

Management of Incidents, Incorporating Serious Incidents

Unique Identifier:	CORP/POL/	CORP/POL/605			
Version Number:	1.2				
Type of Update / Status:	Ratified with	Major Chan	ges / Comple	te Rewrite	
Divisional and	Quality Gove	ernance (Cor	porate)		
Department:					
Author / Originator and	Stefan Verst	raelen, Depu	ity Director o	f Quality Gov	rernance
Job Title:					
Replaces:	Version 12 I	ncident and	Serious Incid	ent Investiga	tion
	Procedure CORP/PROC/101				
Description of	Policy revision – REPLACES CORP/PROC/101: 'Incident and				
amendments:	Serious Incident Investigation Procedure'				
Approved by:	Learning from Incidents and Risks Committee (LIRC) by				
	Chairman's Action				
Approved Date:	18/10/2019				
Issue Date:	28/10/2019				
Review Date from Date	1 Year	2 Years	3 Years	4 Years	5 Years
of Approval:	\boxtimes				
	28/10/2020				

Version Control Sheet

This must be completed and form part of the document appendices each time the document is updated and approved

Date dd/mm/yy	Version	Author	Reason for changes
28/10/19	1	Stefan Verstraelen, Deputy Director of Quality Governance	General review
04/11/19	1.1	Stefan Verstraelen, Deputy Director of Quality Governance	Appendix 2, hyperlink to title.
			Appendix 7 update to hyperlink.
			Appendix 10 update and addition of hyperlink.

Version Co	Version Control Sheet			
07/11/19	1.2	Stefan Verstraelen, Deputy Director of Quality Governance	Section 1.3 minor update to second bullet.	
			Appendix 7 removal of two hyperlinks.	
			Appendix 10 removal of 4 hyperlinks.	

Consultation / Acknowledgements with Stakeholders				
Name	Designation	Date Response Received		
Nick Harper	Acting Medical Director	24/7/2019		
Peter Murphy	Director of Nursing and Quality	24/7/2019		
Berenice Groves	Interim Director of Operations	29/7/2019		
Janet Barnsley	Interim Director of Operations	22/8/2019		
Simone Anderton	Deputy Director of Nursing	24/7/2019		
Tracy Crumbleholme	Interim Director of Quality Improvement	2/8/2019		
Helena Lee	Governance, Risk & Patient Safety Manager	27/08/2019		
	<u>Divisional Triumvirates</u> :			
Lisa Horkin Johanne Lickiss	Associate Director of Nursing (USC) Associate Director of Nursing (SC)			
Carole McCann	Associate Director of Nursing (ALTC)			
Nicola Parry	Associate Director of Nursing (Families)	Face il with the al		
Steve Wiggans Grahame Goode	Divisional Director (SC)	Email with final draft document		
	Divisional Director (USC)	sent to Divisional		
John Sweeney Peter Curtis	Divisional Director (ALTC) Divisional Director (Families and CS)	Triumvirates and		
Neil Upson	Associate Director of Operations (USC)	Quality Managers		
Liz Holt	Associate Director of Operations (OSC) Associate Director of Operations (ALTC)	on 25 July 2019.		
Anne Conley	Associate Director of Operations (ACTC) Associate Director of Operations (SC)	011 23 July 2019.		
Pauline Tschobotko	Associate Director of Operations (SC) Associate Director of Operations (Families)	Final meeting held		
Vera Mountain	Associate Director of Operations (CS)	with Divisional		
	Divisional Quality Managers:	representatives to receive feedback and agree final		
Dean Quinn	Divisional Quality & Governance Manager	draft policy:		
Anders Coleman	Acting Head of Divisional Quality	1/8/2019		
Richard Matthews	Quality Managers			
Louise Dowell	Quality Manager			
Clare Ellis	Quality Manager			

1 0	Hospitals NHS Foundation Trust	ID No. CORP/POL/605 Title: Management of Incidents, Incorporating
Revision No: 1.2	Next Review Date: 28/10/2020 No you have the up to date version? S	Serious Incidents

CONTENTS

Ver	/ersion Control Sheet1				
Cor	Consultation / Acknowledgements with Stakeholders2				
1	Introduction / Purpose	5			
2	General Principles / Target Audience	5			
2					
3	Definitions and Abbreviations	6			
4	Responsibilities (Ownership and Accountability)	6			
4	Chief Executive	6			
4					
4					
4	1 /				
4					
4 4	5				
5	Incidents – Description and Explanation				
6 6	Levels of Harm10 No Harm / Near Miss:10				
6					
6					
6	· ·				
6		2			
7	Never Events1	2			
8	Reporting and Managing Incidents1	3			
8					
9	Initial (Clinical) Review: the '72 hour review'1				
10	Duty of Candour14				
11	Levels of Investigation1	5			
1	1 Local, Informal Investigation1	5			
1	2 72 hour review and, if further investigation is required, an After Incident Review				
	(AIR) – also known as 'concise investigation'1	5			
1	3 72 hour review and Root Cause Analysis (RCA) – also known as 'comprehensive	_			
4.0	investigation'				
12	References and Associated Documents1				
	ndix 1: A Just Culture Guide1				
	ndix 2: Incident Grading Process20	O			
App	ndix 3: Standard Operating Procedure (SOP) and Guidance Note for Establishing if	_			
_	an Incident is a Never Event				
App	ndix 4: Standing Operating Procedure (SOP) and Guidance Notes for Reporting and				
	Investigating Incidents	3			
App	ndix 5: Standard Operating Procedure (SOP) and Guidance Notes for 72 Hour	_			
۸	Review				
	ndix 6: Standard Operating Procedure (SOP) for Duty of Candour	3			
App	ndix 7: Standard Operating Procedure (SOP) and Guidance Notes for After Incident	^			
۸	Review	9			
Abk	Appendix 8: Standard Operating Procedure (SOP) and Guidance Notes for Root Cause Analysis (RCA)31				
	, triaryolo (1007)				
	Blackpool Teaching Hospitals NHS Foundation Trust ID No. CORP/POL/605				
	Revision No: 1.2 Next Review Date: 28/10/2020 Title: Management of Incidents, Incorporating Serious Incidents				

Appendix 9: Ground Rules and Guidance Notes for Investigating Incidents (Incorporating
72 Hour Review, AIR and RCA)	32
Appendix 10: Supporting Documents	33
Appendix 11: Equality Impact Assessment Form	

1 Introduction / Purpose

Under Regulation 12: *Safe care and treatment* of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Crown, 2014), the Trust has got a legal duty to provide care and treatment in a safe way for service users. The intention of this regulation is to prevent people from receiving unsafe care and treatment and prevent avoidable harm or risk of harm.

The Trust Board and the Chief Executive are therefore committed to the establishment of a supportive, open, transparent and honest learning culture that encourages staff to report incidents, including near misses and Serious Incidents (moderate harm incidents, severe harm incidents and death incidents) through the appropriate channels. The aim is to learn from incidents, improve practice accordingly and thus establish a robust safety culture.

The Trust will take a systems approach to reporting and investigating incidents and supports a 'just culture', adapting a fair and consistent approach by using the NHSI 'Just Culture Guide (March 2018) (Appendix 1).

Safety is everybody's business. All staff will ensure they report incidents and, if required, participate proactively and positively in investigations, and that they are familiar with policies, procedures and protocols, which are essential to delivering a safe service.

This policy details the Trust's procedures for the reporting and the investigation of all incidents, including Serious Incidents. This procedure should be read in conjunction with the Trust's 'Risk Management Policy' (CORP/POL/547 (BTHFT - Procedure, 2019)) and other relevant policies referred to in this document. However, it is recognised that there are other Trust policies, for example: '*Information Governance Framework Policy 2019-202'* – (CORP/POL/065), regulations and investigative principles, such as Human Factors, relevant to this policy, but which are not necessarily explicitly referred to within this document.

The Trust promotes an open, transparent and honest process of incident management and ensures that 'being open' is practised routinely for all incidents involving harm. The Duty of Candour statutory requirements are applied to all incidents of moderate harm, severe harm or unexpected death.

