1. Introduction

This policy supports the requirements of the NHS Patient Safety Incident Response Framework (PSIRF) and sets out Bourn Hall Clinics approach to developing and maintaining effective systems and processes for responding to NHS patient safety incidents and issues for the purpose of learning and improving patient safety.
As Bourn Hall Clinic is a small provider, we have incorporated our plan as part of this policy document.

2. Purpose

The PSIRF advocates a co-ordinated and data-driven response to NHS 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.

The PSIRF will focus on enabling and monitoring improvement in the safety of care, not simply monitoring investigation quality.

Oversight should ensure learning focuses on identifying the system factors that contribute to patient safety incidents, not finding individuals to blame.

Responding to a patient safety incident for learning is an active strategy towards continuous improvement, not a reflection of an organisation having done something wrong.

A meaningful approach to oversight cannot be developed and maintained by individuals or organisations working in isolation – it must be done collaboratively.

Oversight requires a climate of openness to encourage consideration of different perspectives, discussion around weaknesses and a willingness to suggest solutions.

3. Scope

Patient safety incidents are any unintended or unexpected incident which could have, or did, lead to harm for one or more patient's receiving healthcare. Reporting them supports Bourn Hall Clinic and the NHS to learn from mistakes and to take action to keep patients safe.

This policy is specific to patient safety incident responses conducted solely for the purpose of learning and improvement across all treatment provided to NHS patients treated at all Bourn Hall Clinics. Treatments provided include In Vitro Fertilisation (IVF), Intra-cytoplasmic Sperm Injection (ICSI), Donor insemination, Egg donation.

This policy follows a systems-based approach.
Patient safety incidents 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, in a patient safety investigation conducted, it is for the purpose of learning and improvement.

Staff have a right, and a duty, to raise any matters of concern they may have about patient safety within the organisation relating to the delivery of care. This is detailed in Bourn Hall Clinics freedom of speech procedure (HR020).

Other processes, such as claims handling, human resources investigations into employment concerns, professional standards investigations, exist for that purpose, and are outside the scope of this policy.

Bourn Halls process for investigating and reporting patient safety incidents is included in QA023.
Duty of Candour is detailed in HR019.

4. Policy Statement

Bourn Hall Clinic have an internal process that details what staff should do in the event of discovering an incident, safeguarding issue etc. All incidents whether relating to patient safety or not are initially reported in the same way and can be reported by any member of staff.

All staff are encouraged to report an incident, relevant members of staff including quality assurance staff will work together to identify what happened, why the incident occurred and to identify where improvements can be made.

If the incident is a patient safety incident, the patient will be contacted and invited to discuss the incident and any concerns the patients may have.

Once the investigations are complete and reported all involved in the investigation will receive a copy of the report.

Any learning outcomes identified through the process are shared with the Bourn Hall group.

There are already requirements to report some incidents to regulatory bodies for example the HFEA (Human Fertilisation and Embryology Authority), CQC (Care Quality Commission), ICO (Information Commissioners Office). The methods for investigating and reporting are included in Bourn Halls policies.

Bourn Hall Clinic promotes a culture that encourages candour, openness, and honesty at all levels.

This is an integral part of a culture of safety that supports organisational and personal learning.

The HFEA and CQC review all Bourn Halls incidents as part of their inspection process.

4.1 Bourn Halls patient safety incident response plan

Our plan sets out how Bourn Hall Clinic intends to respond to patient safety incidents over a period of 12 to 18 months. The plan is not a permanent set of rules that cannot be changed. We will remain flexible and consider the specific circumstances in which each patient safety incident occurred and the needs of those affected, as well as the plan.

Staff members from different departments, within all three Bourn Hall Clinics, including Quality Assurance, Nursing, Medical, Embryology, Patient Services and Directors were involved in the collaborative review of all incidents, complaints, claims and patient feedback between 2020 and 2023. The review concluded that over the four years there were 6 incidents that would constitute a Patient Safety Incident. None of these 6 were relating to NHS patients.
A review of previous NHS never events were also carried out to determine what would be applicable to Bourn Hall Clinic.

Following the review and consideration of the NHS National Event response requirements there was a collaborative decision made that the following would initiate a Patient Safety Incident Investigation (PSII) and would require investigation, engagement, reporting and learning outcomes:

- Breach of confidentiality (only if reportable to the ICO).
- Severe OHSS (Ovarian Hyperstimulation Syndrome).
- Ovarian torsion.
- Retained foreign object post procedure.

