fail to report or delay the reporting of an incident may also face disciplinary action.

9.3 Incidents to Be Reported

Patient safety incidents are any unintended or unexpected events (including omissions) in healthcare that could have, or did, lead to harm for one or more patients involving the health, safety or welfare of patients, employees, visitors or other persons in contact with CES Medical Ltd services.

Examples of the types of incidents that should be reported are (but not exhaustive);

- Unexpected deaths or serious injuries
- Delays in care

- Incidents that indicate a risk of future harm
- Incidents that affect the quality of care
- Incidents that involve communication issues
- Incidents that involve ineffective teamwork
- Incidents that involve issues between different organizations
- Incidents that involve infection prevention and control

Reporting Incidents relating to medicines and medical devices
Suspected safety concerns relating to medicines, vaccines, medical devices and blood products must be on the organisations incident reporting system, and additionally reported to the Yellow Card Scheme http://yellowcard.mhra.gov.uk/.

The Health and Safety Responsible Person should also be informed of any incidents involving medical equipment and can advise on reporting requirements.

Health and Safety Incidents
Health and Safety incidents must also be reported via Mentor (such as RIDDOR), however incident reporting for accidents should be read in conjunction with the Health and Safety Policy.

RIDDOR
If someone has died or has been injured because of a work related accident, this may also require reporting under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR).

Examples of the types of incidents that should be reported are (but not exhaustive);

- Injuries at work
- Work related deaths
- Diseases
- Dangerous occurrences such as gas incidents

In these instances, the Health and Safety Responsible Person should be notified immediately.

Further details can be found Types of reportable incidents - HSE

Never Events
A Never Event is defined as a Serious Incident(s) that are wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers.

Never events include;

- Wrong site surgery
- Wrong implant / prosthesis
- Retained foreign object post procedures
- Mis selection of a strong potassium solution
- Administration of medication by the wrong route
- Overdose of insulin due to abbreviations or incorrect device
- Overdose of methotrexate for non-cancer treatment
- Mis-selection of high strength midazolam during conscious sedation
- Failure to install functional collapsible shower or curtain rails
- Falls from poorly restricted windows
- Chest or neck entrapment in bed rails
- Misplaced naso or oro-gastric tubes
- Transfusion or transplantation of ABO-incompatible blood components or organs
- Unintentional connection of a patient requiring oxygen to an air flow meter

Further information relating to these can be found on NHS England's website 2018-Never-Events-List-updated-February-2021.pdf

WHAT TO DO

9.2 Immediate response to the Incident

- The initial response to any incident must be to make the situation safe thus preventing further harm to people using the organisations services, visitors, staff and / or others.

- Immediate medical assistance must be requested where necessary. If appropriate the emergency services (Fire, Police, and Ambulance) must be contacted as per our Accident and Incident Management Policy.

- It is important to protect and support other service users, staff and visitors who may be present or in the vicinity of the incident. This support must be on-going.

- All information must be added to clinical records as soon as possible following an incident.

- The review should be an impartial factual review of incident to cover care and treatment provided in summary. If the incident involves a person who is no longer in the care of the organisation, all information will need to be added to the person's

clinical records, this will be completed by the manager of the team the person was last open to.

9.3 Preservation of Evidence

For incidents which involve medical devices do not disassemble, clean, decontaminate or alter control settings. Clearly identify defective items, isolate the equipment and contact the Health and Safety Manager See S09 Medical Devices Policy

In the case of a possible or actual criminal incident **no action must be taken to clean up an area until the Police have attended.** Any evidence must be preserved until the Scene of Crimes Officers have completed their investigation. However, if the safety of service users or staff is at risk reasonable precautions must be taken to remove the danger.

9.4 Incidents Reporting Harm to Staff

- All incidents reporting harm to staff must be reported on the Accident and Incident Log and identified as a staff incident. As with patient safety incidents, these must include racial, verbal and sexual incidents.

- If the incident being reported includes both harm to patient and staff, report according to the greatest level of harm and the incident form should include all people involved in the incident

- RIDDOR must be considered where there is a need for the staff member have sustained harm that necessitates time off work.