2 General Principles / Target Audience

2.1 Objectives

- To maintain the safety of patients, staff or any other person in relation to the Trust's business or services.
- To maintain continuity of safe services within the Trust and uphold the reputation of the Trust.
- To promote, encourage and support effective, timely incident reporting.
- To promote, encourage and support effective, high quality and timely investigations of incidents.
- To promote and encourage shared learning following incidents.

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/POL/605	
Revision No: 1.2	Next Review Date: 28/10/2020	Title: Management of Incidents, Incorporating Serious Incidents	
Do you have the up to date version? See the intranet for the latest version			

- To ensure effective feedback is provided to those involved incidents and/or those reporting incidents.
- To ensure the principles of 'openness', 'transparency' and 'honesty' are applied when things go wrong and that investigations are carried in line with these principles to determine root causes of an incident and identify learning.
- To ensure Duty of Candour is applied and that there is effective, open and honest communication with patients and families with regards to incidents involving moderate and higher levels of harm.
- To share high quality incident data and information with other organisations as appropriate, e.g. Clinical Commissioning Groups (CCGs), the Care Quality Commission (CQC) and partners within the Integrated Care Group (ICG) and Integrated Care Service (ICS).

3 Definitions and Abbreviations

AIR	After Incident Review
CQC	Care Quality Commission
CCG	Clinical Commissioning Groups
FAQ	Frequently asked questions
ICG	Integrated Care Group
ICS	Integrated Care Service
NOK	Next of Kin
LIRC	Learning from Incidents and Risk Committee
NRLS	National Reporting and Learning System
RCA	Root Cause Analysis
SMART	Specific, Measurable, Attainable, Relevant, Time-bound
SOP	Standard Operating Procedures
StEIS	Strategic Executive Information System

4 Responsibilities (Ownership and Accountability)

4.1 Chief Executive

• Ensures the Trust has adequate systems and processes for the reporting and the investigation of all incidents, including Serious Incidents (moderate harm incidents, severe harm incidents and death incidents).

4.2 Medical Director

- Ensures organisational learning occurs following the investigation into reported incidents.
- Ensures the Trust Board are appraised of all Serious Incidents by presenting 'Serious Incident' reports as necessary.
- Authorised named person who will be (jointly) responsible for deciding if an incident triggers the 'Serious Incident' investigation process and decide the level of investigation that is required to be carried out.

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/POL/605	
Revision No: 1.2	Next Review Date: 28/10/2020	Title: Management of Incidents, Incorporating Serious Incidents	
Do you have the up to date version? See the intranet for the latest version			

4.3 Director of Nursing and Quality

- Has the Executive Lead role for incident and investigation management.
- Reviews high-level performance reports in relation to incident and investigation management.
- Ensures organisational learning occurs following the investigation into reported incidents.
- Authorised named person who will be (jointly) responsible for deciding if an incident triggers the Serious Incident investigation process and decide the level of investigation that is required to be carried out.

4.4 Divisional Triumvirates (Divisional Senior Leadership Team)

- Ensure that all staff in the Division are fully aware of and compliant with this Trust policy, including the associated Standard Operating Procedures (SOP), to ensure the timely and effective reporting and investigation of all incidents.
- Ensure that all staff in the Division are fully aware of and compliant with Trust policies affiliated to and relevant to the 'Management of Incidents, Incorporating Serious Incidents' policy, such as the 'Patient Safety Including Being Open and Duty of Candour' policy (CORP/POL/538 (BTHFT Procedure, 2019)) and the 'Reporting of Injuries, Diseases and Dangerous Occurrences' policy (CORP/PROC/320 (BTHFT Procedure, 2017)).
- Ensure that support is instigated for patients and/or families and/or staff when an
 incident has occurred, in particular if the incident was of a stressful or traumatic
 nature.
- Ensure that any equipment that may have been involved in the incident is isolated and/or decommissioned. In the case of Serious Incidents, to ensure any danger areas or areas that may need to be preserved are isolated.
- Ensure any potential Serious Incident or Never Event is escalated to the Incident and Risk Management Team, the Medical Director (and/or their deputy), the Director of Nursing and Quality (and/or their deputy), or, when out of hours, to the Senior Manager / Director on-call / Out of Hour Manager On Call (ALTC).
- Ensure effective mechanisms and processes are in place to ensure timely reporting and management of incidents and investigations, against national and local standards, including strict compliance with Duty of Candour.
- Ensure that incident investigation reports are completed comprehensively to a high quality standard (including SMART¹ plans of action) and that such reports have received Divisional sign-off by a member of the Divisional Triumvirate (or their delegated deputy) prior to forwarding to the Incident and Risk Management Team by no more than 10 working days prior to the final deadline of submission of the report to the CCG.

¹ SMART: **S**pecific, **M**easurable, **A**ttainable, **R**elevant, **T**ime-bound

Blackpool Teaching Hospitals NHS Foundation Trust

Revision No: 1.2

Next Review Date: 28/10/2020

Do you have the up to date version? See the intranet for the latest version

- Ensure that recommendations and actions resulting from incident investigations are implemented against agreed timescales and impact is audited to provide assurance to the Board that learning has taken / is taking place.
- Develop mechanisms within their Departments / Divisions for sharing learning effectively within the Division, across the wider Trust or, where appropriate, outside the Trust in a timely manner.
- To ensure that a contemporaneous Divisional Investigation log containing all open and ongoing investigations is kept up to date and that all closed investigations are archived, and readily available for inspection by internal and external stakeholders.
- To ensure a contemporaneous Divisional Action Log is maintained and proactively managed, to provide assurance that actions following investigations are managed and closed within agreed timescales. The Divisional Action Log requires to be readily available for inspection by internal and external stakeholders.
- Ensure that trends or themes arising from incidents are reviewed, risk assessed and responded to, by implementing processes that mitigate ongoing risk and/or, where appropriate to do so, manage these via the Divisional Risk Register.

4.5 All Staff

- Must ensure they report incidents accurately and responsibly through the Trust's Risk Management System and ensure that all relevant information is included within the report with regards to any incident they have been involved in or witnessed.
- Make sure they, patients and other persons are safe.
- Must, whilst ensuring their own, patients' and other persons' safety, take immediate reasonable actions to prevent further incidents from happening.
- To provide initial care, treatment and support to those affected by the incident.
- Inform their manager of the incident straight away and submit an incident report as soon as possible within 24 hours of the incident occurring.
- Seek support as necessary following a stressful or traumatic incident.
- Must pro-actively engage with investigations into incidents and promptly provide data and/or information that support the investigations, including providing open, honest and transparent witness statements where required.

4.6 Line managers

- Must ensure their staff, patients and other persons are safe.
- Must take immediate actions to ensure no further incidents can happen.
- Provide support to staff following a stressful or traumatic incident.
- Review and confirm the level of harm on the incident report form.
- Escalate incidents, as appropriate, to the senior management team.
- Carry out a risk assessment as appropriate and identify actions that would minimise ongoing risk to patients, staff, other persons and the Trust.

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/POL/605	
Revision No: 1.2	Next Review Date: 28/10/2020	Title: Management of Incidents, Incorporating Serious Incidents	
Do you have the up to date version? See the intranet for the latest version			

- Carry out a local, informal investigation for no harm / near miss / minimal harm incidents and update and close incidents within 20 working days (or sooner) of the incident having been submitted.
- On the request of the senior management team, carry out formal incident investigations into moderate harm / severe harm / death incidents, or otherwise support such formal investigations where appropriate to do so.
- Ensure learning from incidents is shared with their staff.

