

## Policy Under Review

Please note that this policy is under review. It does, however, remain current Trust policy subject to any recent legislative changes, national policy instruction (NHS or Department of Health), or Trust Board decision. For guidance, please contact the Author/Owner.

| Information Category                                             | Detailed Information                                                                                                                                                                                                                                               |
|------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Document Title:</b>                                           | Harm Reviews Standard Operating Procedure V2.0                                                                                                                                                                                                                     |
| <b>This document replaces (exact title of previous version):</b> | Harm Reviews Standard Operating Procedure V1.0                                                                                                                                                                                                                     |
| <b>Date Issued/Approved:</b>                                     | 24 March 2023                                                                                                                                                                                                                                                      |
| <b>Date Valid From:</b>                                          | March 2023                                                                                                                                                                                                                                                         |
| <b>Date Valid To:</b>                                            | December 2026                                                                                                                                                                                                                                                      |
| <b>Author/Owner:</b>                                             | Allister Grant, Chief Medical Officer                                                                                                                                                                                                                              |
| <b>Contact details:</b>                                          | 01872 253402                                                                                                                                                                                                                                                       |
| <b>Brief summary of contents:</b>                                | To provide explanation to all staff (clinical and non-clinical) about why harm reviews should be carried out and the standardised approach to harm reviews. for all specialties to follow along with clearly defined roles and responsibilities of those involved. |
| <b>Suggested Keywords:</b>                                       | Harm review, potential harm, Clinical Harm, Review Panel, risk stratification.                                                                                                                                                                                     |
| <b>Target Audience:</b>                                          | <b>RCHT:</b> Yes<br><b>CFT:</b> No<br><b>CIOS ICB:</b> No                                                                                                                                                                                                          |
| <b>Executive Director responsible for Policy:</b>                | Chief Medical Officer                                                                                                                                                                                                                                              |
| <b>Approval route for consultation and ratification:</b>         | Clinical Harm Review Panel – 2022.<br>Quality Assurance Committee – 2020.                                                                                                                                                                                          |
| <b>Manager confirming approval processes:</b>                    | Deputy Medical Director                                                                                                                                                                                                                                            |

| Information Category                                                                    | Detailed Information                                      |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------|
| <b>Name of Governance Lead confirming consultation and ratification:</b>                | Deputy Medical Director                                   |
| <b>Links to key external standards:</b>                                                 | Not applicable                                            |
| <b>Related Documents:</b>                                                               | External Clinical Harm Review Handbook (V.5.). 2016 NHSE. |
| <b>Training Need Identified:</b>                                                        | Yes                                                       |
| <b>Publication Location (refer to Policy on Policies – Approvals and Ratification):</b> | Internet and Intranet                                     |
| <b>Document Library Folder/Sub Folder:</b>                                              | Chief Executive / Corporate Governance                    |

**This document is only valid on the day of printing.**

#### **Controlled Document.**

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy on Document Production. It should not be altered in any way without the express permission of the author or their Line Manager.