- Police contact should be considered when harm or threats of harm occur.

- All staff should be named in the incident for staff harm incidents.

- All staff harmed should be supported to seek medical support in a timely way using the most appropriate route, for example ambulance service in emergency.

- Where appropriate and as soon as possible, witnesses should be encouraged to document (written) the incident.

- Debrief and support should be offered to all who were involved and witnessed the incident. This can be organised in your local area by the HR Team.

- If an incident occurs that results in moderate and above harm to both staff and patient, a separate incident will need to be completed for both.

9.5 Duty of Candour (Being Open)

The Duty of Candour must be applied in all patient safety incidents with a outcome of moderate or above harm, or where the person has, or is likely to experience 28 consecutive days of psychological distress. In these situations, facts known at the time must be shared and support offered.

9.6 Incident Grading, and Escalation

Not all incidents need to be investigated to the same extent or depth. Categorising incidents according to the actual impact and the potential future risk to people using services, visitors, staff, others and the establishes the level of local investigation and causal analysis that should be carried out. Specific considerations apply to categorisation and severity grading of Information Governance incidents.

The Clinical Operations Manager is responsible for reviewing and grading the incident within 48 hours of the incident occurring, using the risk grading matrix which is included on the incident report form on the patient record.

The Patient Safety Team will review incidents to identify those that meet the criteria for further review/investigation under the Patient Safety Incident Review Framework.

During this review the requirement for the Duty of Candour is confirmed. If further information is needed to support decision making this will be identified, requested and then re-reviewed at the earliest opportunity; to ensure compliance with reporting timescales.

Where appropriate the Patient Safety Team will:

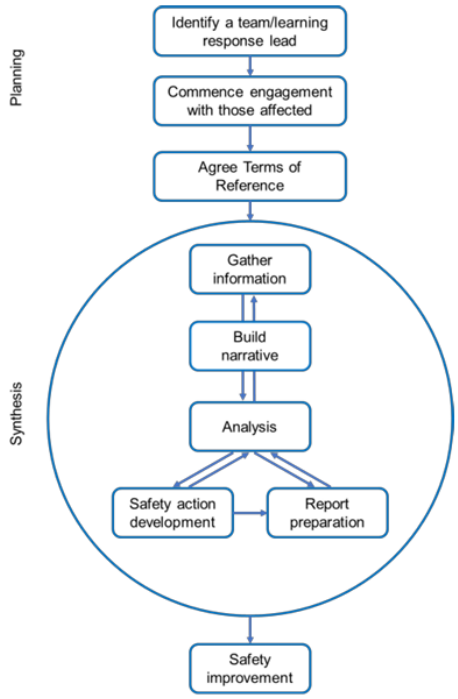
- Escalate any incidents of concern to the Managing Director and Clinical Lead (if appropriate)
- Work with the Clinical Lead to determine the nature and extent of the required communication with patients, relatives and staff and identify responsibilities of individual staff accordingly
- Report any significant event to the ICB in accordance with their Patient Safety Incident Reporting Policy
- Consider any reputational impact or need to address or prepare for media interest

9.7 Patient Safety Incident Investigations (PSII)

All incidents that meet the requirements a PSII will be subject to a full investigation.

An overview of the patient safety incident investigation process and the stages can be found here Patient Safety Incident Investigation (B1465-PSII-overview-v1-FINAL.pdf). A diagram of the stages has been provided below.

Figure 1: Overview of patient safety incident investigation stages



All incidents requiring a full investigation, will include an action plan which will link to the causative factors, human factors and recommendations identified during the investigation.

The clinicians and services involved in PSII are responsible for the development of the investigation action plans, The Clinical Operations Manager will provide the draft report including the action plan template and can facilitate this process but will not write the action plan.

Each action plan **must include** an identified action and management lead, agreed timescales for the completion of each action and details of the expected outcome from the action. Every action plan **must include** an action to provide feedback to the service users/families/carers that have been involved in the investigation review at an agreed time, normally on completion of the action plan or at an earlier time if the action plan has extended timescales.