4.7 Deputy Director of Quality Governance / Incident and Risk Management Team

- To ensure that the Medical Director and Director of Nursing and Quality are notified of all incidents of moderate harm, severe harm or unexpected death.
- To oversee that all reported incidents and near misses are assigned to a manager and appropriate actions are taken by the manager according to severity of the incident and, where appropriate to do so, report to relevant external bodies.
- To review incidents and trends on an organisation wide basis and escalate any significant concerns to the senior leadership team.
- Ensure lessons learned are collated at the Learning from Incidents and Risk Committee (LIRC) and applied across the organisation for example by way of the Trust Lessons Learned Newsletter (BTHFT - Newletter, n.d.).
- Report to the Trust Board, via the Quality Committee, trends and outcomes from Serious Incidents (broken down in moderate harm incidents, severe harm incidents and death incidents).
- Maintain a contemporaneous record of all Serious Incident investigations performed within the Trust and escalate any (emerging) delays in investigations to the senior leadership team.
- Report relevant incidents to monitoring organisations as required, against agreed timescales.
- Maintains and reports on performance data in relation to incident and investigation management.
- Ensure all incidents are collated, anonymised and sent to the National Reporting and Learning System (NRLS) via the Trust's Risk Management System on at least a monthly basis by the Authorised User.
- Review all reported incidents as they are submitted for any trends and to identify Serious Incidents if not yet escalated by the Divisional Triumvirates.
- Ensure that the Local Security Management Specialist will receive notification of incidents in the following categories:
 - Physical assault on staff.
 - Non-physical assault on staff.
 - Theft or criminal damage (including burglary, arson and vandalism) to NHS property or equipment (including equipment issued to staff).

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/POL/605	
Revision No: 1.2	Next Review Date: 28/10/2020	Title: Management of Incidents, Incorporating Serious Incidents	
Do you have the up to date version? See the intranet for the latest version			

 Theft or criminal damage to staff or patient personal property arising from these types of security incident.

5 Incidents – Description and Explanation

"Patient safety incidents are any unintended or unexpected incidents which could have, or did, lead to harm for one or more patients receiving healthcare" ((NHS Improvement, n.d.)). For the purpose of this policy, this description also applies to staff or any other person in relation to the Trust's business or services, or the Trust itself.

Reporting incidents supports the NHS to learn from mistakes and to take action to keep patients safe.

For the purpose of delivering of safe and effective services, the Trust requires that all incidents which:

- Could have, or did, lead to harm for one or more patients receiving healthcare, or,
- Could have, or did, lead to harm for one or more members of staff or any other person/s whilst on Trust premises or in connection with the business of the Trust, or,
- Could have, or did, result in an adverse impact (including financial loss) on services within the Trust, or adversely impact on the reputation of the Trust,

must be reported on the Trust's Risk Management System, within 24 hours of the incident having been identified.

For the purpose of this policy, the Trust includes 'near misses' (impact prevented) and 'Serious Incidents' (moderate harm incidents, severe harm incidents and death incidents) in the umbrella definition of: 'incident'.

The different levels of harm attributed to a person involved in an incident are described in section 6.

6 Levels of Harm

Levels of harm as per the NHS Improvement - National Reporting and Learning System (NRLS) (NHS National Reporting and Learning System, n.d.):

6.1 No Harm / Near Miss:

- No harm (impact prevented): any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care. This will be locally termed as a 'near miss'.
- No harm (impact not prevented) Any patient safety incident that ran to completion but no harm occurred to people receiving NHS funded care.

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/POL/605 Title: Management of Incidents, Incorporating
Revision No: 1.2	Next Review Date: 28/10/2020 No you have the up to date version? S	Serious Incidents

6.2 Minimal Harm

Patient(s) required extra observation or minor treatment:

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

A Serious Incident is declared when a patient or person suffered 'moderate harm', 'severe harm' or 'unexpected death':

6.3 Moderate Harm (Short Term):

Patient(s) required further treatment or procedure:

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

Under the *Health and Social Care Act 2008 (Regulated Activities) Regulations 2014:* Regulation 20, "moderate harm" means:

- a) harm that requires a moderate increase in treatment, and
- b) significant, but not permanent, harm;

"moderate increase in treatment" includes an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care).

6.4 Severe Harm (Permanent or Long Term):

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

Under the *Health and Social Care Act 2008 (Regulated Activities) Regulations 2014:* Regulation 20, "severe harm" means:

A permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition.

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/POL/605	
Revision No: 1.2 Next Review Date: 28/10/2020		Title: Management of Incidents, Incorporating Serious Incidents	
Do you have the up to date version? See the intranet for the latest version			

6.5 Unexpected death:

 Any incident that potentially directly resulted in death or potentially contributed to the death of one or more persons.

Frequently asked questions (FAQ) about degree of harm can be found on the NHS Improvement National Reporting and Learning System (NRLS) website:

https://improvement.nhs.uk/documents/1673/NRLS Degree of harm FAQs
final_v1.1.pdf and further descriptions of moderate harm and severe harm can be found on the Care Quality Commission (CQC) website: <a href="https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour#guidance-providers/regulations-enforcement/regulation-20-duty-candour#guidance-providers/regulations-enforcement/regulation-20-duty-candour#guidance-providers/regula

When attributing the level of harm to an incident, it is important to document the **ACTUAL** level of harm (based on a best assessment at time of the incident), not the potential level of harm.

For incidents with moderate or severe harm / unexpected death, Duty of Candour applies. Duty of Candour is described in section 8 of this policy.

In case an incident occurs that could have, or did, result in an adverse impact (including financial loss) on services within the Trust, or adversely impacted on the reputation of the Trust, consult the Incident Grading Process in Appendix 2, to establish the level of harm.

7 Never Events

Never Events are incidents that meet all the criteria given below and require full investigation under the Serious Incident framework:

- Never Events are patient safety incidents that are wholly preventable where guidance
 or safety recommendations that provide strong systemic protective barriers are
 available at a national level and have been implemented by healthcare providers.
- Each Never Event type has the potential to cause serious patient harm or death.
 However, serious harm or death does not need to have happened as a result of a specific incident for that incident to be categorised as a Never Event.
- For each Never Event type, there is evidence that the Never Event has occurred in the past – for example, through reports to the National Reporting and Learning System (NRLS) – and that the risk of recurrence remains.

The full list of Never Events can be found on the NHS Improvement website: https://improvement.nhs.uk/documents/2266/Never_Events_list_2018_FINAL_v5.pdf

Standard Operating Procedure and guidance notes for establishing if an incident is a Never Event (Appendix 3)

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/POL/605	
Revision No: 1.2 Next Review Date: 28/10/2020		Title: Management of Incidents, Incorporating Serious Incidents	
Do you have the up to date version? See the intranet for the latest version			

8 Reporting and Managing Incidents

Incident reporting can be a powerful tool for developing and maintaining an awareness of risks in healthcare practice and contributes to a positive effect on safety, not only by leading to changes in care processes, but also by changing staff attitudes and knowledge.

Observing the description of 'incident' in section 5 of this policy, the Trust therefore promotes the principle: "if you think it is an incident, report it".

The Trust believes that a clear process for reporting and investigating incidents helps staff to create and maintain a safe environment for patients, staff and other persons alike. To this effect, the Trust has developed Standard Operating Procedures (SOPs) for reporting and investigating incidents.

8.1 Some ground principles with regards to reporting incidents:

- Make sure you, patients and other persons are safe.
- Where safe to do so, take immediate reasonable actions to ensure no further incidents can happen and/or minimise ongoing risk.
- Provide initial care, treatment and support to those affected by the incident.
- Inform your manager of the incident straight away and submit an incident report as soon as possible <u>within 24 hours</u>:
 - Brief description of the incident / describe facts.
 - No names / patient identifiable information in the incident description.
 - What you believe is the level of ACTUAL harm (not potential harm).
 - Document the immediate actions taken on the incident reporting system.

Standard Operating Procedure and guidance notes for reporting and investigating incidents (Appendix 4).

Some ground principles with regards to investigating incidents:

- Take it very seriously; more often than not, there is a fellow human being at the centre of the incident, who may have been harmed.
- Investigate promptly and thoroughly.
- Focus on learning with the aim to preventing or minimising an incident of a similar kind from occurring again.
- Support colleagues affected by the incident.
- Seek advice and help communicate with the Incident and Risk Management Team, who can provide help and support.

In case of an incident having been reported as moderate harm, a 72 hour review and, -if required-, an After Incident Review (AIR) will be directed by the Deputy Director of Quality

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/POL/605
Revision No: 1.2	Next Review Date: 28/10/2020	Title: Management of Incidents, Incorporating Serious Incidents
Do you have the up to date version? See the intranet for the latest version		

Governance, managed by the Divisional Triumvirates and overseen by the Incident and Risk Management Team.

In case of severe harm or unexpected death, a 72 hour review <u>and</u> Root Cause Analysis (RCA) will be directed by the Medical Director and/or Director of Nursing and Quality (or their deputy), managed by the Divisional Triumvirate and overseen by the Executive Team (usually the Director of Nursing and Quality and Medical Director). This process will be supported by the Incident and Risk Management Team.

