TRUST POLICY FOR HARM REVIEWS

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Version / Amendment History	Version	Date	Author	Reason
	V1	February 2024	RF	New policy
Intended Recipients: All staff groups.				
Training and Dissemination: Launched via Divisional and Specialty meetings and via NET-i.				
To be read in conjunction with: • Duty of Candour - Being Open - Trust Policy and Procedure • Incident Reporting, Management and Learning - Trust Policy and Procedure.				
In consultation with and Date: Harms Review Group - 13th December 2023 Patient Safety Group - 13th December 2023				
EIRA stage One Completed Yes stage Two Completed No				
Approving Body and Date Approved			Trust Delivery Group / February 2024	
Date of Issue			February 2024	
Review Date and Frequency			February 2027 - every 3 years	
Contact for Review			Richard Faleiro Medical Director Quality and Safety	
Executive Lead Signature			 Dr Gis Robinson, Interim Executive Medical Director	

Contents

1. Purpose of this Policy

The purpose of this Policy is to identify a standardised approach to Harm Reviews for all specialities at University Hospitals of Derby and Burton NHS Foundation Trust (the Trust) that support the governance and assurance processes as well as maintaining practice in line with national expectations. Successful implementation of this P olicy will provide assurance to external bodies that the Trust understands the risks that waiting for treatment can pose to patients and is taking steps to mitigate against these risks.

Whilst this Policy is applicable across the Trust, it is recognised that specialities may wish to further develop their own harm review procedures to reflect the treatments / investigations offered within the speciality. An example template to be used is included in this document (see section 6.5).

2. Purpose of Harm Reviews

Harm Reviews give assurance to patients, patient groups, Commissioners, and the public, as to whether patients have been harmed, or are at risk of harm, as well as helping to avoid future harm to patients (NHSE, 2016).

Clinical Harm Reviews should form part of the normal monitoring process and their purpose is to:

- Identify any harm which may have arisen as a result of a delay in waiting for appointments and / or treatment
- Ensure any harm is recorded and appropriate action taken in regard to any patient affected
- Implement change from lessons learned
- Minimise any risk of recurrence
- Mitigate any risks to patients that could occur.

Patients may be harmed not only by clinical treatment, but also as a result of the need to be on a waiting list for clinical treatment, as this may result in deterioration of their physical or mental condition. Psychological harm will be considered but not specifically reviewed.

The experience of waiting for an assessment and / or intervention could lead to a deterioration in the condition that the patient was primarily referred for. This is conceptually different to the “unintended harm” that can potentially occur over the course of an assessment or intervention. Appraising harm because of waiting for an assessment or intervention using a single measure is challenging due to the following complexities:

- The diverse range of services the Trust offers
- The decline in health (understood as increase disability or distress) varies across health conditions and settings
- A decline in health is different depending on the pathology of the condition (asthma vs lung cancer and hospital vs community)
- The experience of distress and disability and the fact that the coping response can be subjective.

Any potential harm should be reported in accordance with the Trust’s incident reporting process and system (Datix).

For patients suffering from moderate or severe harm it is a legal requirement that the duty of candour process must be followed as per the Duty of Candour - Being Open - Trust Policy and Procedure.

3. Definitions

Definition of Harm

The Definition of harm will differ according to the circumstances which are being reviewed, eg. waiting list validation work, Referral to Treatment (RTT) pathway, or cancer pathway. NHS England have suggested definitions for the different levels of patient harm that may occur for those pathways, as per the table below. There will be other condition-specific factors that could be used to contribute to the definition of harm at a specialty level.

