Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

Clinical Harm Review Policy

This is a new procedural document, please read in full

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Executive Sponsor(s):	Medical Director
Author/reviewer: (this version)	Denise Smith, Chief Operating Officer
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Target audience:	Trust-wide

Amendment Form

Please record brief details of the changes made alongside the next version number. If the procedural document has been reviewed **without change**, this information will still need to be recorded although the version number will remain the same.

Version	Date Issued	Brief Summary of Changes	Author
Version 1	November 2023	• This is a new procedural document, please read in full	Denise Smith
Version 1.2	October 2024	Amended to include patient safety event decision response flow (appendix 5)	Julie Butler

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Quick reference

Patient pathway	Tolerance to trigger a harm review	Other actions to be taken
Patients whose planned surgery is cancelled on the day	Any patient whose planned surgery is not rescheduled to occur within 28 days	Thematic review as well as Clinical Harm Review
Patients on 62 day Cancer pathway	Any patient on a 62 day cancer pathway who breaches 104 days for a pathway completion	Thematic review as well as Clinical Harm Review
Patients on P2 admitted pathway	Any patient who exceeds 8 weeks	Clinical prioritisation as well as Clinical Harm Review, no Thematic Review required Where harm suspected to be associated with current and/or projected wait, case to be reviewed against FSSA guidance to upgrade to next pathway unless date booked. Referral signposting to wellbeing service where psychological harm identified.
Patients on P3 admitted pathway	Any patient who exceeds 6 months	Clinical prioritisation as well as Harm Review Assessment or Clinical Harm Review if required, no Thematic Review required Where harm suspected to be associated with current and or projected wait, case to be reviewed against FSSA guidance to upgrade to next pathway unless date booked Referral signposting to wellbeing service where psychological harm identified.
Patients on P4 admitted pathway	Any patient who exceeds 12 months	Clinical prioritisation as well as Harm Review Assessment or Clinical Harm Review if required, no Thematic Review required

		Where harm suspected to be associated with current and or projected wait, case to be reviewed against FSSA guidance to upgrade to next pathway unless date booked Referral signposting to wellbeing service where psychological harm identified.
Patients whose wait has exceeded 104 weeks on an RTT pathway	Any patient who exceeds 104 weeks RTT	Clinical Harm Review, no Thematic Review required

1 INTRODUCTION

A Clinical Harm Review process is an important element within the Trust's governance framework, requiring senior clinical involvement and oversight.

COVID-19 has had a severe impact on elective services and subsequently the volume of patients who have had very long waits has increased significantly. This reinforces the need for a robust clinical harm review process that is widely understood across the Trust and that seamlessly fits with the risk and governance structure, to minimise the risk of patient harm.

Despite the challenges in elective care currently there are key principles of waiting list management that remain

- Clinicians should clinically prioritise patients when booking follow up appointments, ordering tests, and adding patients to the admitted waiting list
- Clinicians should set due dates for patients added to planned and follow-up waiting lists
- Patients should be booked in clinical priority and then waiting time order
- Patients with excessive waits relative to their clinical priority are at risk of harm.

If the above processes are in place, Trusts, for the first time, have a clinically risk stratified admitted waiting list which provides greater context for clinicians to identify where harm may have occurred or has the potential to occur.

2 PURPOSE

The purpose of the policy is to:

- Standardise the approach across the Trust to clinical harm review
- Implement agreed triggers for clinical harm reviews to be undertaken for each priority code
- Implement agreed definitions of levels of physical and psychological harm in relation to long waiting patients
- Ensure that patients are treated in order of clinical priority and those of the same clinical priority are treated in chronological order of their waiting time
- Ensure all patients who have excessive waits for treatment on an admitted pathway are assessed by an appropriately trained Healthcare Professional to identify if they are experiencing physical or psychological harm
- Ensure that appropriate action is taken where harm is identified and that patients are re-prioritised in line with the national coding system in order to prevent anticipated harm
- Signpost patients to help and support whilst waiting (e.g. wellbeing service)
- ensure learning is recorded and remedial actions taken as stated in this policy, to reduce harm to patients and to avoid similar issues in the future

- identify high risk patient pathways across the Trust to inform clinicians of patients who have a potential to incur significant harm as a result of an excessive wait

This policy covers all patient groups, adult and children, and covers the following pathways:

- admitted waiting list

This policy does not cover patients on elective non-admitted (outpatient or diagnostic) pathways.

However, where patients on non-admitted pathways are identified as having come to harm or suspected harm due to prolonged waits, responsible clinicians are required to use the same definitions of harm and to follow the standard Trust incident management policy.