9 Initial (Clinical) Review: the '72 hour review'

Following an incident with a moderate or severe level of harm, or an unexpected death (i.e. a 'Serious Incident'), the 72 hour review will be carried out by an appropriate (clinical) member of staff appointed by the Divisional Triumvirate. This will typically be a person with relevant expertise, but who is not involved in the care of the patient and was not involved in the incident. The purpose of the 72 hour review is to:

- Create a clear and comprehensive chronological timeline.
- Identify immediate and ongoing risks.
- Identify immediate actions to mitigate the risk.
- Confirm or re-assign the level of harm.
- Identify if there is a need to progress to a further, formal investigation. If not, document the reason/s why.
- In case of some incidents of moderate harm, the 72 hour review <u>may</u> also be accepted as the conclusive investigation report (please see section 11.2).

It is pertinent that the 72 hour review is completed within 72 hours (3 working days) or sooner from the incident having been reported, and has received Divisional Triumvirate sign-off prior to submission to the Incident and Risk Management Team. Compliance against this standard is monitored by the Executive Team (usually the Director of Nursing and Quality and Medical Director, or a delegated deputy) and reported monthly at the Quality Committee.

Standard Operating Procedure (SOP) and guidance notes for 72 hour review and Glossary of Terms/Acronyms (Appendix 5)

10 Duty of Candour

Duty of Candour is a legal requirement under the *Health and Social Care Act 2008* (*Regulated Activities*) *Regulations 2014: Regulation 20* (https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour#guidance).

The intention of this regulation is to ensure that providers are open and transparent with people who use services and other 'relevant persons' (people acting lawfully on their behalf) in general in relation to care and treatment. It also sets out some specific requirements that providers must follow when things go wrong with care and treatment,

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/POL/605
Revision No: 1.2	Next Review Date: 28/10/2020	Title: Management of Incidents, Incorporating Serious Incidents
Do you have the up to date version? See the intranet for the latest version		

including informing people about the incident, providing reasonable support, providing truthful information and an apology when things go wrong.

As the Trust is subject to the NHS Standard Contract, the Trust requires that the notification to the patient, Next of Kin (NoK) or family (the 'relevant person/s'), must be within at most 10 working days of the incident being reported to local systems, and sooner where possible. Standard Operating Procedure (SOP) for Duty of Candour (Appendix 6). Further information and guidance templates can be found within the Patient Safety Including Being Open and Duty of Candour Policy (CORP/POL/538). http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-POL-538.docx

11 Levels of Investigation

All patient safety incidents are reported on the National Reporting and Learning System (NRLS), but not all incidents require a formal investigation.

The Trust requires that incidents with a harm level of 'moderate' or 'severe' (see definitions in section 5) or unexpected deaths are formally investigated.

Incidents with this level of harm are called: 'Serious Incidents'. Serious Incidents resulting in severe harm or death are required to be reported externally to the Trust onto the 'Strategic Executive Information System' ('StEIS').

The following levels of investigation are to be carried out in the event of an incident:

11.1 Local, Informal Investigation

For:

No harm / near miss / minimal harm incidents.

11.2 72 hour review and, if further investigation is required, an After Incident Review (AIR) – also known as 'concise investigation'

For:

- Moderate harm incidents, or,
- Incident trends / cluster reviews, or,
- <u>Some</u> near miss incidents (on the direction of the Deputy Director of Quality Governance).

11.3 72 hour review <u>and</u> Root Cause Analysis (RCA) – also known as 'comprehensive investigation'

For:

- Severe harm / death incidents, or,
- Moderate harm incidents or some serious near miss incidents (on the direction of the Director of Nursing and/or Quality or Medical Director).

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/POL/605
Revision No: 1.2 Next Review Date: 28/10/2020		Title: Management of Incidents, Incorporating Serious Incidents
Do you have the up to date version? See the intranet for the latest version		

In exceptional circumstances, an external / review investigation) may be carried out.

- **Local, informal investigations** for minimal harm incidents are investigated by the line manager.
- 72 hour reviews and, if further investigation is required, AIR investigations for moderate harm incidents are directed by the Deputy Director of Quality Governance, managed by the Divisional Triumvirates and overseen by the Incident and Risk Management Team.
- 72 hour reviews and RCA investigations for severe harm and death incidents are
 directed by the Medical Director and/or Director of Nursing and Quality (or their
 deputy), managed by the Divisional Triumvirate and overseen by the Executive Team
 (usually the Director of Nursing and Quality and Medical Director). This process will
 be supported by the Incident and Risk Management Team.

Incidents resulting in severe harm or unexplained death are submitted by the Incident and Risk Management Team to the 'Strategic Executive Information System' ('StEIS') system within two working days of the incident having been identified and local Clinical Commissioning Groups (CCG) will receive notification of the incident via the StEIS reporting system. For some incidents, direct contact may be made by a member of the senior leadership team with the CCG, the Care Quality Commission (CQC) and the Integrated Care Group (ICG). However, this timescale may be reasonably extended if the 72 hour review is expected to re-assign the level of harm. In such case, the local CCG and the CQC will be kept informed by the Director of Nursing and Quality, Medical Director or their deputy.

The Divisions have:

- **72 hours (3 working days)** to complete a 72 hour review for moderate harm, severe harm and death incidents, from the date of the incident having been reported.
- **20 working days** to close no harm / near miss / minimal harm incidents on the Trust Risk Management System, from the date of the incident having been reported.
- **20 working days** to complete an After Incident Review (AIR) for moderate harm incidents requiring further investigation (in addition to the 72 hour review), from the date of the incident having been reported.
- **50 working days** to complete a Root Cause Analysis (RCA) report for severe harm or death incidents, from the date of the incident having been reported, allowing the Trust to complete the entire investigation process within the regulated 60 working day standard, as directed by the NHS England Serious Incident Framework (2015).

The Trust takes the primary view that prompt and thorough investigations demonstrate due respect, consideration and empathy to patients and families and helps them to make sense of when something has gone wrong. It also helps the Trust to make swift improvements in care and treatment for all patients. Investigation reports should be written in such a way that the lay-person would understand the report, as the Trust endeavours to share investigation reports with the patient/Next of Kin (NoK)/family of the patient.

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/POL/605
Revision No: 1.2 Next Review Date: 28/10/2020		Title: Management of Incidents, Incorporating Serious Incidents
Do you have the up to date version? See the intranet for the latest version		

As performance against these standards is also monitored by external regulators to the Trust, to ensure timely engagement with the patient and/ or NoK/family of the patient, compliance with timescales are closely monitored by the Executive Team (usually the Director of Nursing and Quality or Medical Director and their deputy) and reported monthly at the Quality Committee, with a view to drive continuous improvement in safe care and treatment.

The Standard Operating Procedures (SOPs) for investigations detail the timescales the Divisions and the Trust will work to:

Standard Operating Procedure (SOP) and guidance notes for Level 1 RCA or AIR investigation (Appendix 7)

Standard Operating Procedure (SOP) and guidance notes for Level 2 RCA investigation (Appendix 8)

Further Ground rules and guidance notes for investigating incidents (incorporating 72-hour review, Level 1 RCA, AIR and RCA Level 2) can be found in Appendix 9.

A list of supporting documents can be found in Appendix 7.

All STEIS reportable Serious Incidents will undergo a review by the Trust's Safety Panel, which is attended by a representative from the CCG, for approval prior to sign off by the Director of Nursing and Quality / Medical Director and the Chief Executive.

12 References and Associated Documents

BTHFT - Newletter, n.d. Lessons Learned. [Online]

Available at: http://fcsp.xfvldecoast.nhs.uk/C/clinical-

governance/riskmanagement/Lessons%20Learned/Forms/AllItems.aspx

[Accessed 20 8 2019].

BTHFT - Procedure, 2017. Reporting of Injuries, Diseases and Dangerous Occurrences (RIDDOR). [Online]

Available at: http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-PROC-320.docx

[Accessed 21 5 2019].

BTHFT - Procedure, 2019. *Patient Safety Including Being Open and Duty of Candour.* [Online]

Available at: http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-POL-538.docx

[Accessed 20 6 2019].