3.1 NHSE Definition of Harm – 52-week Pathway

Severe	• Irreversible progression of disease • Death on the waiting list from index condition
Moderate	• Increase in symptoms • Increase in medication or treatment
Low	• Prolongation of symptoms

3.2 NHSE Definition of Harm – Cancer Pathway

Severe	• Delayed diagnosis • Progression of cancer • Death on the waiting list from index condition
Moderate	• Increase in symptoms • Increase in medication or treatment
Low	• Prolongation of symptoms

3.3 Other definitions

Harm Review	A harm review is conducted by a clinician (non-specialist doctor or nurse)
Clinical Harm Review	A clinical harm review is performed by specialist clinician e.g., an oncologist. Where a clinician conducts a more detailed review of identified harm review patient cohorts i.e. 52-week breaches, which may involve reviewing patient records in more detail, contact with the patient's GP, and / or an appointment with the patient. This can be for prospective or retrospective reviews.
Risk Stratification	A process whereby a clinician identifies and predicts which patients are at a high risk or likely to be at a high risk and prioritises the waiting lists accordingly to mitigate potential harm and maximise all available capacity. This includes: • Vetting referrals for new patients and addressing key questions such as 'Is it urgent or routine?', 'Which

	specific sub-specialty does the patient require an appointment in?', 'Does the patient require any tests prior to their appointment?' • Reviewing overdue follow up patients addressing key questions such as 'Does the patient still require a follow up appointment?', 'Is it urgent or routine?', 'Can the patient be seen by an alternative clinician – nurse led or alternative clinician?'

4. Responsibilities

Harm Review Group (HRG)	The HRG oversees arrangements for the clinical review of patients who have waited longer than the timescale set in national standards, or by local clinicians. The HRG supports, but does not replace, appropriate specialty, Business Unit, Divisional or corporate clinical governance processes. The HRG will have strategic responsibility for the development, management, and implementation of this Policy.
Executive Medical Director (EMD)	The EMD is the Senior Responsible Owner who has oversight of the Harm Review process.
Chief Operating Officer (COO)	The COO will receive escalations from the DMDs in respect of circumstances, where acting on recommended actions is difficult and cannot be resolved.
Divisional Medical Directors (DMDs)	The DMDs will receive escalations from the CDs in respect of circumstances, where acting on recommended actions is difficult and cannot be resolved, and in turn will escalate up to the COO where necessary.
Clinical Directors (CDs)	The CDs are responsible for: • Ensuring Harm Reviews are carried out for the defined patient cohorts. • Developing specialty level procedures with specialty leads for Harm Reviews (see section 6.5 for template) that are signed off at HRG. • Ensuring that Clinical Harm Reviews are carried out by the relevant clinicians in their department within the agreed time frame. • Ensuring that actions are taken because of these Clinical Harm Reviews • Ensuring the Harm Review process is integrated into the governance framework of the Business Unit • Ensuring that any evidence of potential or moderate to severe harm is reported as an incident and that duty of

	candour process applied where appropriate. • Ensuring that the outcomes of Harm Reviews are acted upon and that actions are taken to mitigate the risk of harm to the patient. • Escalating to the DMDs where acting on recommended actions is difficult and cannot be resolved. • Collating Harm Reviews to report to the HRG.
Clinical Governance Team	The Clinical Governance Team will be involved in any serious incident investigation management and will ensure harm incidents are raised in Datix and the Trust risk register. The Clinical Governance Team will inherently support the Harm Review process - agree with the CD a process by which patients are identified and then facilitate the harm review i.e., process for obtaining the patient records, recording the outcome, etc.
Individual Clinician	Individual clinicians are responsible for supporting the implementation of this Policy within their speciality / Business Unit as required. The actual Clinical Harm Review should be carried out by a clinician with knowledge of the index condition. The responsible clinician should ensure that the patient and their GP is notified of the outcome of the Clinical Harm Review if the outcome is moderate or severe harm (see section 5.2) and include the statutory responsibilities of Duty of Candour.

5. Standards and Practice

There are two categories of Clinical Harm Reviews:

5.1 Prospective Reviews

A review which aims to ascertain what the risk is of a patient coming to harm. Categories include, Cancer pathway and Oncology Harm Review processes.