# **Harm Reviews Standard Operating Procedure**

**V2.0**

**March 2023**

## Table of Contents

|                                                                                                                    |           |
|--------------------------------------------------------------------------------------------------------------------|-----------|
| 1. Introduction .....                                                                                              | 6         |
| 2. Purpose of this Procedure .....                                                                                 | 7         |
| 3. Ownership and Responsibilities .....                                                                            | 8         |
| 3.1. Role of the Clinical Harm Review Panel .....                                                                  | 8         |
| 3.2. Role of Clinical Directors:.....                                                                              | 8         |
| 3.3. Role of Care Group General Manager .....                                                                      | 9         |
| 3.4. Role of individual clinical staff .....                                                                       | 9         |
| 3.5. Role of all staff .....                                                                                       | 9         |
| 4. Standards and Practice .....                                                                                    | 9         |
| 4.1. Prospective versus retrospective clinical harm reviews .....                                                  | 9         |
| 4.2. Patient Cohorts .....                                                                                         | 11        |
| 4.3. Communications .....                                                                                          | 11        |
| 4.4. Harm Review Process .....                                                                                     | 12        |
| 5. Dissemination and Implementation .....                                                                          | 13        |
| 6. Monitoring compliance and effectiveness.....                                                                    | 13        |
| 7. Updating and Review .....                                                                                       | 14        |
| 8. Equality and Diversity.....                                                                                     | 14        |
| <b>Appendix 1. Governance Information .....</b>                                                                    | <b>15</b> |
| <b>Appendix 2. Equality Impact Assessment .....</b>                                                                | <b>17</b> |
| <b>Appendix 3. Additional specialty specific cohorts for review and exemptions from review per specialty .....</b> | <b>20</b> |
| <b>Appendix 4. Standard Operating Procedure for Harm Review for Cancer Treatment Standard Breaches .....</b>       | <b>26</b> |
| <b>Appendix 5. Harm Review Handover .....</b>                                                                      | <b>29</b> |
| <b>Appendix 6. Harm review quick guide .....</b>                                                                   | <b>33</b> |
| <b>Appendix 7. How to Record Clinical Harm Reviews using the Chirp Tool .....</b>                                  | <b>35</b> |
| <b>Appendix 8. CHiRP – Clinical Harm Review Pathway Tool .....</b>                                                 | <b>39</b> |
| <b>Appendix 9. Harm Review Dashboard Template.....</b>                                                             | <b>40</b> |

### **Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation**

The Trust has a duty under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team

Royal Cornwall Hospital Trust [rch-tr.infogov@nhs.net](mailto:rch-tr.infogov@nhs.net)

UNDER REVIEW

# 1. Introduction

- 1.1. This section should provide an overview of the importance and role of the subject covered by the document. If the document is created in support of a parent procedure, then this should be referenced.
- 1.2. 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).
- 1.3. 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.
- 1.4. Definitions of harm will differ according to the circumstances which are being reviewed, e.g. Referral to Treatment (RTT) pathway, or Cancer pathway. However, NHSE have suggested definitions for the different levels of patient harm that may occur in for these pathways, as demonstrated in 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.
- 1.5. Definitions of Harm –52-week RTT pathway

| Category | Information                                                                           |
|----------|---------------------------------------------------------------------------------------|
| Severe   | Irreversible progression of disease<br>Death on the waiting list from index condition |
| Moderate | Increase in symptoms.<br>Increase in medication or treatment                          |
| Low      | Prolongation of symptoms                                                              |

- 1.6. Definitions of Harm – Cancer pathway

| Category | Information                                                                                  |
|----------|----------------------------------------------------------------------------------------------|
| Severe   | Delayed diagnosis<br>Progression of cancer<br>Death on the waiting list from index condition |
| Moderate | Increase in symptoms.<br>Increase in medication or treatment                                 |
| Low      | Prolongation of symptoms                                                                     |

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

1.8. 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 Being Open and Duty of Candour Policy and Procedure. For the latter group the serious incident (SI) process should also be followed in accordance with the Incident and Serious Incident Management Policy and Procedure.

1.9. This version supersedes any previous versions of this document.

## **2. Purpose of this Procedure**

2.1. The purpose of this SOP is to identify a standardised approach to Harm Reviews for all specialities at RCHT that support the Trusts governance and assurance processes and maintains practice in line with national expectations. Successful implementation of this policy will also 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.

2.2. Whilst this SOP is applicable across RCHT, it is recognised that for some specialities within RCHT the cohorts for review will vary and external circumstances may result in Board agreement for deviation from the cohorts within this SOP. Any specialty specific cohorts for review or significant deviation from the SOP will be agreed and minuted [at Trust Board].

### **2.3. Definitions**

#### **2.3.1. Desktop Harm Review**

Clinician conducts a review of identified harm review patient cohorts for their specialty i.e. 52-week breaches using records available from Maxims. A harm review assessment is made based on this information i.e. no, low, moderate, or severe harm. This can be for prospective or retrospective reviews (see section 5.1).