BTHFT - Procedure, 2019. Risk Management Policy. [Online]

Available at: http://fcsp.xfyldecoast.nhs.uk/trustdocuments/Documents/CORP-POL-547.docx

[Accessed 23 04 2019].

CQC, 2014. Regulation 20: Duty of candour. [Online]

Available at: https://www.cgc.org.uk/guidance-providers/regulations-

enforcement/regulation-20-duty-candour#guidance

[Accessed 2 8 2019].

Crown, 2014. The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. [Online]

Available at: https://www.legislation.gov.uk/ukdsi/2014/9780111117613/regulation/12 [Accessed 2 8 2019].

NHS Improvement, 2018. Revised Never Events policy and framework. [Online]

Available at: https://improvement.nhs.uk/resources/never-events-policy-and-framework/ [Accessed 2 8 2019].

NHS Improvement, n.d. A just culture guide. [Online]

Available at: https://improvement.nhs.uk/resources/just-culture-guide/ [Accessed 2 8 2019].

NHS Improvement, n.d. Report a patient safety incident. [Online]

Available at: https://improvement.nhs.uk/resources/report-patient-safety-incident/ [Accessed 2 8 2019].

NHS National Reporting and Learning System, n.d. *Degree of harm FAQ.* [Online] Available at:

https://improvement.nhs.uk/documents/1673/NRLS_Degree_of_harm_FAQs_-_final_v1.1.pdf

[Accessed 20 8 2019].

Do you have the up to date version? See		ee the intranet for the latest version
Revision No: 1.2	Next Review Date: 28/10/2020	Title: Management of Incidents, Incorporating Serious Incidents
Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/POL/605



A just culture guide

Supporting consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents

whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safety. 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

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 se 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.

- 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



improvement.nhs.uk

Based on the work of Professor James Reason and the National Patient Safety Agency's Incident Decision Tree

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

Supported by:





5a. Were there any significant mitigating circumstances?





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.













collaboration respect innovation courage compassion trust

Blackpool Teaching Hospitals NHS Foundation Trust ID No. CORP/POL/605 Title: Management of Incidents, Incorporating Revision No: 1.2 Next Review Date: 28/10/2020 Serious Incidents Do you have the up to date version? See the intranet for the latest version

Appendix 2: Incident Grading Process

INCIDENT GRADING PROCESS

Choose the most appropriate description of the identified risk from the table below

	Level of harm and examples				
Impact on:	No harm / near miss	Minimal harm	Moderate harm	Severe harm	Death
Patients, staff or other persons (physical / psychological harm)	No harm (impact prevented): any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care. This may be locally termed a 'near miss'. No harm (impact not prevented) - Any patient safety incident that ran to completion but no harm occurred to people receiving NHS funded care.	Any unexpected or unintended incident that required extra observation or minor treatment and caused minimal harm to one or more persons receiving NHS-funded care.	Moderate increase in treatment, possible surgical intervention, cancelling of treatment, or transfer to another area, and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care.	Any unexpected or unintended incident that appears to have resulted in permanent harm to one or more persons.	Any unexpected or unintended incident that directly resulted in the death of one or more persons.
Quality / complaints / audit	Peripheral element of treatment or service suboptimal Informal complaint/inquiry	Overall treatment or service suboptimal Formal complaint (stage 1) Local resolution Single failure to meet internal standards Minor implications for patient safety if unresolved Reduced performance rating if unresolved	Treatment or service has significantly reduced effectiveness Formal complaint (stage 2) complaint Local resolution (with potential to go to independent review) Repeated failure to meet internal standards Major patient safety implications if findings are not acted on	Non-compliance with national standards with significant risk to patients if unresolved Multiple complaints/ independent review Low performance rating Critical report	Totally unacceptable level or quality of treatment/service Gross failure of patient safety if findings not acted on Inquest/ombudsman inquiry Gross failure to meet national standards
Human resources /organisational development/ staffing/ competence	Short-term low staffing level that temporarily reduces service quality (< 1 day)	Low staffing level that reduces the service quality	Late delivery of key objective/ service due to lack of staff Unsafe staffing level or competence (>1 day) Low staff morale Poor staff attendance for mandatory/key training	Uncertain delivery of key objective/service due to lack of staff Unsafe staffing level or competence (>5 days) Loss of key staff Very low staff morale No staff attending	Non-delivery of key objective/service due to lack of staff Ongoing unsafe staffing levels or competence Loss of several key staff No staff attending mandatory training /key training on an

3 -1		ID No. CORP/POL/605
Revision No: 1.2 Next Review Date: 28/10/2020		Title: Management of Incidents, Incorporating Serious Incidents
Do you have the up to date version? See the intranet for the latest version		

Appendix 2: Incident Grading Process

INCIDENT GRADING PROCESS

				mandatory/ key training	ongoing basis
Statutory duty / inspections	No or minimal impact or breech of guidance/ statutory duty	Breech of statutory legislation Reduced performance rating if unresolved	Single breech in statutory duty Challenging external recommendations/ improvement notice	Enforcement action Multiple breeches in statutory duty Improvement notices Low performance rating Critical report	Multiple breeches in statutory duty Prosecution Complete systems change required Zero performance rating Severely critical report
Adverse publicity/ reputation	Potential for public concern	Local media coverage – short-term reduction in public confidence Elements of public expectation not being met	Local media coverage – long-term reduction in public confidence	National media coverage with <3 days service well below reasonable public expectation	National media coverage with >3 days service well below reasonable public expectation. MP concerned (questions in the House) Total loss of public confidence
Business objectives/ projects	Insignificant cost increase/ schedule slippage	<5 per cent over project budget Schedule slippage	5–10 per cent over project budget Schedule slippage	Non-compliance with national 10–25 per cent over project budget Schedule slippage Key objectives not met	Incident leading >25 per cent over project budget Schedule slippage Key objectives not met
Finance including claims	Small loss Risk of claim remote	Loss of 0.1–0.25 per cent of budget Claim less than £10,000	Loss of 0.25–0.5 per cent of budget Claim(s) between £10,000 and £100,000	Uncertain delivery of key objective/Loss of 0.5–1.0 per cent of budget Claim(s) between £100,000 and £1 million Purchasers failing to pay on time	Non-delivery of key objective/ Loss of >1 per cent of budget Failure to meet specification/ slippage Loss of contract / payment by results Claim(s) >£1 million
Service/business interruption Environmental impact	Loss/interruption of >1 hour Minimal or no impact on the environment	Loss/interruption of >8 hours Minor impact on environment	Loss/interruption of >1 day Moderate impact on environment	Loss/interruption of >1 week Major impact on environment	Permanent loss of service or facility Catastrophic impact on environment

Blackpool Teaching Hospitals NHS Foundation Trust		spitals NHS Foundation Trust	ID No. CORP/POL/605	
	Revision No: 1.2	Next Review Date: 28/10/2020	Title: Management of Incidents, Incorporating Serious Incidents	
	Do you have the up to date version? See the intranet for the latest version			

Appendix 3: Standard Operating Procedure (SOP) and Guidance Note for Establishing if an Incident is a Never Event

An incident should be declared as a potential Never Event if the incident meets all the criteria given below:

- The incident was wholly preventable where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and have been implemented by the Trust.
- The incident had the potential to cause serious patient harm or death. However, serious harm or death does not need to have happened as a result of the specific incident.
- There is evidence that the Never Event has occurred in the past for example, through reports to the National Reporting and Learning System (NRLS) – and that the risk of recurrence remains.

Never Events and exclusions are detailed in the Never Events list 2018 (January 2018) on the NHS Improvement website:

https://improvement.nhs.uk/documents/2266/Never_Events_list_2018_FINAL_v 5.pdf and this list should be consulted in order to declare a potential Never Event.

Ward / Departmental manager or Matron informs Quality Manager (QM). Associate Director of Nursing (ADON) and Divisional Director (DD), who will contact the Incident and Risk Management Team, Director of Nursing and Quality (DONQ) and Medical Director (MD), who will review the incident against the above criteria and either:

- 1) Declare a Never Event, in which case a 72-hour review and a formal investigation will be initiated (on direction of the DONQ and/or MD, or their deputy), or,
- 2) De-escalate the incident, in which case the Standard Operating Procedure (SOP) and guidance notes for reporting & managing incidents will be followed.