- A patient waiting over an agreed threshold on an inpatient or outpatient pathway
- Virtual 'waiting list' to real waiting list
- Overdue follow ups over 6 months
    - Patients are not waiting for a procedure but are just waiting to be seen by a clinician. The clinician may prescribe a specialist initiation only medicine or recommended a specific therapy.

Method required:

- Specialties to agree local thresholds (maximum acceptable waiting times for the conditions that they treat or procedures that they carry out) and incorporate this information into the harm review for their specialty.
- Harm review of a patient using patient records, assignment of 'level' of harm and subsequent actions taken.
- Results reported through Divisional governance to the HRG.

5.2 Retrospective Reviews

A review which ascertains the level of harm a patient has suffered and whether this was because of their increased waiting time. Categories include, a patient who has died whilst on a waiting list.

Example
SJR can be requested by any doctor, but is typically requested by an ME, when a patient dies. E.g., a patient attends hospital and dies from a Myocardial infarction (MI). They have an MI because they have cholecystitis. Cholecystitis is caused by an inflammation of their gall bladder due to stones. They are on the waiting list for a Cholecystectomy and because of a delay to surgery they have a complication and die.

- Was the death related to the delay in treatment? If yes, raise a Datix. If no, no further action.
- A patient is admitted as an emergency and assessed by clinical team - was admission related to a delay in treatment if yes, raise a Datix, if no, no further action.

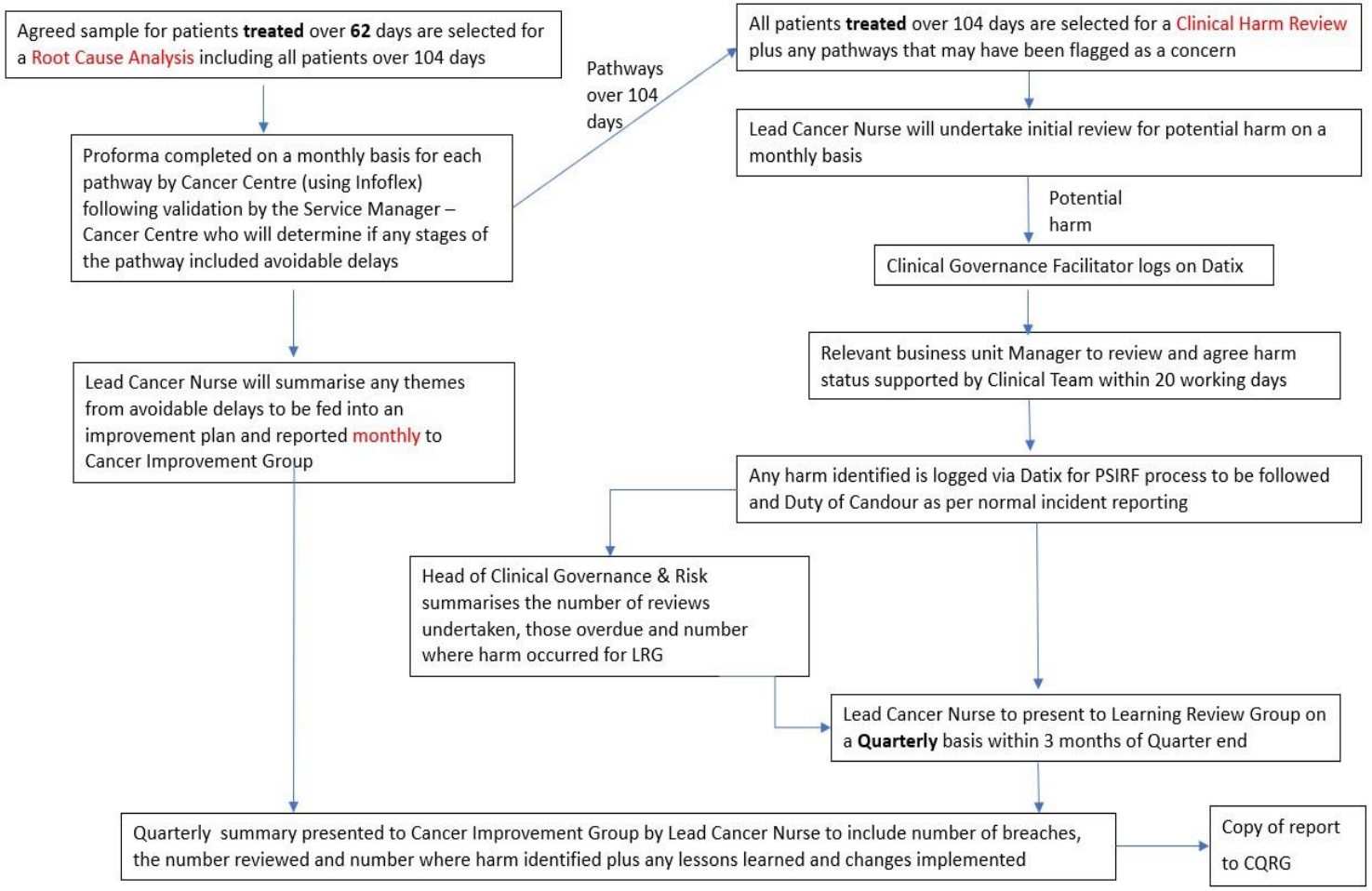
Example
If the same patient develops cholecystitis and has an MI but does not die they can have a Harm Review.