3 DUTIES AND RESPONSIBILITIES

Chief Executive Officer (CEO)
Overall responsibility on behalf of the Trust board to ensure resources, policies and procedures are in place, for the effective reporting, recording and investigation of clinical harm and changes in prioritisation if harm or potential harm is identified suitable arrangements established to support staff

In practice the CEO delegates the day to day responsibility to relevant executive directors and heads of departments

Medical Director or Delegated Deputy
To establish and maintain a harm review group; holding monthly meetings, to ensure that the Trust is managing both cancer and non-cancer patients according to clinical priority and duration of wait, identifying those patients at risk from harm in line with this policy.

Chief Operating Officer or Delegated Deputy
To ensure that the Trust is following the approved standardised clinical harm review process
To implement trust-wide systems and processes, to monitor and report compliance against all waiting time standards and ensure adherence with this policy

Divisional Leadership Team
Have the overall responsibility for implementing and adherence to this policy within their division

Ensuring oversight, escalation and implementation of actions required to manage or mitigate risks and issues for patients exceeding waiting time thresholds within their division

Ensuring all staff operationalise this policy and receive training so that they can meet the policy requirements

Responsible Healthcare Professional / Consultant
All Healthcare Professionals are responsible for reporting patients in whom they suspect harm has occurred in line with policy

Consultants or their delegated deputies are responsible for actively identifying patients who may have suffered harm due to excessive waits on all pathways in conjunction with the Operational Manager

Consultants or their delegated deputies must take necessary mitigating actions to minimise further harm to the patient

Consultants or their delegated deputies must report and grade all confirmed or potential harms to patients in line with this policy (see appendix 1)

Consultants or their delegated deputies are required to assist with an investigation if required and undertake a Thematic Review to determine the cause of delays and harm to the patient.

Consultants are responsible for all relevant communication with the patient including Being Open and Duty of Candour requirements in accordance with Trust Policy

All healthcare professionals are required to assist with appropriate sharing of learning

Clinical Harm Review Group (CHR)
The CHR group is responsible for developing, approving and following a local standard operating procedure (SOP) in line with this policy

The CHR group will monitor compliance with the local SOP across all specialities

The CHR group will provide local intelligence and learning from harm review activity to include high risk pathways, reprioritisation activity, and emerging risk areas to inform the relevant Trust Governance Committee and its constituent work streams as requested

4 POLICY PRINCIPLES

4.1 Why is Clinical Harm Review Required?

The Clinical harm review (CHR) and Harm Review Assessment (HRA) are to assess the impact of the waiting time on both the physical and psychological status of the patient against their condition and presentation of symptoms and functional level at their original referral. They aim to answer two key questions – has the patient come to harm due to the wait so far, and are they at risk of harm from the anticipated wait?

The clinical harm review is not about allocating blame, but about identifying where and why delays have occurred and whether those delays have resulted in clinical harm. The results should support future learning, improved risk assessment and process improvements so that patients at risk of ongoing/future harm can be identified in advance and care prioritised in order to prevent harm occurring. (NHSE June 2021)

4.2 Why is Thematic Review Required?

The Thematic Review aims to determine the reasons behind a delay to a patient's care, in order to learn from this and to prevent similar delays (and hence harms) in future.

4.3 When to undertake a Clinical Harm Review or Root Cause Analysis

Summary of when to undertake a Clinical Harm Review and or Thematic Review is outlined in appendix 2.

A Clinical Harm Review and Thematic Review should be undertaken when a patient whose planned surgery is cancelled on the day and is unable to be rebooked within 28 days, and when a patient on a 62 day cancer pathway completes their treatment beyond 104 days.

A Clinical Harm Review should also be undertaken when a patient on a 62-day cancer pathway exceeds 62 days.

A Clinical Harm Review should also be undertaken when a patient on a P2 pathway exceeds 8 weeks (and every 4 weeks thereafter until they undergo their treatment).

A Clinical Harm Review should be undertaken when a patient on a P3 pathway exceeds 6 months (and every 3 months thereafter until they undergo their treatment).

A Clinical Harm Review should be undertaken when any patient on any pathway exceeds 52 weeks RTT (and every 3 months thereafter until they undergo their treatment).

All Clinical Harm Reviews are to be undertaken within 3 weeks of the date the patient wait exceeds the patient waiting time trigger points.

A Clinical Harm Review can also be undertaken at any point during the patient's pathway, including at patient or General Practitioner (GP) request to consider expediting a treatment, as well as during routine review appointments, and at set points on the patient pathway.

4.4 Who can undertake a Clinical Harm Review

The Consultant in charge of the patient's care can undertake the Clinical Harm Review and matrix assessment (appendix 3) when the patient is physically reviewed. However, this review may be delegated to an appropriately trained and experienced healthcare professional and may also be supplemented by screening tools (harm review assessments) in line with local SOPs. The treating clinician is responsible for deciding and documenting who is clinically competent to complete the Clinical Harm Review and matrix assessment either autonomously or under supervision for each condition as well as approving the method used in line with local SOP.