Every action plan **must include** an action to for the final review of the action plan and all the supporting evidence for completed actions prior to the action plan being closed. This review should be completed by the senior leads identified on the action plan at the time of its development.

All reports will be reviewed and agreed by the Board

The action plans will be added to the original incident on the incident reporting system and will be reviewed routinely to ensure the timely closure of actions through local governance processes.

9.8 Ensuring Local Learning

The Patient Safety Incident Response Framework (PSIRF) sets out CES Medical Ltd 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. Please see the PSIRF section on the NHS England website for more information (NHS England » Patient Safety Incident Response Framework).

CES Medical Ltd will ensure learning responses are **not** led by staff who were involved in the patient safety incident itself or by those who directly manage those staff.

Those responsible for developing learning responses will be of an appropriate level of seniority and influence, mainly the Clinical Lead.

Learning responses are **not** undertaken by staff working in isolation and will be conducted via a team where possible.

Staff affected by patient safety incidents are given time and are supported to participate in learning responses.

Subject matter experts with relevant knowledge and skills will be involved, where necessary, throughout the learning response process to provide expertise (eg clinical or human factors review), advice and proofreading.

Oversight of incidents as well as their action plans and learning will be overseen by the Clinical Operations Manager and Governance Lead who will review / analyse any themes and trends relating to incidents, and potential for wider learning. Additionally, outcomes will also be shared with staff via supervision, within Clinical Governance Meetings, team meetings and staff newsletters.

CES Medical Ltd will use a range of information and intelligence to inform learning including information on patient safety incidents that have taken place in other similar settings, in order to inform clinical practice.

9.9 Support for Staff

Following an incident, the immediate needs of staff in relation to support and supervision should be taken into account, this should take into account both internal organisational staff and external staff who have been affected by the incident. Immediate supportive debriefing will be provided by a manager / senior health professional as part of the management of the incident; time should be given to allow people to talk through both the events that have occurred and the effect it has had upon them.

Formal debriefing will be arranged following an incident which has the potential to cause any on-going distress; any staff affected by the incident should be given the opportunity to attend; however, participation in this process is a matter of individual choice. Guidance on debriefing and contacts for facilitators is given on the organisation Intranet. A range of options are available for staff that may be affected by an incident (e.g. supervision and counselling) but colleagues, managers and staff may need to bridge a gap until more

structured / independent support mechanisms are in place. See Appendix 6 - Guidance on the Support of Staff Affected by Incidents, Complaints or Claims and Appendix 7 – Dealing With A Critical Incident.

Events and/or incidents highlighted that appear to meet requirements for reporting externally to national bodies such as Health Safety Investigation Branch (HSIB), Health & Safety Executive (HSE), Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) and Medicines and Healthcare products Regulatory Agency (MHRA) will be overseen by the Director and nominated Patient Safety Team.

It is recognised, there will be occasions where events require the efforts of cross-system working with relevant partners or their seriousness require escalation into the Integrated Care Board (ICB), where this is required the Managing Director will escalate and make contact as required.

9.10 Patient safety incident response decision-making

In the context of PSIRF (Patient Safety Incident Response Framework), a "proportionate approach" means responding to patient safety incidents with the appropriate level of investigation and action based on the severity of the incident and the potential for learning,

Key points about a proportionate approach in PSIRF:

- **Not all incidents require the same response:** Depending on the potential harm caused and the learning opportunity, some incidents might only need a brief review, while others might warrant a full investigation.
- **Focus on high-impact learning:** The aim is to prioritize learning from incidents that can significantly improve patient care, rather than spending excessive time on minor issues.
- **System-based analysis:** When investigating incidents, a proportionate approach considers the wider system factors contributing to the event, not just individual errors.
- **Resource efficiency:** By tailoring responses to the severity of incidents, organizations can allocate resources effectively.

The Patient Safety Team will hold a monthly meeting with service leads to review incidents and cross check and balance that the appropriate level of response has been enacted and to confirm those events that required a PSII, did meet the need for further exploration and investigation.