Method required:

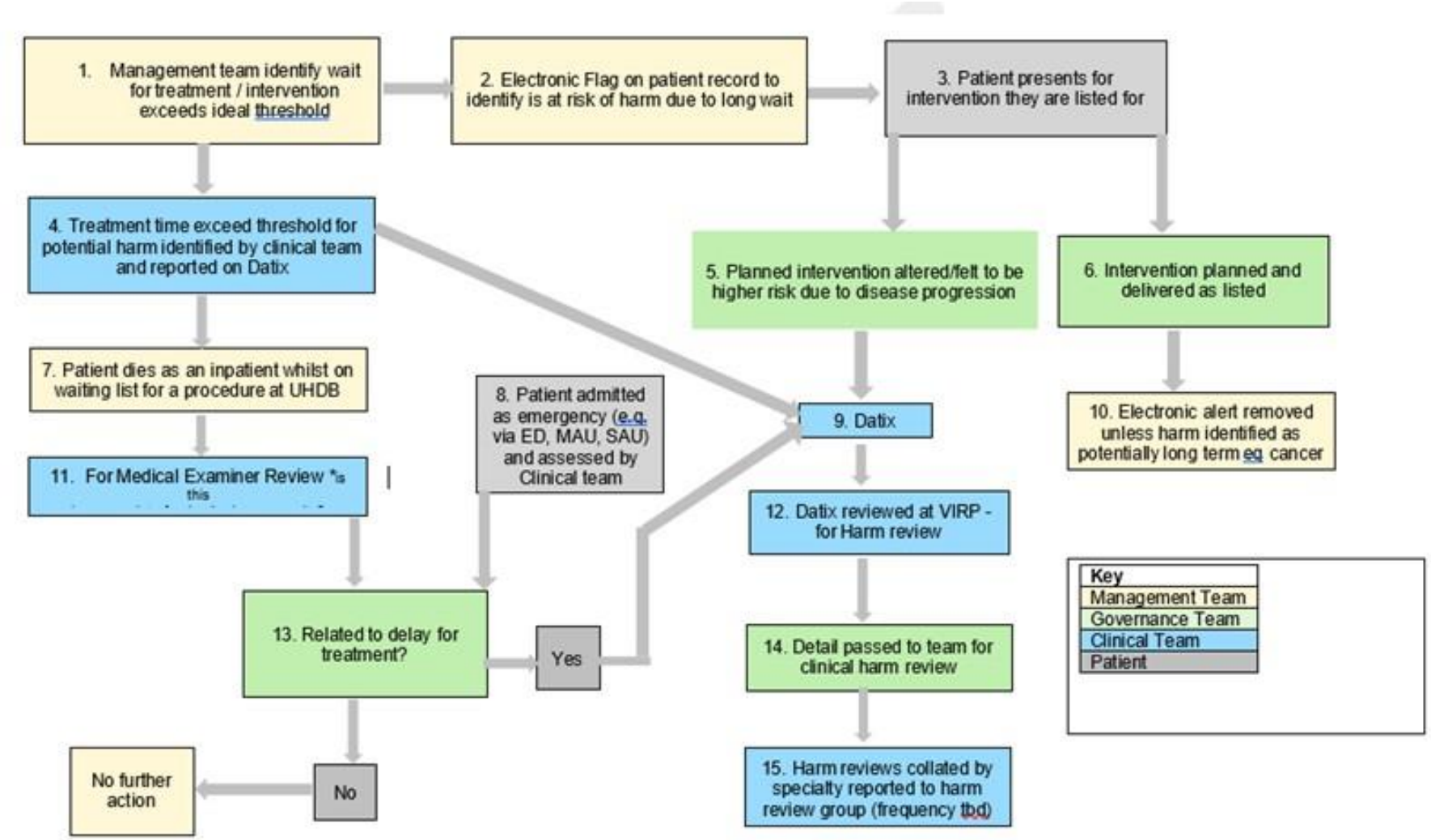
- Review of episode where harm may have occurred (i.e., ED attendance) and 'level' of harm assigned
- Incident Reporting, Management and Learning - Trust Policy and Procedure followed including Duty of Candour - Being Open - Trust Policy and Procedure requirements completed and recorded
- Results reported through Divisional governance to the HRG.