4.5 Clinical Harm Review Process

The patient's health records are reviewed to identify previously assigned priority category (if present) and any other pertinent information. This could be in an outpatient setting, telephone consultation, at referral (e.g. referral from another NHS provider), pre- operatively, on receipt of further information from the GP or patient, or during monitoring and follow up of a condition.

The following points are to be considered:

- Has the current wait induced physical or psychological harm? (set harm rating)
- Does any immediate action need to be taken, e.g. signposting to wellbeing service or referral for psychological support if low harm is identified?
- Will the current priority wait risk harm? (set harm rating)
- Is the patient COVID vulnerable or do they have additional requirements? (Modify place/ intervention/ consent)
- Involvement with the patient shared decision making regarding the level of harm

Where potential or confirmed moderate, severe or catastrophic harm is identified the patients named consultant is to be informed as soon as is practicably possible.

Mitigation and / or an action plan must be put in place and the incident must be logged on the local Trust incident management system and managed in line with PSIRF Policy. The named Consultant is responsible for Being Open and carrying out the Duty of Candour requirements in accordance with the Trust Policy.

All practicable efforts will be made to contact the patient however, there will be patients that may not respond to correspondence, please refer to the Trust Access Policy.

Any patient waiting a prolonged period of time for a planned procedure may have undergone a degree of psychological harm, and if this is apparent, it should be graded in line with the definitions in appendix 1.

However, for patients on cancer pathways, an initial screening question may be used: do you consider that your mental health has been affected by how long you have had to wait for your treatment? If the answer is no, no specific psychological assessment is required. If the answer is yes, it is recommended that two further screening questions are asked – see appendix 4.

4.6 Incorporate patient wishes or new clinical events

A patient may request a delay in investigations and/or treatment that will trigger a change in P code. A new clinical event may also indicate that a further delay is clinically indicated. It is the responsibility of the healthcare professional to explain the risks associated with delaying investigation or treatment.

The decision to delay a patient treatment is at the discretion of the treating clinician in consultation with the patient, based on additional information or clinical events that require postponing of the current surgical order.

In the event a patient's treatment or investigation incurs a delay or the patient is downgraded, it is to be documented in the patients' healthcare records and on the local Trusts patient administration system.

4.7 When and how to conduct a Thematic Review

A Thematic Review is to be undertaken when planned surgery is cancelled on the day and is unable to be rebooked within 28 days, and when a patient on a 62-day cancer pathway completes their treatment beyond 104 days.

The Thematic Review is to include:

- a timeline, set out in chronological order, documenting when the events on the patient's pathway occurred, including referral, patient attendance, diagnostics, decisions and booking dates in order to identify where delays have occurred and the reason they occurred, to support breach analysis
- an assessment of harm, assessing whether the delay has resulted in a change of condition, change of treatment options, or other harm to the patient
- the main cause/s of delay to the patient pathway
- identification of actions to address the causes of delays
- communication to the patient about the length of wait and the plan for treatment as well as appropriate compliance with statutory Duty of Candour.

The completed and approved Thematic Review is to be uploaded onto the incident management system.

The Thematic Review is to be updated and reviewed following the patient's treatment or other clock stop event.

In addition, all cases where a harm review has identified a confirmed moderate harm or above, a full incident investigation and Thematic Review is required in line with the Trusts incident management policy & PSIRF Policy.

4.8 Group Thematic Review

Where there are high volumes of patients (greater than 100) on the same specialty pathway requiring a harm review, a group Thematic Review should be considered to provide key causes of delays. This will enable more effective use of current resources by transferring the emphasis from the quantity of reviews to a higher quality, and a more proportionate response to pathway delays, as a whole.

A sample size of 10% or a minimum of 25 pts of the patients on the pathway is required for a group Thematic Review.

If greater than or equal to 20% of the sample has suffered moderate or above harm, a full Thematic Review is required for each case.

A Group Thematic Review is to incorporate all of the elements in 3.6.

4.9 What to do when harm is identified

Any identified instances of harm must be reported through the Trust incident management system. Any occurrence of harm is to be reported as a Patient Safety Event and follow the local Trusts Patient Safety Event management process. The Trust will confirm the level of harm, the duty of candour requirements and the level of investigation to be undertaken in line with the local Trusts PSIRF Policy.

Where actual or suspected harm, or the potential for harm is identified from the current anticipated waiting times for surgical procedures, the case is to be reviewed in line with the Federation of Surgical Specialty Associations (FSSA) guidance and upgraded to the next or most appropriate priority rating, unless the patient has an appropriate date for their procedure confirmed. See section 7 for more detail and a link to the FSSA guidance.