This group will have responsibility for the retrospective consideration of events for PSII (Patient Safety Incident Investigation) or a patient safety learning response for oversight of outcomes.

The Clinical Lead will hold overall oversight of such processes, allowing for challenge where required, to ensure the Board of Directors can be assured the true intent of PSIRF is being implemented across our organisation to ensure we are meeting to the national response standards. Quality assurance, oversight and sign-off of incident investigations and reviews will feature as a high priority risk on the risk register until PSIRF is fully embedded within the organisation and assurances learning responses result in the desired system improvements are evidenced.

The Patient Safety Team, with support from administrative colleagues, will also provide regular reports to governance forums to identify and track emerging themes and trends outside of normal variation.

9.11 Responding to cross-system incidents/issues

The Patient Safety Team will assist in the coordination of these events identified to other providers directly, via each organisations reporting processes. We will work with partner providers and relevant ICBs to establish and maintain robust procedures to facilitate flow of information and minimise delays to joint working on cross-system events.

If a complex cross-system event is identified, we will refer to ICBs to assist with the co-ordination. We anticipate the ICB will provide support and advice with identifying a suitable reviewer, should this circumstance arise.

10. Learning

10.1 Timeframes for learning responses

When an incident has been reported on the Accident and Incident Log, this will be assigned to the most appropriate Manager or Lead of that service/department by the Patient Safety Team this will be done within 3 days.

Timeframe for completion will be agreed with those affected, as part of setting the terms of reference; this remains subject to them willing and able to be involved in that decision.

- Where a full PSII is indicated, this will be started within 7 days following the identification and completed within 60 days.

- Locally led PSII involving partner organisations should not exceed six months in duration.

- Locally led responses that are taking more than 6 months or exceeding timeframes set with those affected will be reviewed to understand how timeliness can be improved.

- Where external bodies (or those affected by patient safety incidents) cannot provide information; to enable completion within six months or the agreed timeframe, we will work with all the information they have to complete the response to the best of their ability.

- We will consider whether new information would indicate the need for further review once this is received.

There may be occasions where a longer timeframe is required for completion, in this case, all extended timeframes will be agreed between CES Medical Ltd and those affected.

10.2 Safety action development and monitoring improvement

CES Medical Ltd use the principles outlined in the NHS England Safety Action Development Guide (2022) to develop our safety actions. We have systems and processes in place to design, implement and monitor safety actions using an integrated approach of reducing risk and limit the potential for future harm.

All action plans must be developed with and agreed by the staff that will implement the change. Safety actions arising from learning responses must incorporate means of monitoring completion and sustained effectiveness.

Action plans should:

- Follow SMART (Specific, Measurable, Achievable, Realistic, Time-bound) principles and have designated owners to monitor and measure of success.
- Be concise, consisting of a small number of action points that have been prioritised based on impact.
- Agree areas for improvement: specify where improvement is needed, without defining solutions.
- Define safety actions to address areas of improvement focuses on systems in collaboration with those teams involved.
- Define safety measures to demonstrate if actions are influencing what is intended.
- Allow staff to focus resource on those actions that are likely to result in sustained beneficial change.

The Patient Safety Team will be available to assist with the improvement plan development stage to help support defining and implementing impactful and informed change ensuring the issues raised have been fully explored. Improvement plans will be centrally documented on Mentor.

10.3 Safety action monitoring

Each planned response detailed in our PSIRP will have defined improvement routes and oversight. Safety actions must continue to be monitored within service lines governance arrangements to ensure any actions put in place remain impactful and sustainable.

Monitoring of completion and effectiveness of safety actions will be conducted through our Clinical Governance Meetings.

We recognise 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.

10.4 Safety improvement plans

Safety improvement plans will bring together findings from various responses to patient safety events and issues.

Each theme will be developed due to the opportunity they offer for learning an improvement across areas where there is no existing plan or where improvement efforts have not been accompanied by a reduction in risk or harm. Each theme will have its own improvement plan.

A Quality Improvement (QI) approach is valuable in this aspect of learning and improvement following a patient safety investigation. To achieve successful improvement, safety action development will be completed in a collaborative way.

