



Cleveland Clinic
London

**Patient
Information**

Patient Safety Incident Investigation Information booklet

What to expect and how you can be involved

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Why have I been given this booklet?

We are sorry to hear that you, a family member or someone you care for has been involved in a patient safety incident whilst under the care of Cleveland Clinic London. It is important to us that we understand the circumstances surrounding the incident and this is therefore being reviewed as part of a patient safety incident investigation. This booklet aims to provide you with information of what to expect from this process and how you can be involved if you would like to.

We know that the investigation cannot change what happened in your case, but the aim of a patient safety incident investigation is to help us as a healthcare provider to understand what happened so we can learn how things can be changed, and improvement made to prevent it from happening again.

We feel it is important to have your involvement in this process so that you can understand what happened and how we as an organisation are committed to change and improve.

What is a patient safety incident?

The definition of a patient safety incident is: “**Unintended or unexpected incidents which could have or did lead to harm for one or more patients receiving healthcare.**” These can range from incidents which cause no harm, such as a missed dose of a medicine, to rarer incidents which can have a devastating impact on someone's life, such as a problem with diagnosing a condition or disease leading to irreversible progression of that condition or disease.

PSIRF is a framework followed by all Hospitals in England in how to identify and respond to patient safety incidents. In almost all cases, incidents occur because of problems in the system people work in, and not because individuals meant to cause any harm. In Cleveland Clinic London it is important that we learn from patient safety incidents, so that we can try and prevent them from happening again.

Not all patient safety incidents require an investigation and may benefit from a different type of learning responses.

At Cleveland Clinic, we have created a Patient Safety Incident Response Plan that details our approach to various patient safety incidents. If you wish to obtain a copy of the Cleveland Clinic London Patient Safety Incident Response Plan, please feel free to request one.

What is a Patient safety incident investigation?

The purpose of investigating a patient safety incident is to comprehend what occurred and why, with the aim of reducing the chances of it happening again through an in-depth examination. We will assess the conditions that led to the incident and review procedures and practices using a systems-based methodology to identify areas for improvement or modification. This investigation process is not designed to establish the cause of death or assign blame to individuals, as those actions are governed by other specific protocols when necessary.

What to expect?

Initial Conversation

As soon as possible after recognition of the incident you should be informed that the incident has happened and be provided with an apology. Our professional and personal Duty of Candour¹ responsibility reinforces our principles of being open and involving our patients in the delivery of their care as part of our restorative just and learning culture. The statutory duty asks that healthcare providers make sure that patients or service users are told openly, honestly and in a timely manner when mistakes happen.

Starting the Investigation

Once Cleveland Clinic London have identified that a patient safety incident investigation is the appropriate response, a lead investigator will be appointed. This will be a specially trained member of staff to lead the investigation, who was not involved in the care provided.

Informing you of the investigation

You will be contacted either by the investigation lead or an allocated main point of contact. They will introduce themselves, talk to you about the incident and the investigation process. They will explore your support needs and preferences for being involved in the process including how and when you would like to be contacted. You can of course ask a friend or family member to join for support or to speak on your behalf if you do not feel able to do so. We will also do all we can to support you.

Your dedicated contact will provide their details and they, or a designated deputy (who you will be introduced to), will be available Monday to Friday from 9.00am to 5.00pm.

¹ For further information on the duty of candour please visit the Care Quality Commission (CQC) website at: <https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour>

You will be provided with their contact details, and they can arrange for you to share your experience and provide any questions or concerns that you would like answered as part of the investigation. They will keep you informed of progress and timescales as you prefer.

The point of contact will remain with you throughout the investigation process, your preference for involvement may change and you can talk to them about being more or less involved at any time

During the investigation we will ask you to help in several ways. This includes:

- Telling us about any issues or concerns you have about the care and treatment provided
- Sharing questions, you would like answered
- Describing your experience and giving your account of what happened to help us establish the facts about the incident and how it happened
- Reviewing the draft investigation report
- Helping to inform recommendations and action for improvement
- Receive further information about the investigation.
- The opportunity to discuss the final report
- Access to support organisations

We will work with you to understand how we can support your involvement in each of these areas if you are happy to be involved in this way

Scale and Scope of the Investigation

The lead will determine the extent and breadth of the investigation. The investigation's scale is influenced by its complexity and whether your incident is the sole focus. Occasionally, multiple similar incidents may occur, which will be examined collectively.

The scope of the investigation is when the 'Terms of Reference' are set. These act as a guide for those involved in the investigation as to what will be included and what questions need to be answered.

You will be offered the opportunity to review and discuss the terms of reference by your point of contact. If any of your questions are outside the scope of the investigation, you will be informed why and supported to the right people to answer this for you.

Conducting a thorough investigation of a patient safety incident requires time. We strive to finish all investigations within 1 to 3 months. We will inform you of the proposed timelines and keep you informed throughout the investigation. Additionally, we can agree in advance on how frequently and by what means you would like to be updated.

Gathering the information

The lead investigator will gather relevant information to answer the questions set out in the 'Terms of Reference'. These include:

- Medical notes (electronic / paper)
- Cleveland Clinic London policies and guidelines
- National policies and guidelines
- Verbal or written accounts from people who experienced the incident
- Visits to ward or area where incident occurred

This information will be used to understand exactly what happened.

Analysing the information

From identifying a clear picture of what happened, will identify different factors that may have contributed to the incident. It is rarely one single thing, and they will use a systems-based method of investigation to identify areas that need to be changed or improved. From these findings actions will be created to prevent or reduce the likelihood of further reoccurrence. 'Subject Matter Experts' (SME) will form part of an investigation panel supporting the lead investigator in reviewing the information by giving their specialist knowledge which is relevant to the investigation.

Writing the report

Once the lead investigator has written the first draft, they will send it to investigation panel for review and relevant area/service leads to ensure the information is accurate and actions are achievable.

Your point of contact will also establish if you would like the report to be shared with you to check and ensure the information is factually accurate. If you do, you will be provided with the draft report or sections of the report that impacted on you and allocated specific time to check for accuracy.

All reports will be anonymised unless you specifically ask us to include your name, or the name of your friend or family member if the investigation relates to an incident that involved them. You can help us to decide how to refer to you, or your friend or family member, or if you would prefer the report to be written anonymously.

To support the purpose of learning and improvement and avoid any inappropriate blame, staff will remain anonymous in the final patient safety incident investigation report.

Closing the investigation

At the end of the investigation, you will be offered the final report which provides the findings and conclusion of the investigation.

We appreciate this may be a difficult time and will offer you a meeting with the lead investigator to discuss what they found in the investigation and how they decided on their suggested actions.

You will also have the chance to ask any questions you might have. Additionally, they will discuss any support you may require going forward and assist in arranging this if you wish.

Once the report is finished it will be signed off by the Executive Board. Some actions to reduce future risk may need to begin immediately, however, where the findings from other investigations will help our organisation to understand and tackle similar risks, we will wait until all findings can be considered before developing and implementing an improvement plan. This will be shared and discussed with you.

We will keep monitoring the improvement plans to see if the steps we're taking are effectively lowering risks and enhancing patient safety. The Safety and Quality Improvement Council will supervise this process. We will continue to update you on our progress for as long as you are interested.

Other investigations

If the investigation lead knows there is going to be another investigation alongside or immediately after this one, they will tell you. For example, following an unexplained death there will be an inquest led by the coroner. They will also support you to find out more information about the additional investigation process if you would like to know more.

What if I am not happy?

The investigation should have addressed the majority, if not all, of your inquiries. If you still have unresolved questions, please notify your point of contact, who will direct you to the appropriate departments or organisations that can assist.