Feedback and advice will be provided to the Divisional Triumvirate.

Appendix 4: Standing Operating Procedure (SOP) and Guidance Notes for Reporting and Investigating Incidents

STANDARD OPERATING PROCEDURE (SOP) AND GUIDANCE NOTES FOR REPORTING AND INVESTIGATING INCIDENTS



If you think it is an incident, report it



- 1) Make sure you, patients and other persons are safe.
- 2) Where safe to do so, take immediate reasonable actions to ensure no further incidents can happen and/or minimise ongoing risk.
- 3) Provide initial care, treatment and support to those affected by the incident.
- 4) Inform your manager of the incident straight away and submit an incident report as soon as possible <u>within 24 hours</u>:
- Brief description of the incident / describe facts.
- No names / patient identifiable information in the incident description.
- What you believe is the level of ACTUAL harm (not potential harm).
- Document the immediate actions taken on the incident reporting system.



Ward/area manager to review the incident, confirm or amend the level of harm and investigate / escalate as appropriate within the divisional hierarchy, or, when out of hours, escalate to the Senior Manager / Director on call / Out of Hour Manager On Call (ALTC)

No harm / near miss

Minimal harm

Moderate harm

Severe harm / death / Never Event

Some ground principles with regards to investigating incidents (Standard Operating Procedures for investigations outlined on pages below):

- Take it very seriously; more often than not, there is a fellow human being at the centre of the incident, who may have been harmed.
- Investigate promptly and thoroughly.
- Focus on learning with the aim to preventing or minimising an incident of a similar kind from occurring again.
- Support colleagues affected by the incident.
- Seek advice and help communicate with the Incident and Risk Management Team, who can provide help and support.

Blackpool Teaching Hospitals NHS Foundation Trust

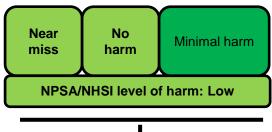
Revision No: 1.2

Next Review Date: 28/10/2020

Do you have the up to date version? See the intranet for the latest version

Appendix 4: Standing Operating Procedure (SOP) and Guidance Notes for Reporting and Investigating Incidents

STANDARD OPERATING PROCEDURE (SOP) AND GUIDANCE NOTES FOR **REPORTING & MANAGING INCIDENTS**





Ward / area / department manager to investigate (or delegate investigation), introduce learning, provide feedback to staff and update / complete the incident on the Trust Risk Management system within 20 working days from the date of the incident having been reported. Attach evidence of learning to the Trust Risk Management System to ensure audit trail / evidence of learning + complete 'lessons learned' section.

Next Review Date: 28/10/2020

Do you have the up to date version? See the intranet for the latest version

Appendix 4: Standing Operating Procedure (SOP) and Guidance Notes for Reporting and Investigating Incidents

Moderate harm

Duty of Candour (Regulation 20) applies

Ward / area / department manager or Matron informs QM, ADON and DD, who will contact the Incident and Risk Management Team to discuss and agree the next steps. When out of hours, escalate to the Senior Manager / Director on call / Out of Hour Manager On Call (ALTC)



Clock starts ticking: 10 working days for DoC and 20 working days for the investigation (if level of harm confirmed) to be completed

If level of harm confirmed: initiate Duty of Candour in line with Regulation 20 / Trust Policy – letter of apology + explanation of next steps to be completed and send out to patient or family by day 10



Ward / area / department manager, Matron or Doctor to carry out 72-hour review (use Trust template); Quality Check (QC) by QM, then ADON or DD before forwarding to the Incident and Risk Management Team for QC and final sign-off by DDQG or DDON (or their deputy). Upload final, approved report to the Trust Risk Management system. At this point, the 72-hour review may also be accepted as the conclusive investigation report



If a further investigation beyond the 72 hour review is required, the ADON and DD appoint investigation lead and support this person to carry out an After Incident Review (AIR). The AIR report (including Plan of Action) will be scrutinised and quality checked by the QM / ADON / DD within 15 working days, before further quality checking by the Incident and Risk Management Team and final sign-off by the DDQG or DDON (or their deputy) by working day 20.



Division to upload AIR report and Plan of Action on the Trust Risk Management system and on the Divisional Investigation Log. Divisional Log will be monitored by the Divisional Triumvirate to ensure pro-active and timely management of investigations and actions within the Division.

Blackpool Teaching Hospitals NHS Foundation Trust

Revision No: 1.2

Next Review Date: 28/10/2020

Next Revision Po you have the up to date version? See the intranet for the latest version

Appendix 4: Standing Operating Procedure (SOP) and Guidance Notes for Reporting and Investigating Incidents

Severe harm / death

Duty of Candour (Regulation 20) applies

NPSA/NHSI level of harm: Severe harm / death *StEIS reportable*

Ward / area / department manager or Matron informs Quality Manager (QM), ADON and DD, who will contact the Incident and Risk Management Team to discuss and agree the next steps. When out of hours, escalate to the Senior Manager / Director on call / Out of Hour Manager On Call (ALTC).



Clock starts ticking: 10 working days for DoC and 60 working days for the investigation to be completed

If level of harm confirmed: initiate Duty of Candour in line with Regulation 20 / Trust Policy – letter of apology + explanation of next steps to be completed and send out to patient or family by day 10



Ward /area / department manager, Matron or Doctor to carry out 72-hour review (Trust template); Quality Check (QC) by QM, then ADON or DD before forwarding to the Incident and Risk Management Team. DDQG or DDON to QC before final sign-off by DONQ or MD. Upload final, approved version to the Trust Risk Management system.



Risk Management Team to inform CQC and CCG + upload to StEIS

ADON and DD appoint investigation lead and this support person to carry out a Root Cause Analysis (RCA) + set date for RCA Panel. Create a Tactical Implementation Plan (TIP) to evidence timely progress and update on actions. The RCA report (including Plan of Action) will be scrutinised, quality checked and submitted by the QM and the ADON / DD within 50 working days. There will be a further quality check by the Incident and Risk Management Team and/or DDQG or DDON prior to the Safety Panel. Following agreement at the Safety Panel, the report will then be forwarded to the DONQ and MD for final checking before Executive sign-off by day 59 at the latest, so the report can be received by the CCG by day 60



Division to upload investigation report and Plan of Action on the Trust Risk Management System and on Divisional Investigation Log (*suggested template attached p. 3*). Divisional Log will be monitored by the Incident and Risk Management Team / DDQG, to ensure proactive and timely management of investigations and actions.

Blackpool Teaching Hospitals NHS Foundation Trust

ID No. CORP/POL/605

Title: Management of Incidents, Incorporating

Revision No: 1.2

Next Review Date: 28/10/2020

Serious Incidents

Appendix 5: Standard Operating Procedure (SOP) and Guidance Notes for 72 Hour Review

STANDARD OPERATING PROCEDURE (SOP) AND GUIDANCE NOTES FOR 72-HOUR REVIEW

72-hour review:

- Create a clear and comprehensive chronological timeline with no gaps be factual
- Identify immediate and ongoing risks
- Identify immediate actions to mitigate the risk
- Confirm or re-assign the level of harm
- Identify if there is a need to progress to RCA investigation. If not, document reason why
- If required, collect statements from staff / patient / family as soon as possible (use Trust template)
- Quality Check (QC) by QM, then ADON or DD before forwarding to the Incident and Risk Management Team for QC and final sign-off by DDQG or DDON (or their deputy).
- Once approved, QM to upload the final version of the 72-hour review to Ulysses

**The 72 hour review is required to be completed (i.e. report with the Incident and Risk Management Team) within 72 hours (3 days) of the incident occurring.