We will develop governance systems focused more on measuring and monitoring these outcomes, utilising subjective as well as objective measures. Rather than reporting on action plan completion, we are more focused on measuring and monitoring outcomes.

The development of these outcome measures will be defined over the first 12 months of our plan. We will continue to use the outcomes from patient safety reviews and any relevant learning response conducted under PSIRF to refine and create related improvement plans to assist focus on our improvement work.

11. Audit

As part of our auditing schedule and audit policy, 3 cases will be reviewed and audited every 6 months to ensure the policy is being applied effectively and understand the effectiveness of the investigation practices being applied.

Audits will also look at audit outcomes, safety improvement action plans and learning to see how these have been implemented and embedded within the service.

12. Complaints and appeals

CES Medical Ltd recognise that there will be occasions when patients, services users and carers are dissatisfied with the aspects of care and services provided by the organisation. If patients, relatives and or carers have a concern or complaint in relation to how a patient safety learning response has or is being handled, they will be directed towards CES Medical Ltd Patient Experience Policy.

Every effort will be made to address specific concerns and are committed to dealing with any complaints that may arise quickly and as effectively as possible as set out in the NHS Complaint Standards (2021).

CES Medical Ltd promote a culture that seeks to learn from complaints, treats people fairly, and works to resolve problems in a timely way. Complaints will be handled respectfully ensuring that all parties concerned feel involved in the process and assured that the issues raised have been comprehensively reviewed and the outcomes shared in an open and honest manner.

Patients and families can also be directed to the resources below if further resolution outside of the organisation if required, such as:

- Health Service Ombudsman
- Health Watch
- ICB
- CQC

13. Dissemination

CES Medical Ltd will disseminate the policy and associated documents through the following channels;

- Information cascade via relevant management teams
- Communication via Management/Departmental/Team meetings
- Inclusion of relevant information in local briefings
- Digital - SharePoint administration

The responsibility of implementing this document, including training and other needs that arise shall remain with Managing Director. Line managers have the responsibility to cascade information on new and revised policies/procedures and other relevant documents to the staff for which they manage.

Line managers must ensure that departmental systems are in place to enable staff including agency staff to access relevant policies, procedures, guidelines, and protocols and to remain

up to date with the content of new and revised policies, procedures, guidelines, and protocols.

The document will be displayed on SharePoint.

14. Definitions

Term	Definition/explanation
Patient Safety Audit (PSA)	A review of a series of cases (of the same incident type) using clinical audit methodology to identify where there is an opportunity to improve and more consistently achieve the required standards (e.g., in a policy or guideline)
Patient Safety Incidents (PSIs)	Patient safety incidents are unintended or unexpected events (including omissions) in healthcare that could have or did harm one or more patients.
Patient Safety Incident Investigation (PSII)	PSIIs are conducted to identify underlying system factors that contributed to an incident. These findings are then used to identify effective, sustainable improvements by combining learning across multiple patient safety incident investigations and other responses into a similar incident type. Recommendations and improvement plans are then designed to effectively and sustainably address those system factors and help deliver safer care for our patients.
Patient Safety Incident Response Framework (PSIRF)	This is a national framework applicable to all NHS commissioned outside of primary care. Building on evidence gathered and wider industry best-practice, the PSIRF is designed to enable a risk-based approach to responding to patient safety incidents, prioritising support for those affected, effectively analysing incidents, and sustainably reducing future risk.
Patient Safety Incident Response Plan	Our local plan sets out how we will carry out the PSIRF locally including our list of local priorities. These have been developed through a coproduction approach with the divisions and specialist risk leads supported by analysis of local data.
Patient safety	PSPs are patients, carers, family members or other lay people

partners (PSPs)	(including NHS staff from another organisation working in a lay capacity) who are recruited to work in partnership with staff to influence and improve the governance and leadership of safety within an NHS organisation.
Proportionate Approach	In the context of PSIRF (Patient Safety Incident Response Framework), a "proportionate approach" means responding to patient safety incidents with the appropriate level of investigation and action based on the severity of the incident and the potential for learning, essentially not overreacting to minor incidents while ensuring serious ones are thoroughly examined and addressed; it prioritizes allocating resources where they will have the most impact on improving patient safety.
Safety Improvement Plan	A safety improvement plan in the NHS is a structured approach to improving patient safety and reducing harm