#### **2.3.2. Clinical Harm Review**

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 (see section 5.1).

#### **2.3.3. Risk Stratification**

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 registrar?’

### **3. Ownership and Responsibilities**

#### **3.1. Role of the Clinical Harm Review Panel**

The **Clinical Harm Review Panel** (CHRP) oversees arrangements for clinical review of patients who have waited longer than the timescale set in national standards, or by local clinicians. The Senior Responsible Owner for the Harm Review process and this Panel is the Medical Director. The Panel supports, but does not replace, appropriate Specialty, Directorate and Divisional or Corporate clinical governance processes. The CHRP will have strategic responsibility for the development, management, and implementation of the Harm Reviews SOP.

The CHRP will agree upon the patient cohorts that it believes should be subject to the harm review process (i.e. patients who have breached 52 week wait rules, or who have died on a waiting list), and communicate this to the specialties, who should take responsibility for carrying out the review. This will include retrospective and prospective cohorts. The panel will review the results of these reviews at regular intervals and ensure that any action required as a result of them has been actioned.

#### **3.2. Role of Clinical Directors:**

Clinical Directors will be responsible for ensuring harm reviews are carried out for the patient cohort as defined in this SOP as well as being responsible for reviewing the specialty level cohorts with specialty leads for Harm Reviews (see Appendix 3). They are also responsible for ensuring that harm reviews are carried out by the relevant consultants in their department within the agreed time frame and using the agreed method and data collection tool (CHiRP).

Clinical Directors should also ensure that actions are taken as a result of these reviews and for supporting this process where necessary (i.e. the harm review process must inform and have an impact upon elective booking procedures). They are also responsible for ensuring that any potential harm is reported as an incident (using Datix) and that duty of candour process applied where appropriate. Additionally, they should assist the Directorate Managers in ensuring that the outcomes of harm reviews are acted upon and that actions are taken to mitigate the risk of harm to the patient. In situations where acting upon the recommended actions following a harm review is difficult (i.e. due to lack of capacity), the case should be escalated. In the first instance this should be to the Associate Director for the division and ultimately to the Medical Director and Deputy Chief Operating Officer if the situation cannot be resolved.

### 3.3. Role of Care Group General Manager

The General Manager for each Care Group will be responsible for overseeing the implementation of this SOP and for ensuring that Consultants are provided with all necessary data to enable Harm Reviews to be completed for all Specialties within their Directorate. General Managers are also responsible for ensuring that the results of completed clinical harm reviews are communicated to the patient and their GP as appropriate.

### 3.4. Role of individual clinical staff

All clinical staff members are responsible for supporting the implementation of the Harm Reviews SOP within their Speciality as required. Individual roles will be determined within each Division. The harm review should be carried out by the consultant responsible for the patient's care. The responsible consultant should ensure that the patient and their GP is notified of the outcome of the harm review if the outcome is moderate or severe harm (see section 5.3) and include the statutory responsibilities of Duty of Candour.

### 3.5. Role of all staff

All staff have a responsibility to ensure that if they are aware of any situation that may pose harm to patients, they escalate this appropriately within their department/division.

## 4. Standards and Practice

### 4.1. Prospective versus retrospective clinical harm reviews

As per national policy, there are two categories of clinical harm reviews:

#### 4.1.1. Prospective reviews

A review which aims to ascertain what the risk is of a patient **coming to harm**.