- Administration of medication by the wrong route.
- Safeguarding concern.

4.2 Learning response methods

Patient Safety Incident Investigation (PSII) - A PSII is undertaken when an incident or near miss indicates significant patient safety risks and potential for new learning. It offers an in-depth review of a single patient safety incident or cluster of incidents to understand what happened and how. Investigations explore decisions or actions as they relate to the situation and the goal is to understand why an action and / or decision was deemed appropriate by those involved at the time.

Multidisciplinary Team (MDT) review - An MDT review supports staff to learn from patient safety incidents that have occurred. The aim is, through open discussion to agree the key contributory factors and system gaps that impact on safe patient care.

Swarm Huddle - A facilitated structured debrief, held immediately or within 24hrs of an incident. All those involved in the event gather to quickly analyse what happened, how it happened and what needs to be done next to reduce the risks of a repeat event occurring.

After Action Review (AAR) - A facilitated structured debrief, held within 3 – 5 days of an incident. The review endeavours to: 1. create a common understanding of the event, 2. reflect on successes and failures, 3. identify specific recommendations and agree group safety actions, 4. how lessons will be shared with each clinic.

4.3 Patient safety incident reporting arrangements

Reporting is described in Bourn Hall SOP QA023.

4.4 Timeframes for learning responses

A response must start as soon as possible after an incident is identified and will be completed within one to three months.
The timeframe for completing a PSII (Patient Safety Incident Investigation) will be agreed with those affected by the incident, as part of setting the terms of reference for the PSII, provided they are willing and able to be involved in that decision. PSIIs should take no longer than six months.

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

Learning and improvement following a patient safety incident can only be achieved if supportive systems and processes are in place. The PSIRF 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.

Obligations relevant to the Duty of Candour are upheld. Those affected by patient safety incidents should be:

- Fully informed about what happened.
- Given the opportunity to provide their perspective on what happened.
- Communicated with in a way that takes account of their needs.
- Given an opportunity to raise questions about what happened and to have these answered openly and honestly.
- Helped to access counselling or therapy where needed.
- Given the opportunity to receive information from the outset on whether there will be a specific learning response and what to expect from the process.
- Signposted to where they can obtain specialist advice and / or advocacy and / or support from independent organisations regarding learning response processes.

4.6 Patient safety partners

The role of a Patient Safety Partner is to enable the trust to value, listen and provide meaningful involvement opportunities for patients and families in the ongoing patient safety work of the organisation. This role is currently being recruited for.

4.7 Addressing health inequalities

Through implementation of PSIRF, we will seek to utilise data and learning from investigations to identify actual and potential health inequalities and make recommendations on how to tackle these. This holistic, integrated approach to patient safety under PSIRF will require the Bourn Hall Clinic to continue to be collaborative with the patient experience and inclusivity agenda and ensure investigations and learning do not overlook these important aspects of the wider health and societal agenda. Our engagement with patients, families and carers following a patient safety investigation will 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.

4.8 Resources and training to support patient safety incident response

There are defined PSIRF leads at Bourn Hall Clinic who are trained in the framework and how to investigate patient safety incidents. All other staff have received basic PSIRF training. All staff have been provided with dedicated time to enable full investigation and thorough response and collaboration with other staff and patients.

The PSIRF / learning response leads will review and monitor any patient safety incidents annually and will report to senior management at the management review meetings including any learning outcomes.

Learning responses are led by those with formal training and skills development in learning from patient safety incidents and experience of patient safety incident response.

Learning response leads undertake continuous professional development in incident response skills and knowledge, and network with other leads at least annually to build and maintain their expertise.

4.9 Learning response training

Learning responses are led by those with at least two days' formal training and skills development in learning from patient safety incidents and experience of patient safety incident response.

Learning response leads will have completed level 1 (essentials of patient safety) and level 2 (access to practice) of the patient safety syllabus.

4.10 Patient safety improvement

Bourn Hall Clinic are committed to patient safety. All incidents, patient feedback, complaints and any claims are reviewed by multidisciplinary teams, and there are opportunities where trends and analysis of incidents, patient feedback, complaints and claims occur with the aim to prevent further incidents including learning from and improving our processes. Bourn Hall Clinic have ISO 9001:2015 certification and we adhere to this standard by continually monitoring and improving.