NB: This policy applies specifically to patients on admitted waiting lists. However, where patients on other waiting lists are identified or suspected of coming to harm due to delays in their care, it is recommended that the same definitions of harm are employed. Standard incident reporting, duty of candour and investigation processes should be used in these cases in line with Trust policy.

4.10 Define level of harm

Harm in healthcare is '*a negative effect, whether or not it is evident to the patient*' (The Health Foundation, 2011). The levels of harm range from no harm to catastrophic harm. The harm is determined by physical and psychological parameters. The level of harm may change at a later date when more information is gained further on in the patient's pathway, in which case patient health records and patient tracking systems must be updated accordingly.

4.11 Definitions of psychological and physical harm

The categorisation of harms summarises the Learning from Patient Safety Events (LFPSE) definitions of harm, and the agreed definitions of physical harm and specific measures of psychological harm are included in appendix 1.

4.12 Clinical prioritisation decision parameters

The principle of all clinical priority categories is time based with respect to urgency of provision. The National Clinical Prioritisation Programme (NCPP) summary (appendix 6) for admitted patients indicates timings within which treatments should ideally take place.

Diagnostic procedures are to be prioritised according to clinical need, rather than waiting time. The responsible healthcare professional is to establish the priority for diagnostics based upon clinical need and impact on quality of life.

Mitigation and / or an action plan must be put in place and the incident must be logged on the local Trust incident management system and managed in line with PSIRF Policy. The named Consultant is responsible for Being Open and carrying out the Duty of Candour requirements in accordance with the Trust Policy.

All practicable efforts will be made to contact the patient however, there will be patients that may not respond to correspondence, please refer to the Trust Access Policy.

Any patient waiting a prolonged period of time for a planned procedure may have undergone a degree of psychological harm, and if this is apparent, it should be graded in line with the definitions in appendix 1.

However, for patients on cancer pathways, an initial screening question may be used: do you consider that your mental health has been affected by how long you have had to wait for your treatment? If the answer is no, no specific psychological assessment is required. If the answer is yes, it is recommended that two further screening questions are asked – see appendix 4.

4.14 Redefining waiting times

The matrix approach aims to refine the clinical priority derived from procedure specific

national categorisations with the outcome of the Clinical Harm Review in order to generate an individualised patient centred prioritisation and redefined waiting time (for treatment intervention and/or subsequent clinical review). However, the length of time an individual has already waited is also important in reviewing and preventing harm. When patients are deemed to be at the same clinical priority after Clinical Harm Review, then Priority 3 or 4 category patients will be assigned treatment / investigation according to date order within their priority group. The matrix of actions to be undertaken on completion of the prioritisation and Clinical Harm Review (appendix 3) is to be used.

Where a patient requests a treatment delay or a new clinical event occurs necessitating delay despite the matrix priority: See section 3.5.1

Please see the Trust Access Policy for the appropriate clinical and administrative approach to these patients.

5 GOVERNANCE

5.1 Incident Reporting

Where clinical harm has been identified, the Trust should ensure these are formally reported through the incident management system and investigated and managed in line with the Trust's PSIRF Policy. Any occurrence of harm should be reported as a Patient Safety Event and follow the Trust's Patient Safety Event management process as outlined at Appendix 5.

5.2 Learning

Learning is to be disseminated within the Trust, at specialty, directorate and division level as applicable.

5.3 Clinical Harm Review Panel/Group

Any identified incidences of harm, as well as a sample of all completed clinical harm reviews are to be reviewed by the Trust's clinical harm review panel / group. It is recommended that an appropriate external clinical or governance representative is included in the panel to provide objective oversight and assurance.

5.4 Thematic Review Oversight

The process for completion of Thematic Reviews should be managed by the senior operational manager for the service and signed off by lead clinician with outcomes subject to review by a senior clinician directly reporting to the Medical Director.

Common themes, key actions and cross department issues should be summarised and shared at monthly access meetings and through the Trust governance structure. Where patients remain untreated following the completion of the Thematic Review, it may need to be updated and re-reviewed following the patient's treatment or other clock stop event.

5.5 Senior Oversight

Numbers of patients exceeding waiting time thresholds, causes of delays and the current management actions being taken should be regularly discussed at executive level to ensure senior awareness of areas of risk, the issues involved, and actions required to be taken.

Waiting list size, trajectory monitoring and breach analysis should be reported and monitored through the Trust elective access meeting.

Clinical Harm Review panel reports, themes identified through the Harm Review Assessment, Clinical Harm Review and Thematic Review processes, and any incidence of harm as a result of extended waits should be reported and discussed at a Trust wide clinical governance forum.