Cohorts include:

- 4.1.1.1. Patient waiting over 52 weeks on an admitted or non-admitted pathway.
- 4.1.1.2. New out-patients waiting over 24 weeks with or without an appointment.
- 4.1.1.3. Overdue follow ups over 6 months
- 4.1.1.4. Co-efficient follow ups over local thresholds
- 4.1.1.5. Method required:

- 4.1.1.6. Specialties to agree local thresholds (maximum acceptable waiting times for the conditions that they treat or procedures that they carry out) and provide this information to be appended to this Trust SOP in appendix 3.
- 4.1.1.7. Desktop review of patients using information available on Maxims, assignment of 'level' of harm and subsequent actions taken
- 4.1.1.8. Where the reviewer considers that either further clinical opinion / information is required and/or if harm review has initially assessed as low, moderate, or severe harm, the case should be escalated to the Governance Lead, Specialty Lead or Clinical Director for further discussion.
- 4.1.1.9. Results reported through divisional governance to clinical harm review panel and QAC.
- 4.1.1.10. RTT will review all cases of harm to confirm identified actions have been taken.

#### 4.1.2. **Retrospective reviews**

A review which ascertains the level of harm a patient **has** suffered and whether this was as a result of their increased waiting time.

Cohorts include:

- 4.1.2.1. Emergency admissions on an in-patient waiting list
- 4.1.2.2. Emergency admissions on an out-patient waiting list.
- 4.1.2.3. Emergency admissions with a future booked appointment
- 4.1.2.4. Deaths on an in-patient waiting list
- 4.1.2.5. Deaths on an out-patient waiting list.

In addition, any patients identified as potentially at risk through other means such as those identified at RTT meetings, through screening pathways, or from notifications from primary care should also be harm reviewed.

Method required:

- 4.1.2.6. Review of episode where harm may have occurred (i.e. ED attendance) and 'level' of harm assigned.
- 4.1.2.7. Decide whether harm arose as a result of delay in being seen/treated.

- 4.1.2.8. Where the reviewer considers that either further clinical opinion / information is required and/or if harm review has initially assessed as low, moderate, or severe harm, the case should be escalated to the Governance Lead, Specialty Lead or Clinical Director for further discussion. Results reported through divisional governance to clinical harm review panel and QAC.

## 4.2. Patient Cohorts

This SOP is concerned with clinical harm reviews of the following patient cohorts:

| Patient cohort   |                                                                                            | Data source                                                                    |
|------------------|--------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| 1. Prospective   | Patients who have waited over 52 weeks from GP Referral To Treatment                       | <b>RADAR:</b> Potential Patient Harm Report                                    |
| 2. Prospective   | New patients waiting more than 24 weeks for first appointment                              | <b>RADAR:</b> Potential Patient Harm Report                                    |
| 3. Prospective   | Follow-up patients 6 months past their to be seen date                                     | <b>RADAR:</b> Potential Patient Harm Report                                    |
| 3. Retrospective | Deaths on waiting list                                                                     | <b>RADAR:</b> Potential Patient Harm Report. <b>MAXIMS:</b> Death Certificates |
| 4. Retrospective | Non-elective admissions whilst on waiting list under the same or linked treatment function | <b>RADAR:</b> Patient Harm Report                                              |

The prospective harm review patient cohort concerned with 'Current long waiters of concern / breaching agreed wait time threshold' will be defined by each specialty and detailed in Appendix 3.