As part of improvement Bourn Hall Clinic also review the positive feedback and where things have gone well at various forums to ensure we maintain this good level of care and service to our patients. Any positive feedback is relayed to the staff / departments mentioned, any positive feedback is good for staff morale and also contributes to enhancing the quality of care.

4.11 Reviewing our patient safety incident response policy and plan

This policy will be reviewed on an annual basis in line with our standard procedures for review of Bourn Hall Clinic documents.
Our patient safety incident response plan within this policy 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 months to ensure our focus remains up to date; with ongoing improvement work our patient safety incident profile can change. This will also provide an opportunity to re-engage with stakeholders to discuss and agree any changes made in the previous 12 months.

The updated plan 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 boards (ICBs)) 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, and a review of patient safety incident investigations (PSII).

4.12 Patient safety incident reporting arrangements

Reporting is described in Bourn Hall SOP QA023. In summary all patient safety incidents are reported internally and then externally to the NHS and the HFEA / CQC where applicable.

4.13 Patient safety incident reporting decision-making

Reporting of incidents will continue in line with existing Bourn Hall Clinic procedures. Bourn Hall Clinic has governance and assurance systems in place to ensure oversight of incidents at all levels. Quality Assurance teams work with staff to ensure the following arrangements are in place:

- Identification and escalation of any incidents that have or may have caused significant harm.
- Identification of themes, trends or clusters of incidents relating to specific types of incidents.
- Identification of any incidents requiring external reporting (e.g. – Never Events).
- Identification of any other incidents of concern, such as serious near-misses or significant failures in established safety procedures.

4.14 Responding to cross-system incidents/issues

Due to there being no patient safety incidents in the last four years, if there is a cross organisational incident, the incident will be discussed between Bourn Hall Clinic PSIRF leads and the relevant ICB on a case by case basis and agreed at the time in writing.

4.15 Timeframes for learning responses

A response must start as soon as possible after an incident is identified and will be completed within one to three months.
The timeframe for completing a PSII (Patient Safety Incident Investigation) will be agreed with those affected by the incident, as part of setting the terms of reference for the PSII, provided they are willing and able to be involved in that decision. PSIIs should take no longer than six months.

4.16 Safety action development and monitoring improvement

This is detailed in Bourn Hall procedures SOP QA023. In summary safety actions are identified and actioned within agreed timelines. Once implemented these actions are reviewed to determine their effectiveness.

4.17 Safety improvement plans

Patient safety will be reviewed at annual management review meetings and more often if deemed necessary to ensure that what is learned from patient safety incidents can be shared across the organisation as a whole where necessary.

It is the intention that safety improvement plans will be developed to include the safety actions from learning responses which are useful for Bourn Hall Clinic to make positive changes for patient safety.

4.18 Oversight roles and responsibilities

All patient safety incidents and any other incidents / nonconformities are monitored by the Quality Assurance department, the patient safety incident response plan, delivery of safety actions and improvement are reviewed by Bourn Hall Clinic PSIRF Leads and senior management including Directors at the annual management review meetings.
The following will be reviewed as part of the review of the Patient Safety Incident Response plan; Engagement and involvement of those affected by patient safety incidents, Policy, planning and governance, Competence and capacity, Proportionate responses, Safety actions and improvement. Updates to the policy and plan will be made as required.

The outcome of these meetings are disseminated to all staff to ensure all are aware.

Learning outcomes and improvements are reviewed and are shared with our regulatory bodies and the ICBs as required.

4.19 Complaints

All patients receive or have access to Bourn Hall Clinics complaints policy and any concerns can be put in writing.

All concerns will be investigated and may involve discussions with the patient to ensure resolution is achieved and improvements are identified and acted upon.

All patients receive an outcome letter including details of investigations and any improvements and learning.

5. Revision Details

Version Number	Revision Details
1	New Policy

6. Document Control

Document Attributes	Position
Approved by: Helen Gordon Mike Macnamee	 Document Administrator Head of Bourn Hall Clinic
Reviewed by: Dawn Course John Arthur Richard Walters Thanos Papathanasiou	 Business Support Director Finance Director Sales and Marketing Director Chief Executive and Medical Director
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