Actions identified to address process and other issues, or training requirements should be included in Trust and specialty-level improvement plans, with an identified lead and delivery timescale, to support monitoring of escalation as required.

5.6 Risk Management

Any key risks identified and learning from Thematic Reviews undertaken must be recorded on the Risk Register with mitigating actions identified to reduce the risk level.

6 REPORTING

The Trust will collect and report monthly to the appropriate governance committee on the following key metrics:

- Number and nature of Moderate / Severe / Catastrophic Harms per specialty and site
- Percentage of patients on an admitted pathway with a documented P code
- Percentage of patients within each P code category in whom the Clinical Harm Review has been carried out in line with standards
- Number of patients whose P code has changed after Clinical Harm Review

7 TRAINING AND COMPETENCIES

All clinical and non-clinical staff involved in Cancer and 18-week RTT pathways will have training in relation to the implementation of this policy.

Additional or remedial training will be provided, as required, and all staff have a responsibility to highlight training needs for themselves or the wider team

Staff should take time to read and fully understand the Policy ensuring that they follow process when required. If clarification is needed, then they should approach their line manager who will arrange additional training if required.

8 MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

What is being Monitored	Who will carry out the Monitoring	How often	How Reviewed/ Where Reported to
Adherence and compliance with the Policy	Divisional Directors / Senior Leadership Teams / Clinical Governance Leads	Monthly	Divisional Governance Meetings
Adherence and compliance with the Policy	Divisional Directors / Senior Leadership Teams / Clinical Governance Leads	Bi-monthly	Patient Safety Committee

9 DEFINITIONS

The following terms and abbreviations have been used within this document:

Term	Definition
2 WW	Two Week Wait
CEO	Chief Executive Officer
CHR	Clinical Harm Review
FSSA	Federation of Surgical Specialty Associations
GP	General Practitioner
HRA	Harm Review Assessment
Healthcare professional	A person associated with either a specialty or a discipline and who is qualified and allowed by regulatory bodies to provide a healthcare service to a patient
Incident management	Datix

system	
ICS / ICB	Integrated Care System / Integrated Care Board
LFPSE	Learning from Patient Safety Events (LFPSE)
NHS	National Health Service
NHSE	NHS England
PAS	Patient Administration System
PTL	Patient Tracking Lists
P Codes	Waiting list prioritisation codes
RTT	Referral To Treatment
SOP	Standard Operating Procedure
ToR	Terms of Reference

10 EQUALITY IMPACT ASSESSMENT

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are disadvantaged over others. Our objectives and responsibilities relating to equality and diversity are outlined within our equality schemes. When considering the needs and assessing the impact of a procedural document any discriminatory factors must be identified.

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Fair Treatment For All Policy (CORP/EMP 4).

The purpose of the EIA is to minimise and if possible remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified. (See Appendix)

11 ASSOCIATED TRUST PROCEDURAL DOCUMENTS

The Federation of Surgical Specialty Associations (FSSA) has published an updated list of standard prioritisations for the commonest surgical specialties. These form the basis for initial P coding for all patients, which should then be informed by the outcome of the clinical harm review as per this policy. The FSSA has also produced multiple guides relevant to individual specialties, which can be accessed through the link in the following:

https://fssa.org.uk/_userfiles/pages/files/covid19/prioritisation_master_28_01_22.pdf

PAT/PA 1 - Referral to Hospital Access Policy

CORP/RISK 36 - Patient Safety Incident Response Policy (PSIRF)

CORP/RISK 30 - Risk Identification, Assessment and Management Policy

12 DATA PROTECTION

Any personal data processing associated with this policy will be carried out under 'Current data protection legislation' as in the Data Protection Act 2018 and the UK General Data Protection Regulation (GDPR) 2021.

For further information on data processing carried out by the trust, please refer to our Privacy Notices and other information which you can find on the trust website: https://www.dbth.nhs.uk/about-us/our-publications/information-governance/

13 REFERENCES

NHS England and NHS Improvement (June 2021) Elective Care Improvement Support Team 'How to' Guide: Clinical Harm Review Process Version 3

The Health Foundation (2011) *Levels of Harm* amended Nov 2011

Department of Constitutional Affairs Mental Capacity Act (2005): Code of Practice, 2007 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/497253/Mental-capacity-act-code-of-practice.pdf