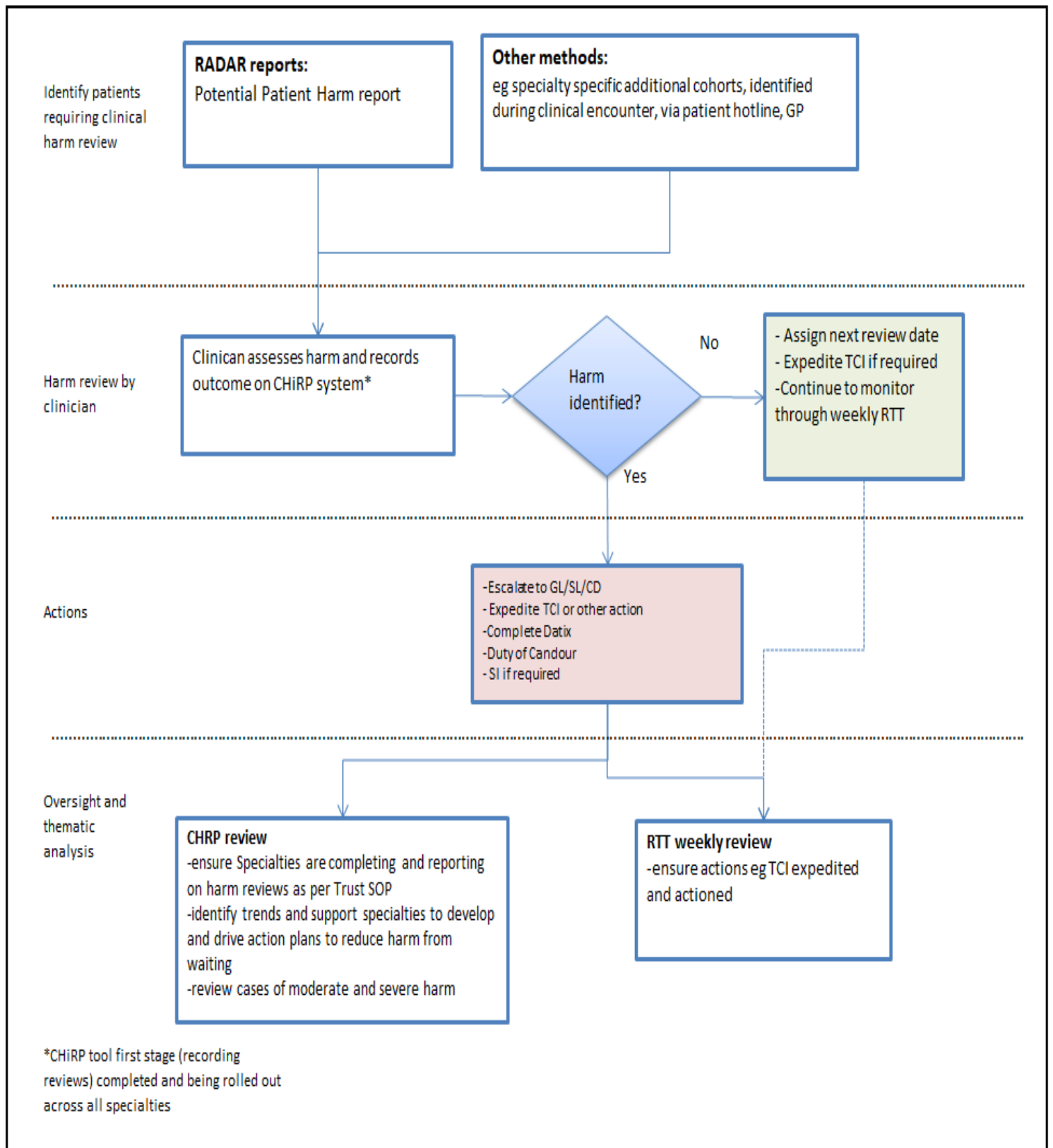
Harm reviews for patients who may have come to harm due to long waits on the cancer pathway are as defined by the 'SOP for harm reviews for Cancer Pathways' (Appendix 4).

## 4.3. Communications

The result of harm reviews with an outcome of low harm only must be communicated to both the patient and their GP. For patients who have been deemed to have suffered moderate or severe harm, this should be communicated to them and their GP in line with the Being Open and Duty of Candour Policy and Procedure and investigated through the serious incident framework if indicated.

## 4.4. Harm Review Process

The following process should be used in order to implement harm reviews across all specialties:



## 5. Dissemination and Implementation

- 5.1. This document will be disseminated by the CHRP to all Care Group Managers for cascade to each of the Specialties.
- 5.2. Support for implementation of the Harm Reviews SOP will be available from the Transformation Team, though responsibility for completion of and reporting on Harm Reviews will remain within the Directorates/Specialties.