6. Flow-templates for Reviews in Specific Areas

6.1 Cancer Pathway Harm Review Process

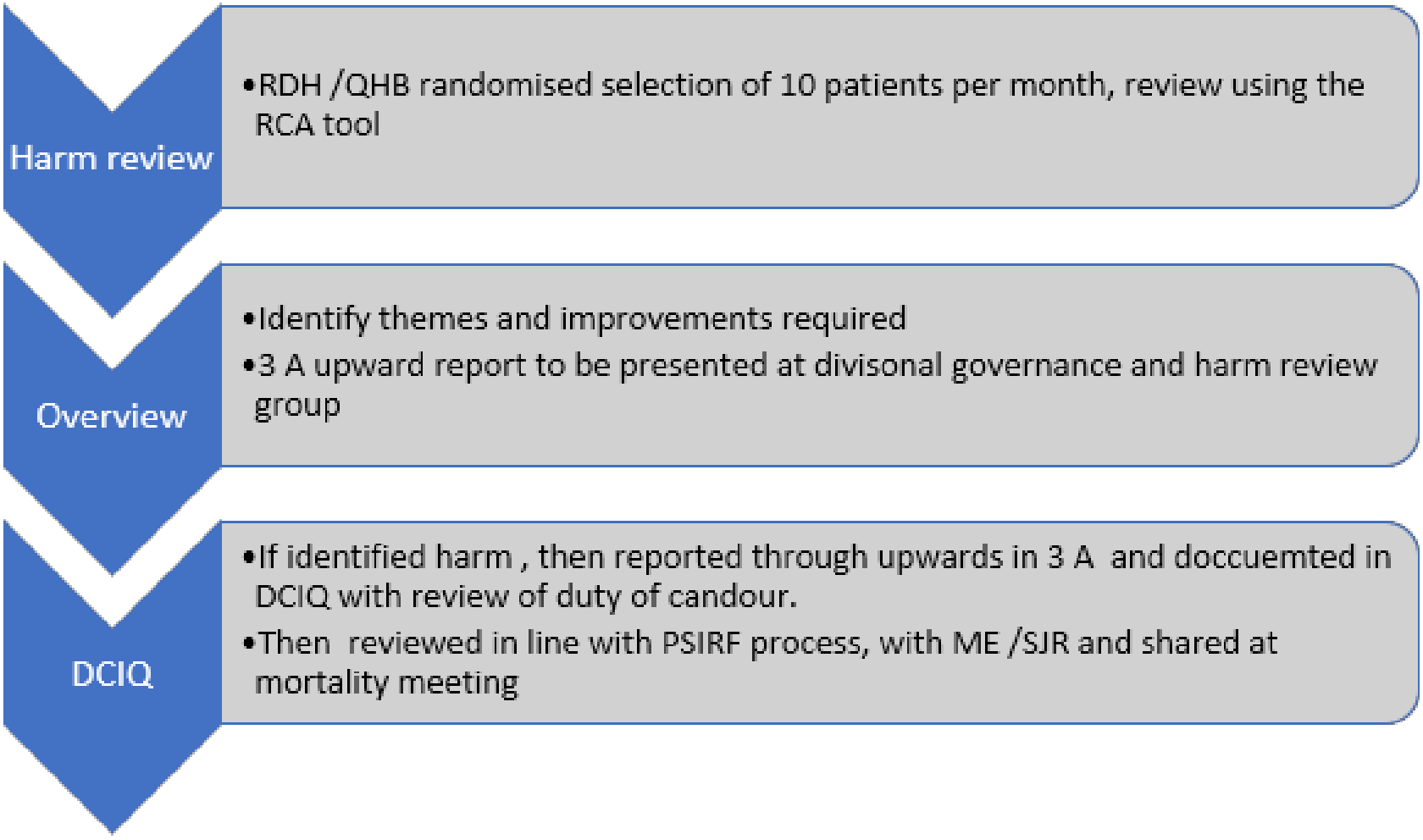


6.2 Clinical Oncology Harm Review Process

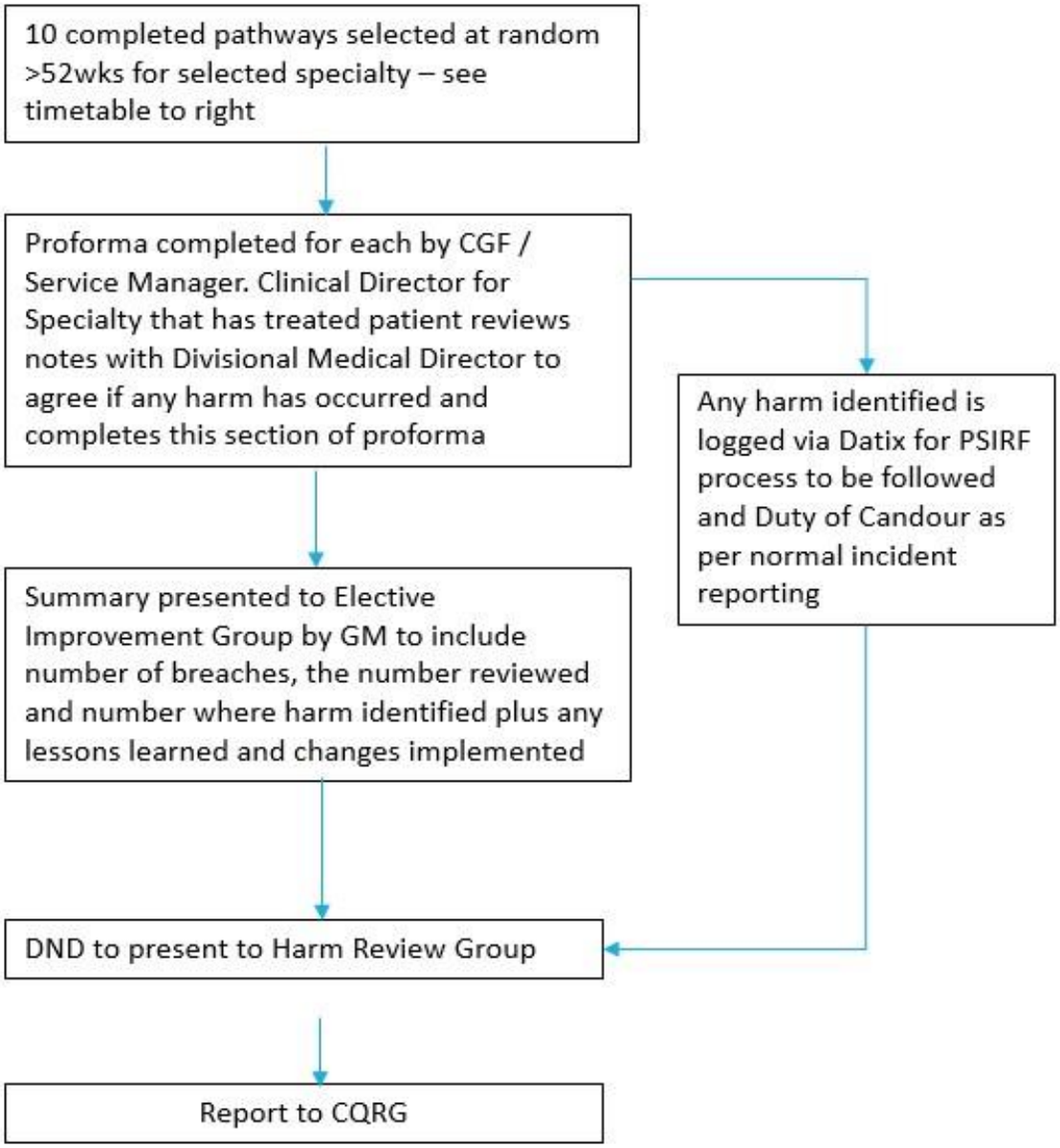


6.3 Emergency Department Harm Review Process

Both RDH and QHB Emergency Department audit 10 patients per month, if harm has been identified then a Datix will be raised and follow the PSIRF framework.