APPENDIX 1 – CATEGORISATION OF HARMS

Physical Harm	
No physical harm	No physical harm
Low physical harm	Low physical harm is when **all of the following** apply: • minimal harm occurred – patient(s) required extra observation or minor treatment • did not or is unlikely to need further healthcare beyond a single GP, community healthcare professional, emergency department or clinic visit • did not or is unlikely to need further treatment beyond dressing changes or short courses of oral medication • did not or is unlikely to affect that patient's independence • did not or is unlikely to affect the success of treatment for existing health conditions.
Moderate physical harm	Moderate harm is when **at least one** of the following apply: • has needed or is likely to need healthcare beyond a single GP, community healthcare professional, emergency department or clinic visit, and beyond dressing changes or short courses of medication, but less than 2 weeks additional inpatient care and/or less than 6 months of further treatment, and did not need immediate life-saving intervention • has limited or is likely to limit the patient's independence, but for less than 6 months • has affected or is likely to affect the success of treatment, but without meeting the criteria for reduced life expectancy or accelerated disability described under severe harm.
Severe physical harm	Severe harm is when **at least one** of the following apply: • permanent harm/permanent alteration of the physiology • needed immediate life-saving clinical intervention • is likely to have reduced the patient's life expectancy • needed or is likely to need additional inpatient care of more than 2 weeks and/or more than 6 months of further treatment • has, or is likely to have, exacerbated or hastened permanent or long term (greater than 6 months) disability, of their existing health conditions • has limited or is likely to limit the patient's independence for 6 months or more.
Fatal (previously	You should select this option if, at the time of reporting, the

documented as 'Death' in NRLS)	patient has died and the incident that you are recording may have contributed to the death, including stillbirth or pregnancy loss. You will have the option later to estimate to what extent it is considered a patient safety incident contributed to the death.
PSYCHOLOGICAL HARM Please note that when recording psychological harm, you are not required to make a formal diagnosis; your answer should be an assessment based on the information you have at the point of recording and can be changed if further information becomes available.	
No psychological harm	Being involved in any patient safety incident is not pleasant, but please select 'no harm' if you are not aware of any specific psychological harm that meets the description of 'low psychological harm' or worse. Pain should be recorded under physical harm rather than psychological harm.
Low psychological harm	Low psychological harm is when **at least one** of the following apply: • distress that did not or is unlikely to need extra treatment beyond a single GP, community healthcare professional, emergency department or clinic visit • distress that did not or is unlikely to affect the patient's normal activities for more than a few days • distress that did not or is unlikely to result in a new mental health diagnosis or a significant deterioration in an existing mental health condition
Moderate psychological harm	Moderate psychological harm is when **at least one** of the following apply: • distress that did or is likely to need a course of treatment that extends for less than six months • distress that did or is likely to affect the patient's normal activities for more than a few days but is unlikely to affect the patient's ability to live independently for more than six months • distress that did or is likely to result in a new mental health diagnosis, or a significant deterioration in an existing mental health condition, but where recovery is expected within six months
Severe psychological harm	Severe psychological harm is when **at least one** of the following apply:

	• distress that did or is likely to need a course of treatment that continues for more than six months • distress that did or is likely to affect the patient's normal activities or ability to live independently for more than six months • distress that did or is likely to result in a new mental health diagnosis, or a significant deterioration in an existing mental health condition, and recovery is not expected within six months

APPENDIX 2 – WHEN TO UNDERTAKE A CLINICAL HARM REVIEW AND/OR THEMATIC REVIEW

Patient pathway	Tolerance to trigger a harm review	Other actions to be taken
Patients whose planned surgery is cancelled on the day	Any patient whose planned surgery is not rescheduled to occur within 28 days	Thematic review as well as Clinical Harm Review
Patients on 62 day Cancer pathway	Any patient on a 62 day cancer pathway who breaches 104 days for a pathway completion	Thematic review as well as Clinical Harm Review
Patients on P2 admitted pathway	Any patient who exceeds 8 weeks	Clinical prioritisation as well as Clinical Harm Review, no Thematic review required Where harm suspected to be associated with current and/or projected wait, case to be reviewed against FSSA guidance to upgrade to next pathway unless date booked. Referral signposting to wellbeing service where psychological harm identified.
Patients on P3 admitted pathway	Any patient who exceeds 6 months	Clinical prioritisation as well as HRA or CHR if required, no Thematic review required Where harm suspected to be associated with current and or projected wait, case to be reviewed against FSSA guidance to upgrade to next pathway unless date booked Referral signposting to wellbeing service where psychological harm identified.
Patients on P4 admitted pathway	Any patient who exceeds 12 months	Clinical prioritisation as well as HRA or CHR if required, no Thematic review required Where harm suspected to be associated with current and or projected wait, case to be reviewed against FSSA guidance to upgrade to next pathway unless date booked Referral signposting to wellbeing service where psychological harm identified.
	Any patient who exceeds 6 months	Clinical prioritisation as well as HRA or CHR if required, no Thematic review required Where harm suspected to be associated with current wait, case to be highlighted to responsible clinician for individual discussion with patient to consider returning to the main waiting list. Prioritisation against FSSA guidance to determine correct pathway at that stage. Referral signposting to wellbeing service where psychological harm identified.