## 6. Monitoring compliance and effectiveness

| Information Category    | Detail of process and methodology for monitoring compliance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Element to be monitored | Completion of harm reviews in accordance with this policy and actions taken as a result of these.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Lead                    | The Medical Director is the Senior Responsible Owner for RCHT's Harm Reviews SOP. The operational lead is the Director of Operations.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Tool                    | <p>The Potential Patient Harm Report on the RADAR system should be used to identify those patients who will trigger a Harm Review (as detailed in section 5.2 above).</p> <p>The Maxims system can be used to access death certificates for those patients who have died in hospital whilst on a waiting list.</p> <p>Consultants carrying out desktop harm review processes on these cohorts of patients will be required to use the electronic data collection tool (CHiRP).</p>                                                                                                                                                                                                   |
| Frequency               | <p>Frequent monitoring of each element of the Harm Review process will provide the most contemporaneous information for learning/action and will also limit the size of the task. The patient lists will be pulled from Radar at month end and distributed to clinicians for review.</p> <p>Outcomes will be monitored at the weekly RTT pre-meetings, RTT panel meetings, and divisional meetings. Complete data (including exception reports) for each month will be reviewed in the CHRP meeting 6 weeks after that month concludes.</p>                                                                                                                                          |
| Reporting arrangements  | <p>The resultant outcomes of clinical harm reviews should be subject to divisional and trust-wide governance processes. There should be a clear and auditable process which can describe the process of harm review from identification of patient cohort through to implementation of suggested action for that individual. This process is as follows:</p> <p>Specialities should review all patients triggering a harm review alert, as identified above (under 'Tool' section). Details of those patients experiencing moderate or severe harm should be reviewed by the CHRP. The CHRP will escalate concerns arising from Harm reviews to the Quality Assurance Committee.</p> |

| Information Category                               | Detail of process and methodology for monitoring compliance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|----------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                    | <p>The RTT panel will receive a summary of harm reviews that have been completed by specialty; this will allow specialties to use the Patient Access Policy in order to inform their management of their respective waiting lists.</p> <p>The CHRP will interrogate the submitted Harm Reviews to identify any additional actions required and this will be documented in the meeting minutes. This requirement of the CHRP will be reflected in the Terms of Reference for the group.</p> <p>Communications with patients, CCG's, GP's, and other involved parties regarding the outcome of a harm review (i.e. where the Duty of Candour Process or Serious Untoward Incident process has been invoked), should be completed.</p> |
| <b>Acting on recommendations and Lead(s)</b>       | <p>Care Group Managers will be responsible for ensuring that recommendations arising from the CHRP are actioned within reasonable timeframes.</p> <p>Care Group Managers should liaise with their Clinical Director to ensure that plans suggested as a result of harm reviews are carried out in a timely manner. In a situation where a directorate is struggling to carry out these plans, this should be discussed at the weekly trust wide RTT meeting. If no solution can be found, this should be escalated to the Deputy Chief Operating Officer and Medical Director.</p>                                                                                                                                                  |
| <b>Change in practice and lessons to be shared</b> | <p>System or practice changes will be implemented by Clinical Leads and Care Group Managers. Lessons learned will be shared with stakeholders and across the organisation as appropriate. Use of the above processes for data collection and monitoring will result in learning at specialty and divisional level. In addition to this, the quality accounts and annual plan should be shared with external stakeholders.</p>                                                                                                                                                                                                                                                                                                       |

## 7. Updating and Review

This SOP will be reviewed not longer than three years following the date of ratification, or at any point before this if deemed necessary by the Senior Responsible Officer.

## 8. Equality and Diversity

8.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the ['Equality, Inclusion and Human Rights Policy'](#) or the [Equality and Diversity website](#).