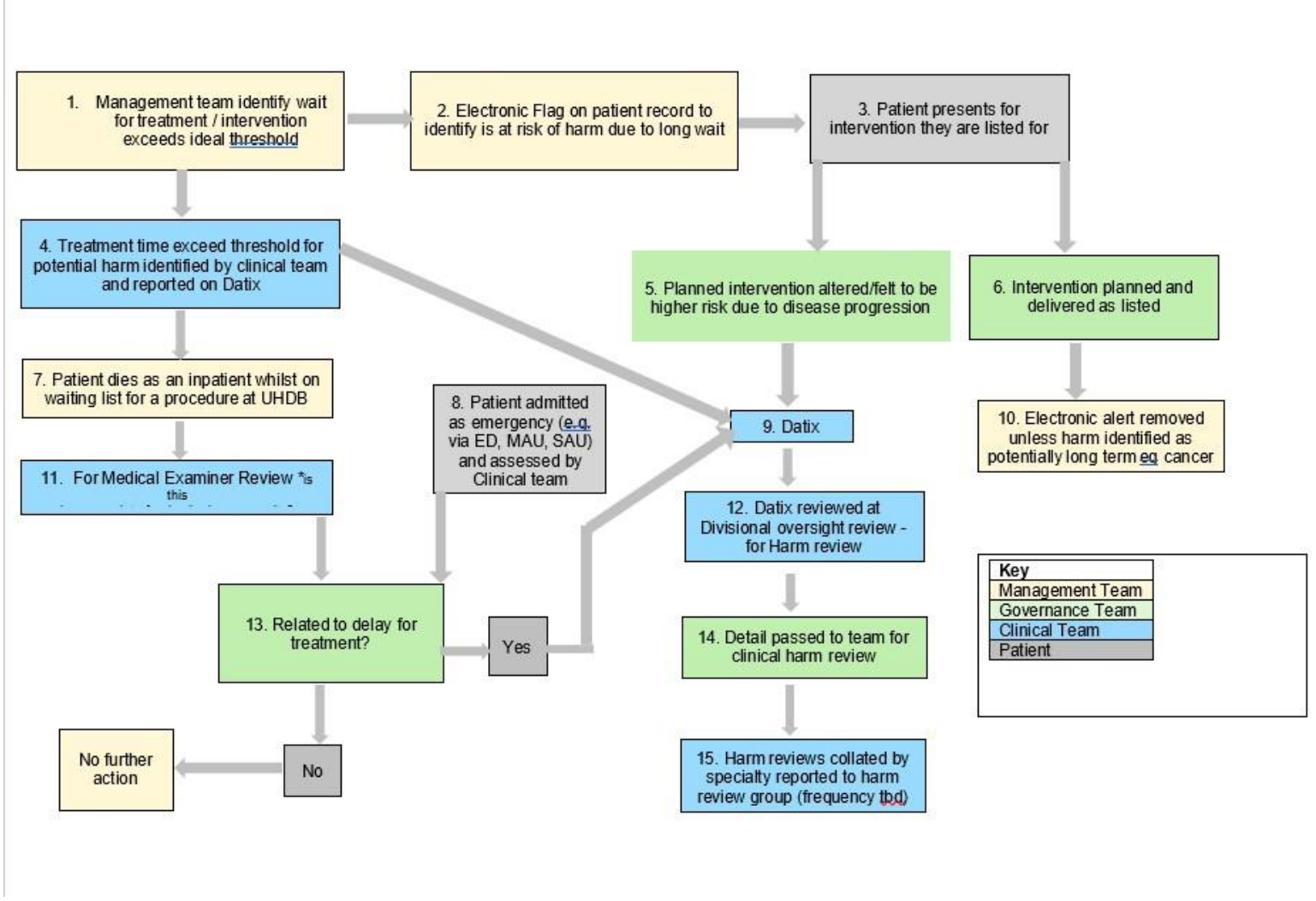


6.4 Elective Waits Harm Review Process



6.5 Generic Harm Review Process

The following process should be followed to implement harm reviews across all specialties.



HARM REVIEW REPORT TEMPLATE

DIVISION:

BUSINESS UNIT:

Numerical Information

Number of patients waiting in total based on the national timeframes:

National Timeframe	Number of Patients
4 Hours (Emergency Departments)	
104 Day (Cancer)	
52 Weeks (Elective)	

Data by Business Unit

Detail	Number of Patients
Number of patients escalated for harm reviews based on the processes and criteria presented.	
Number of harm reviews undertaken.	
Number of harms confirmed	

Narrative Update

National Timeframe	Update
If the cancer centre raises a datix for a Harm review how is this tracked, escalated, and concluded?	
Duty of Candour Process Undertaken?	
For the elective procedures waiting list each Division needs to describe how they are managing their waiting lists	
What checks are performed on a patient's clinical condition and how are additional risk factors including disease progression discerned. (Clinical validation)	
How is information communicated between the hospital, patient, and GP?	
Are patients given information on how to escalate concerns (safety netting) while they are on the waiting list or out with of clinic appointments?	

7. Dissemination and Implementation

This Policy will be disseminated by the HRG to all CDs for cascade to each of the specialities.

Responsibility for completion of and reporting on Harm Reviews will remain within the BU / specialities.

8. Monitoring Compliance and Effectiveness

Adherence with this Policy will be monitored through a quarterly review at the HRG and annual reporting to the Quality Governance Steering Group.The frequency of reviews may be subject to change.

9. Updating and Review

This Policy will be reviewed after three years following the date of ratification unless an earlier update is required.