APPENDIX 3 – MATRIX OF ACTIONS

Matrix of actions to be undertaken on completion of the Prioritisation and Clinical Harm exercises

Vulnerable / additional needs (V) : bespoke risk /care	Priority 1 a <24 hrs Priority 1b <72 hrs	Priority 2 <1/12 (urgent & cancer)	Priority 3 <3/12 (routine expedited)	Priority 4 >3/12 (routine)	ACTIONS wrt Vulnerability / additional needs :
Clinical harm None	n/a	Stay P2	Stay P3	Stay P4	Adapt or bespoke investigation/ treatment / site. Follow up
Clinical harm Low	n/a	Stay P2 but prioritise above P2 no harm	Stay P3 but prioritise above P3 no harm	Stay P4 but prioritise above P4 no harm	Adapt or bespoke investigation/ treatment / site. Follow up
Clinical harm Moderate	Stay P1 *PTL review daily or weekly*	Stay P2 *But prioritise above P2 Low harm & PTL review by 1/12*	NEW P2 *Upgrade and treat as P2, prioritise above P2 Low harm & PTL review by 1/12*	NEW P3 *Upgrade and treat as P3 and prioritise above P3 Low harm & PTL review by 3/12*	Adapt or bespoke investigation/ treatment / site. Follow up
Clinical harm Severe	NEW P1a *PTL review daily*	NEW P1 b *PTL review daily or weekly*	NEW P2 or P1b *PTL review by 1/12*	NEW P2 or 1b *PTL review by 1/12*	Adapt or bespoke investigation/ treatment / site. Follow up

APPENDIX 4 – PSYCHOLOGICAL HARM ASSESSMENT

Psychological harm assessment – for anxiety and depression

Patient Health Questionnaire 2 (PHQ2)

Score of 3 or more indicates need for referral for further evaluation

Over the **last 2 weeks**, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	○ 0	○ +1	○ +2	○ +3
2. Feeling down, depressed or hopeless	○ 0	○ +1	○ +2	○ +3

Generalized Anxiety Disorder 2 (GAD-2)

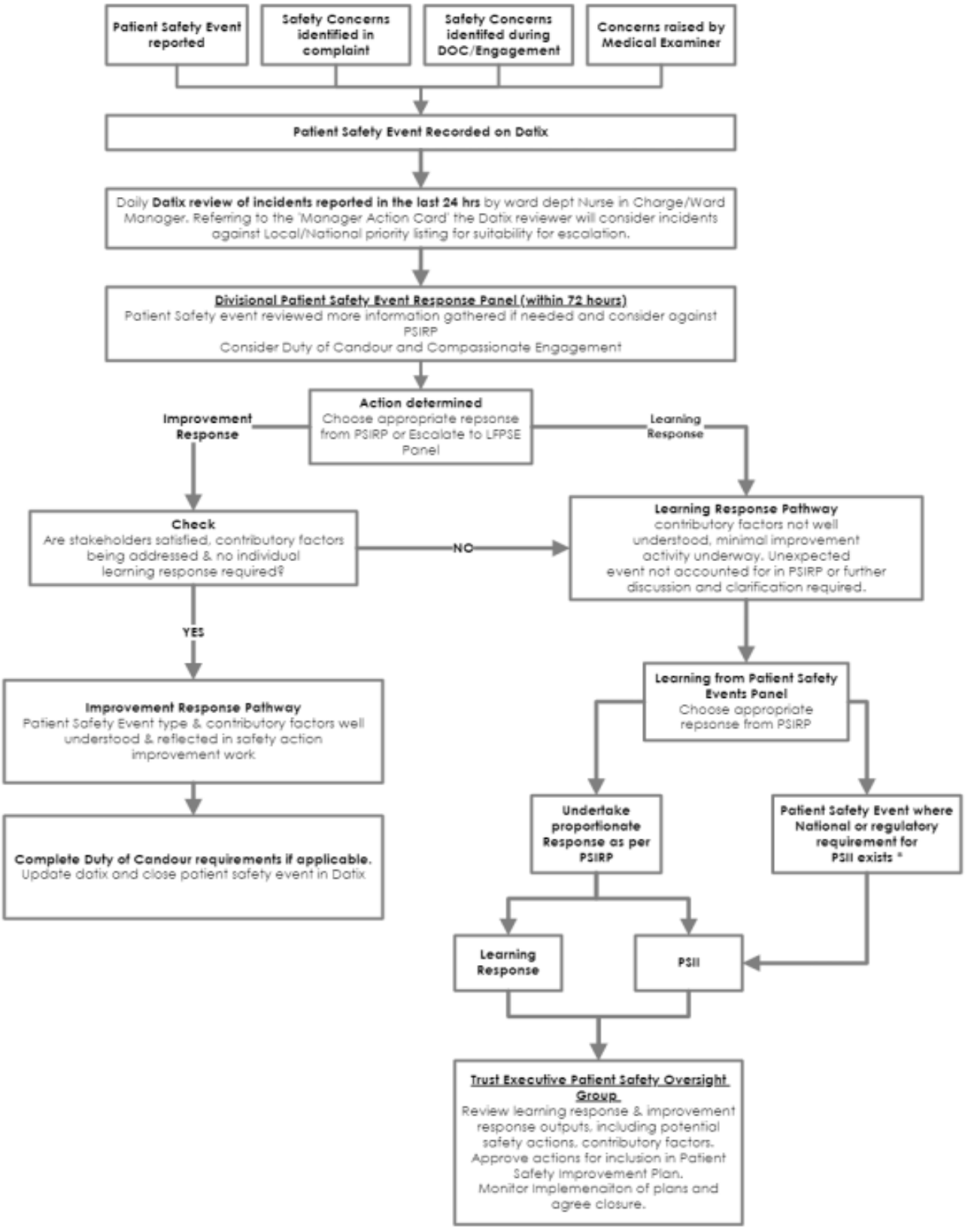
Score of 3 or more indicates need for referral for further evaluation