15. Appendix – Equality Impact Assessment

EQUALITY IMPACT ASSESSMENT

The Equality Analysis (EA) form should be completed in the following circumstances:

- All new policies
- All policies subject to renewal
- Business cases submitted for approval to hospital management impacting service users or staff
- Papers submitted to hospital management detailing service redesign/reviews impacting on service users or staff
- Papers submitted to Board of Directors for approval that have any impact on service users or staff

Name of Policy, Service, Function, Project or Proposal	**Patient Experience Policy**
Lead Assessor	Elion Hyseni
Date Completed	29/04/2025
What is being assessed? Please provide a brief overview.	Patient safety procedures and policy applicable to the provision of CESM services.

Who will be affected (staff, patients, community)	Staff, patients

Section 1 should be completed to analyse whether any aspect of your proposal/document has any impact (positive, negative or neutral) on groups from any of the protected characteristics listed overleaf. When considering any potential impact you should use available data to inform your analysis such as complaints data, Patient or Staff satisfaction surveys, local consultations or direct engagement activity. You should also consult available published research to support your analysis.

Section 1 – Analysis

What is the impact on the equality groups below? Rationale / Detail		
Positive: • Advance equality of opportunity • Foster good relations between different groups • Address explicit needs of equality target groups	• Negative: • Unlawful discrimination, harassment and victimization • Failure to address explicit needs of equality target groups	• Neutral: • It is quite acceptable for the assessment to come out as Neutral impact • Be sure you can justify this decision with clear reasons and evidence if you are challenged

Equality Group	Any Potential Impact? Positive, negative or neutral.	Rationale / Detail
Race	Neutral	There is no negative impact on this equality group in relation to this policy.
Religion or belief	Neutral	There is no negative impact on this equality group in relation to this policy.
Disabled people (including physical and mental health impairment)	Neutral	There is no negative impact on this equality group in relation to this policy.
Sexual orientation	Neutral	There is no negative impact on this equality group in relation to this policy.
Age (young people, older adults)	Neutral	There is no negative impact on this equality group in relation to this policy.
Pregnancy and maternity	Neutral	There is no negative impact on this equality group in relation to this policy.
Gender	Neutral	There is no negative impact on this equality group in relation to this policy.
Gender Reassignment	Neutral	There is no negative impact on this equality group in relation to this policy.
Human Rights	Neutral	There is no negative impact on this equality group in relation to this policy.
Other, e.g. carers	Neutral	There is no negative impact on this equality group in relation to this policy.
Any other group (please detail)		

If you have identified any negative impact, you should consider whether you can make any changes immediately to minimise any risk. This should be clearly documented on your paper cover sheet/policy document detailing what the negative impact is and what changes have been made.

If you have identified any negative impact that has a high risk of adversely affecting any groups defined as having a protected characteristic, then please continue to section 2. In all cases, you should submit this document with your paper and / or policy in accordance with the governance structure with copies to the HR and Operations Team.

If you have identified that there are potentially detrimental effects on certain protected groups, you need to consult with staff, representative bodies, local interest groups and customers that belong to these groups to analyse the effect of this impact and how it can be negated or minimised. There may also be published information available which will help with your analysis.

Section 2 – Full Analysis

Who and how have you engaged to gather evidence to complete your full analysis?	What are the outcomes?	What is your overall analysis based on your engagement activity?
Hr, Clinical Lead and Operations Teams have been consulted.	There is no negative impact on any equality group in relation to this policy.	Minimum risk if applied according to policy guidelines.

Section 3 – Action Plan

You should detail any actions arising from your full analysis in the following table; all actions should be added to the risk register for monitoring.

Issue	Lead	Action Required	How will you measure outcomes?

16. Appendix One – A Just Culture

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

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