8.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

## Appendix 1. Governance Information

| Information Category                                                                                | Detailed Information                                                                                                                                                                                                                                               |
|-----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Document Title:</b>                                                                              | Harm Reviews Standard Operating Procedure V2.0                                                                                                                                                                                                                     |
| <b>This document replaces (exact title of previous version):</b>                                    | Harm Reviews Standard Operating Procedure V1.0                                                                                                                                                                                                                     |
| <b>Date Issued/Approved:</b>                                                                        | 24 March 2023                                                                                                                                                                                                                                                      |
| <b>Date Valid From:</b>                                                                             | March 2023                                                                                                                                                                                                                                                         |
| <b>Date Valid To:</b>                                                                               | March 2026                                                                                                                                                                                                                                                         |
| <b>Directorate / Department responsible (author/owner):</b>                                         | Allister Grant, Chief Medical Officer                                                                                                                                                                                                                              |
| <b>Contact details:</b>                                                                             | 01872 253402                                                                                                                                                                                                                                                       |
| <b>Brief summary of contents:</b>                                                                   | To provide explanation to all staff (clinical and non-clinical) about why harm reviews should be carried out and the standardised approach to harm reviews. for all specialties to follow along with clearly defined roles and responsibilities of those involved. |
| <b>Suggested Keywords:</b>                                                                          | Harm review, potential harm, Clinical Harm Review Panel, risk stratification                                                                                                                                                                                       |
| <b>Target Audience:</b>                                                                             | RCHT: Yes<br>CFT: No<br>CIOB ICB: No                                                                                                                                                                                                                               |
| <b>Executive Director responsible for Policy:</b>                                                   | Chief Medical Officer                                                                                                                                                                                                                                              |
| <b>Approval route for consultation and ratification:</b>                                            | Clinical Harm Review Panel - 2022<br>Quality Assurance Committee - 2020                                                                                                                                                                                            |
| <b>General Manager confirming approval processes:</b>                                               | Deputy Medical Director                                                                                                                                                                                                                                            |
| <b>Name of Governance Lead confirming approval by specialty and care group management meetings:</b> | Deputy Medical Director                                                                                                                                                                                                                                            |
| <b>Links to key external standards:</b>                                                             | Not applicable                                                                                                                                                                                                                                                     |
| <b>Related Documents:</b>                                                                           | External Clinical Harm Review Handbook (V.5.)<br>2016 NHSE                                                                                                                                                                                                         |

| Information Category                                                             | Detailed Information                   |
|----------------------------------------------------------------------------------|----------------------------------------|
| Training Need Identified?                                                        | Yes                                    |
| Publication Location (refer to Policy on Policies – Approvals and Ratification): | Internet and Intranet                  |
| Document Library Folder/Sub Folder:                                              | Chief Executive / Corporate Governance |

### Version Control Table

| Date         | Version Number | Summary of Changes                                                | Changes Made by                       |
|--------------|----------------|-------------------------------------------------------------------|---------------------------------------|
| October 2018 | V1.0           | New Document – Initial Version                                    | Medical Director Office               |
| March 2023   | V2.0           | Full review including update to latest accessible Trust template. | Allister Grant, Chief Medical Officer |

**All or part of this document can be released under the Freedom of Information Act 2000**

**This document is to be retained for 10 years from the date of expiry.**

**This document is only valid on the day of printing.**

### Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy for the Development and Management of Knowledge, Procedural and Web Documents (The Policy on Policies). It should not be altered in any way without the express permission of the author or their Line Manager.

## Appendix 2. Equality Impact Assessment

### Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity, and Inclusion Team  
[richt.inclusion@nhs.net](mailto:richt.inclusion@nhs.net)

| Information Category                                                                                                                | Detailed Information                           |
|-------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Name of the strategy / policy / proposal / service function to be assessed:</b>                                                  | Harm Reviews Standard Operating Procedure V2.0 |
| <b>Directorate and service area:</b>                                                                                                | Chief Executive                                |
| <b>Is this a new or existing Policy?</b>                                                                                            | Existing                                       |
| <b>Name of individual completing EIA</b><br>(Should be completed by an individual with a good understanding of the Service/Policy): | Allister Grant, Chief Medical Officer          |
| <b>Contact details:</b>                                                                                                             | 01872 252875                                   |