Over the **last 2 weeks**, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	○ 0	○ +1	○ +2	○ +3
2. Not being able to stop or control worrying	○ 0	○ +1	○ +2	○ +3

APPENDIX 5 – NATIONAL CLINICAL PRIORITISATION PROGRAMME (NCPP) SUMMARY

A **Code**	**Previous Category**	**Time parameters**	**Surgery / medical '…ologies'**	**'Outpatient' (Triage/ ambulatory care pathways)**	**Investigations- imaging/ endoscopy/ bronchoscopy / biopsy etc**
Emergency	<24 hours	Life saving	N/A	Often inpatient / linked to emergency pathways: Inpatient or ED	Emergency
Emergency	<72 hours	Life saving / protecting	N/A		Emergency
Urgent Expedited	<1/12 (i.e. could be 1/52)	Organ saving/ life protecting / disease cure	Cancer 2ww / urgent or urgent internal referral or results/ management plan follow up	Linked to timed diagnostic or treatment pathways– i.e. Cancer / or P2 surgery	Urgent Expedited
Routine +	<3/12	Deferral or alternative Rx possible / risk balance covid : Rx	Routine Initial referral or Internal referral or results/ management plan follow up	Surveillance (time stamped) Relapse follow up / diagnosis exclusion or linked diagnostic or treatment pathways	Routine +
Routine -	>3/12	Long term deferral/ alternative management / limited change in PS – disease by intervention	Surveillance or monitoring or routine follow up or specific dated follow up	Routine 'to check' Surveillance (time stamped) Gold standard completion with limited change in Rx Linked diagnostic or treatment pathways	Routine -

APPENDIX 5 – PATIENT SAFETY EVENT DECISION RESPONSE FLOW



Flow chart extracted from the Trust's Patient Incident Response Policy [CORP-RISK-36-v.1-Patient-Incident-Response-Policy.pdf (dbth.nhs.uk)]

APPENDIX 6 - EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING

Service/Function/Policy/Project/Strategy	Care Group/Executive Directorate and Department	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
Clinical Harm Review Policy	Executive Medical Director	Julie Butler	New Policy	December 2023

Who is responsible for this policy? Name of Care Group/Directorate: Executive Medical Director

Describe the purpose of the service / function / policy / project/ strategy? Who is it intended to benefit? What are the intended outcomes?
To standardise the approach across the Trust to clinical harm review, ensuring all staff understand the process to benefit patients

Are there any associated objectives? National guidance and internal audit recommendation

What factors contribute or detract from achieving intended outcomes? Compliance with the policy

Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief? No

If yes, please describe current or planned activities to address the impact [e.g. Monitoring, consultation] N/A

Is there any scope for new measures which would promote equality? [any actions to be taken] N/A

Are any of the following groups adversely affected by the policy? No

Protected Characteristics	Affected?	Impact
Age	No	
Disability	No	
Gender	No	
Gender Reassignment	No	
Marriage/Civil Partnership	No	
Maternity/Pregnancy	No	
Race	No	
Religion/Belief	No	
Sexual Orientation	No	

Provide the Equality Rating of the service / function /policy / project / strategy – tick (✓) outcome box

Outcome 1 ✓	Outcome 2	Outcome 3	Outcome 4

Date for next review: December 2026

Checked by: Dr Nick Mallaband Date: December 2023