Please note: the Trust may share the 72 hour review report as a conclusive investigation report with the patient/NoK/family and external agencies, so please ensure a high-quality, presentable report, written for the lay-person to understand**

72 HOUR REVIEW TEMPLATE

GLOSSARY OF TERMS / ACRONYMS

- ADON = Associate Director of Nursing
- DD = Divisional Director
- **DDON** = Deputy Director of Nursing
- **DDQG** = Deputy Director of Quality Governance
- DONQ = Director of Nursing and Quality
- MD = Medical Director
- QC = Quality Check
- QM = Quality Manager

		ID No. CORP/POL/605
Revision No: 1.2	Next Review Date: 28/10/2020	Title: Management of Incidents, Incorporating Serious Incidents
D	o you have the up to date version? S	ee the intranet for the latest version

Appendix 6: Standard Operating Procedure (SOP) for Duty of Candour

STANDARD OPERATING PROCEDURE (SOP) FOR DUTY OF CANDOUR

Notify patient / Next of Kin (NOK) / family (the 'relevant person/s') that the incident has occurred:

The notification must be verbal, by an appropriate person, either by the Divisional Director (or a delegated deputy) for moderate harm incidents or the Medical Director (or deputy) / Director of Nursing and Quality (or deputy) for severe harm / death incidents. This should include as much or as little information as the relevant person/s wants to hear, be jargon free and explain any complicated terms. The account of the facts must be given in a manner that the relevant person can understand and should include all or some of the following:

- Treat the relevant person/s with respect, consideration and empathy.
- Offer the option of direct emotional support during the notifications, for example from a family member, a friend, a care professional or a trained advocate.
- Offer help to understand what is being said, for example, through an interpreter, non-verbal communication aids, written information, Braille etc.
- Provide access to any necessary treatment and care to recover from or minimise the harm caused where appropriate.
- Provide the relevant person/s with details of specialist independent sources of practical advice and support or emotional support/counselling.
- Provide the relevant person/s with information about available impartial advocacy and support services, their local Healthwatch and other relevant support groups, for example Cruse Bereavement Care and Action against Medical Accidents (AvMA), to help them deal with the outcome of the incident
- Arrange for care and treatment from another professional, team or provider if this is possible, if the relevant person wishes.
- Provide support to access the complaints procedure

Record the conversation on the Trust template and summarise the conversation with the relevant person/s in a formal letter (the 'written notification') to them, which needs to be sent to the relevant person/s **no later than 10 workings days after the incident occurred**. The written notification must contain all the information that was provided in person, including an apology, as well as the results of any enquiries that have been made since the notification in person.

The outcomes or results of any further enquiries and investigations must also be provided in writing to the relevant person through further written notifications, if they wish to receive them. The Trust offers to meet with the relevant person/s to explain the outcomes or results of any further enquiries and investigations

Upload the record of the conversation and the written notification to the relevant person/s onto the Incident Reporting system and indicate on the Incident Reporting system that Duty of Candour has been exercised.

		ID No. CORP/POL/605
Revision No: 1.2	Next Review Date: 28/10/2020	Title: Management of Incidents, Incorporating Serious Incidents
D	o you have the up to date version? S	ee the intranet for the latest version

Appendix 7: Standard Operating Procedure (SOP) and Guidance Notes for After Incident Review

STANDARD OPERATING PROCEDURE (SOP) AND GUIDANCE NOTES FOR AFTER INCIDENT REVIEW (AIR)

After Incident Review (AIR)

(Moderate Harm incidents, incident trends / cluster reviews, or <u>some</u> near miss incidents):

- The After Incident Review (AIR) process is a structured approach to undertaking a de-brief and a constructive way of identifying lessons identified from the incident. The After Incident Review (AIR) follows the same principles of the 'After Action Review', which was first used by the US army on combat missions to reflect on the work of a group and identifying strengths, weaknesses and areas for improvement.
- An AIR is constructed of four questions:
 - 1. What was expected to happen?
 - 2. What actually occurred?
 - 3. Why was there a difference?
 - 4. What can be learned?
- Once the AIR report has been produced, the process for Quality Checking (QC) and final sign-off will be as follows: AIR report scrutinised and quality checked by the QM / ADON / DD within 15 working days, before further quality checking by the Incident and Risk Management Team and final signoff by the DDQG or DDON (or their deputy) by working day 20.

- ** Complete the AIR investigation (including final QC and sign-off by ADON/DD) within 15 working days of the incident from occurring; this will include the SMART Plan of Action.

Please note: the Trust endeavours to share the AIR report with the patient/NoK/family and external agencies, so please ensure a high-quality, presentable report, written for the lay-person to understand**

Appendix 7: Standard Operating Procedure (SOP) and Guidance Notes for After Incident Review

http://fcsp.xfyldecoast.nhs.uk/C/clinicalqovernance/riskmanagement/SUI%20Reports/1.1AAR%20Fact%20Sheet.pdf

http://fcsp.xfyldecoast.nhs.uk/C/clinical-governance/riskmanagement/SUI%20Reports/AIR%20debrief.pdf

http://fcsp.xfyldecoast.nhs.uk/C/clinical-governance/riskmanagement/SUI%20Reports/2.TOR%20AIR%20v1%2006.11.2018.doc

http://fcsp.xfyldecoast.nhs.uk/C/clinical-governance/riskmanagement/SUI%20Reports/Levels%20of%20Harm%20-%2021.10.2019.pdf

Appendix 8: Standard Operating Procedure (SOP) and Guidance Notes for Root Cause Analysis (RCA)

STANDARD OPERATING PROCEDURE (SOP) AND GUIDANCE NOTES FOR ROOT CAUSE ANALYSIS (RCA)

Root Cause Analysis (RCA) investigation

(Severe Harm or Death, or some Moderate Harm / Near Miss incidents):

- Purpose is to identify (root) causes for the incident and identify learning to prevent / minimise a similar incident from happening again
- Create a Tactical Implementation Plan (TIP) use template
- Use the information of the 72-hour review as a basis for the RCA Level 2
- Be open and transparent
- Compose a chronological timeline, with no gaps be factual
- Collect statements from staff / patient / NoK / family as soon as possible (use Trust template) – ideally within 72 hours
- Involve the patient/family in the investigation process / keep them up to date
- Organise an RCA Panel Review Meeting at the earliest opportunity; invite at least one independent panel member
- Conclude the investigation, describe root cause/s and suggest recommendations
- Create a Plan of Action; requires SMART (<u>Specific</u>, <u>Measurable</u>, <u>Attainable</u>, <u>Relevant and Time-bound</u>) actions – it is *not* about number of actions, it is about quality of actions
- Quality Check (QC) process: Matron / area / department manager → QM
 → ADON / DD → Incident and Risk Management Team / DDQG or DDON
 → Safety Panel → DONQ / MD → Executive sign-off
- Once approved (Executive sign-off), QM to upload the final version of the RCA the Trust Risk Management System + upload to the Divisional Investigation Log
- DONQ / MD to contact the patient/NoK/family to inform them that the investigation has concluded (use Trust template to draft a personalised letter). Arrange for the report to be shared with the patient/NoK/family, in line with their preference + offer a meeting
- Implement actions + audit compliance with any new processes / guidance introduced
- Share learning with colleagues within the Division and with other Divisions

** Complete the RCAinvestigation (including final QC and sign-off by ADON/DD) within 50 working days of the incident from occurring; this will include the SMART Plan of Action.

Please note: the Trust endeavours to share the RCA report with the patient/NoK/family and external agencies, so please ensure a high-quality, presentable report, written for the lay-person to understand**

RCA LEVEL 2 TEMPLATE

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/POL/605
Revision No: 1.2	Next Review Date: 28/10/2020	Title: Management of Incidents, Incorporating Serious Incidents
D	o you have the up to date version? S	ee the intranet for the latest version

Appendix 9: Ground Rules and Guidance Notes for Investigating Incidents (Incorporating 72 Hour Review, AIR and RCA)

GROUND RULES AND GUIDANCE NOTES FOR INVESTIGATING INCIDENTS (INCORPORATING 72-HOUR REVIEW, AIR AND RCA)

General ground rules and guidance notes:

- Ensure all relevant Senior Managers / Directors have been notified. When out of hours, escalate to the Senior Manager / Director on call
- Seek advice and help communicate with the Risk Management Team, who can provide he and support
- Keep all relevant Senior Managers / Directors up to date
- Before communicating with external agencies (e.g. CQC, CCG, Coroner, NHSI etc.), liaise
 with the relevant Senior Manager / Director (when out of hours, discuss with the Senior
 Manager / Director on call / Out of Hour Manager On Call (ALTC))
- Take it very seriously more often than not, there is a fellow human being at the centre of this, who may have been harmed
- If required, collect statements from staff / patient / NoK / family as soon as possible (use Trust template) ideally within 72 hours
- Investigate promptly and thoroughly
- Be open and transparent
- Focus on learning preventing or minimising an incident of a similar kind from occurring
- Support patient / family / colleagues affected by the incident / keep them informed
- Seek advice and help communicate with the Risk Management Team, who can provide help and support
- Be timely with your investigation; stick to timescales
- Conclude the investigation, describe root cause/s and suggest recommendations
- Ensure the report is of a high-quality, presentable standard, free from spelling and grammatical mistakes
- Create a Plan of Action; requires SMART (Specific, Measurable, Attainable, Relevant and Time-bound) actions – it is not about number of actions, it is about quality of actions
- Stick to the Quality Check (QC) process
- Upload all relevant information / report onto Ulysses + complete 'lessons learned' section

Ground rules and guidance notes for Plans of Actions:

- Plan of Action requires SMART (Specific, Measurable, Attainable, Relevant and Time-bound actions
- It is not about number of actions, it is about quality of actions
- Implement actions + audit compliance with any new processes / guidance introduced
- Share learning with colleagues within the Division and with other Divisions

Ground rules and guidance notes for post-investigation actions:

- Provide ongoing proportionate support to patient / family / NoK / colleagues affected by the incident
- Inform the patient / NoK / family to inform them that the investigation has concluded (use Tru
 template to draft a personalised letter). Arrange for the report to be shared with the patient /
 NoK / family, in line with their preference + offer a meeting relevant staff to ensure they
 prioritise availability for such meeting

Appendix 10: Supporting Documents			
Tactical Implementation Plan (TIP) template	http://fcsp.xfyldecoast.nhs.uk/C/clinical- governance/riskmanagement/SUI%20Reports/Tactical%20I mplementation%20sheet.xls		
Investigation Log template	http://fcsp.xfyldecoast.nhs.uk/C/clinical- governance/riskmanagement/SUI%20Reports/Open%20RC As%20schedule%20template.xlsx		
72-hour review template	http://fcsp.xfyldecoast.nhs.uk/C/clinical- governance/riskmanagement/SUI%20Reports/72%20hour% 20Rapid%20Review%20Template%20310519.docx		
RCA Level 2 template	http://fcsp.xfyldecoast.nhs.uk/C/clinical- governance/riskmanagement/SUI%20Reports/Comprehensi ve%20Serious%20Incident%20Report%20- %20040919.docx		
AIR pack	http://fcsp.xfyldecoast.nhs.uk/C/clinical-governance/riskmanagement/SUI%20Reports/1.1AAR%20Fact%20Sheet.pdf http://fcsp.xfyldecoast.nhs.uk/C/clinical-governance/riskmanagement/SUI%20Reports/2.TOR%20AIR%20v1%2006.11.2018.doc http://fcsp.xfyldecoast.nhs.uk/C/clinical-governance/riskmanagement/SUI%20Reports/AIR%20Review%20Report%20Template%20final.doc http://fcsp.xfyldecoast.nhs.uk/C/clinical-governance/riskmanagement/SUI%20Reports/AIR%20debrief.pdf http://fcsp.xfyldecoast.nhs.uk/C/clinical-governance/riskmanagement/SUI%20Reports/Levels%20of%20Harm%20-%2021.10.2019.pdf http://fcsp.xfyldecoast.nhs.uk/C/clinical-governance/riskmanagement/SUI%20Reports/Incident%20Grading%20-%2024.10.2019.pdf		

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/POL/605
Revision No: 1.2	Next Review Date: 28/10/2020	Title: Management of Incidents, Incorporating Serious Incidents
De	o you have the up to date version? S	ee the intranet for the latest version

Appendix 11: Equality Impact Assessment Form					
Department	Clinical Risk	Service or Policy	CORP/POL/605	Date Completed:	20/08/2019
	Department				

GROUPS TO BE CONSIDERED

Deprived communities, homeless, substance misusers, people who have a disability, learning disability, older people, children and families, young people, Lesbian Gay Bi-sexual or Transgender, minority ethnic communities, Gypsy/Roma/Travellers, women/men, parents, carers, staff, wider community, offenders.

EQUALITY PROTECTED CHARACTERISTICS TO BE CONSIDERED

Age, gender, disability, race, sexual orientation, gender identity (or reassignment), religion and belief, carers, Human Rights and social economic / deprivation.

QUESTION	RESPONS	IMPACT		
	Issue	Action	Positive Ne	egative
What is the service, leaflet or policy development? What are its aims, who are the target audience?	The Management of Incidents, Incorporating Serious Incidents policy details the Trust's process for the reporting of and investigation of all untoward incidents and serious incidents occurring within the Trust.		Yes – Compliance with this policy will ensure the reporting and investigation of all untoward incidents and the sharing of lessons learned from these incidents.	
Does the service, leaflet or policy/ development impact on community safety Crime Community cohesion	The policy is relevant to the safety of all staff within the Trust and in the community.		Yes	
Is there any evidence that groups who should benefit do not? i.e. equal opportunity monitoring of service users and/or staff. If none/insufficient local or national data available consider what information you need.	No. This policy should ensure a positive impact across all groups of staff and patients.		Yes	
Does the service, leaflet or development/ policy have a negative impact on any geographical or sub group of the population?	No		Yes	
How does the service, leaflet or policy/ development promote equality and diversity?	Defines the standardised process to be followed in the event of an untoward incident.		Yes	
Does the service, leaflet or policy/ development explicitly include a commitment to equality and diversity and meeting needs? How does it demonstrate its impact?	The Policy includes a completed EA which provides the opportunity to highlight any potential for a negative / adverse impact.		Yes	
Does the Organisation or service workforce reflect the local population? Do we employ people from disadvantaged groups	Our workforce is reflective of the local population.		Yes	
Will the service, leaflet or policy/ development i. Improve economic social conditions in deprived areas ii. Use brown field sites iii. Improve public spaces including creation of green spaces?	No	N/A	N/A	
Does the service, leaflet or policy/ development promote equity of lifelong learning?	No	N/A	N/A	

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/POL/605
Revision No: 1.2	Next Review Date: 28/10/2020	Title: Management of Incidents, Incorporating Serious Incidents
D	o you have the up to date version? S	ee the intranet for the latest version

Appendix 11: Equality	Impact Assessment Fo	orm			
Does the service, leaflet or policy/ development encourage healthy lifestyles and reduce risks to health?	The procedure identifies the process in relation to reporting, investigating and learning from incidents which occur within the Trust which will result in improving the safety of our patients and staff.	Persons working the Trust are pro with adequate tra order to ensure understanding of process to be fol	vided aining in the lowed.	es	
Does the service, leaflet or policy/ development impact on transport? What are the implications of this?	No	N/A		I/A	
Does the service, leaflet or policy/development impact on housing, housing needs, homelessness, or a person's ability to remain at home?	This policy will have an impact on all members of staff working in the Trust and patients in their care.		Y	es	
Are there any groups for whom this policy/ service/leaflet would have an impact? Is it an adverse/negative impact? Does it or could it (or is the perception that it could exclude disadvantaged or marginalised groups?	The Policy promotes access to information for all members of staff in the Trust.	N/A	Y	es	
Does the policy/development promote access to services and facilities for any group in particular?	No	N/A	N	I/A	
Does the service, leaflet or policy/development impact on the environment • During development	No				
At implementation?					
	ACTION:				
Please identify if you are now require Analysis		Yes	No	,	se delete as opriate)
Name of Author: Ste Signature of Author:	fan Verstraelen		Date S	igned:	20/08/2019
Name of Lead Person: Signature of Lead Person:			Date S	igned:	
Name of Manager: Pet Signature of Manager	er Murphy		Date S	igned:	20/08/2019

Blackpool Teaching Hospitals NHS Foundation Trust Revision No: 1.2 Next Review Date: 28/10/2020		ID No. CORP/POL/605 Title: Management of Incidents, Incorporating Serious Incidents
	o you have the up to date version? S	1 0 0 1 1 0 0 0 1 1 1 1 1 1 1 1 1 1 1 1