| Information Category                                                                                                                  | Detailed Information                                                                                                                                                                      |
|---------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1. Policy Aim - Who is the Policy aimed at?</b><br>(The Policy is the Strategy, Policy, Proposal or Service Change to be assessed) | The aim of this SOP is to standardise the approach to Harm Reviews across RCHT.                                                                                                           |
| <b>2. Policy Objectives</b>                                                                                                           | To provide assurance that Harm Reviews are being conducted within each Speciality across RCHT.                                                                                            |
| <b>3. Policy Intended Outcomes</b>                                                                                                    | To provide assurance that the patients being treated outside of maximum expected times are subject to the clinical harm review process and have action taken as a result of this process. |
| <b>4. How will you measure each outcome?</b>                                                                                          | Outcomes/actions will be documented and monitored by the Clinical Harm Review Panel (CHRP).                                                                                               |

| Information Category                                                                     | Detailed Information                                                                                                                                                                                                                                                                                                            |
|------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>5. Who is intended to benefit from the policy?</b>                                    | Patients who have been potentially harmed will benefit from being identified and informed if the harm level is moderate or severe. These patients may become prioritised if still on the waiting list. The risk to future patients may be reduced by organisational knowledge and subsequent actions arising from harm reviews. |
| <b>6a. Who did you consult with?</b><br><br>(Please select Yes or No for each category)  | <ul style="list-style-type: none"> <li>• Workforce: Yes</li> <li>• Patients/ visitors: No</li> <li>• Local groups/ system partners: No</li> <li>• External organisations: No</li> <li>• Other: No</li> </ul>                                                                                                                    |
| <b>6b. Please list the individuals/groups who have been consulted about this policy.</b> | <b>Please record specific names of individuals/ groups:</b><br>Clinical Harm Review Panel                                                                                                                                                                                                                                       |
| <b>6c. What was the outcome of the consultation?</b>                                     | Agreed                                                                                                                                                                                                                                                                                                                          |
| <b>6d. Have you used any of the following to assist your assessment?</b>                 | <b>National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:</b><br>No                                                                                                                                                                                                       |

|                                                                                                                                                                                                                                                                                                                           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>7. The Impact</b></p> <p>Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.</p> <p>Where a negative impact is identified without rationale, the key groups will need to be consulted again.</p> |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| Protected Characteristic                                                   | (Yes or No) | Rationale                      |
|----------------------------------------------------------------------------|-------------|--------------------------------|
| <b>Age</b>                                                                 | No          | No negative impact anticipated |
| <b>Sex</b> (male or female)                                                | No          | No negative impact anticipated |
| <b>Gender reassignment</b><br>(Transgender, non-binary, gender fluid etc.) | No          | No negative impact anticipated |
| <b>Race</b>                                                                | No          | No negative impact anticipated |

| Protected Characteristic                                                                            | (Yes or No) | Rationale                      |
|-----------------------------------------------------------------------------------------------------|-------------|--------------------------------|
| <b>Disability</b> (e.g. physical or cognitive impairment, mental health, long term conditions etc.) | No          | No negative impact anticipated |
| <b>Religion or belief</b>                                                                           | No          | No negative impact anticipated |
| <b>Marriage and civil partnership</b>                                                               | No          | No negative impact anticipated |
| <b>Pregnancy and maternity</b>                                                                      | No          | No negative impact anticipated |
| <b>Sexual orientation</b> (e.g. gay, straight, bisexual, lesbian etc.)                              | No          | No negative impact anticipated |

**A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.**

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Allister Grant, Chief Medical Officer

**If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:**  
[Section 2. Full Equality Analysis](#)

### Appendix 3. Additional specialty specific cohorts for review and exemptions from review per specialty

| General surgery and cancer |                               |                                                                                                                                                                                                       |
|----------------------------|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Urology                    | Additional cohorts for review | Patients listed as 'urgent' for TURP/HOLEP/UROLIFT who have waited >16 weeks                                                                                                                          |
|                            |                               | Patients listed as 'routine' for TURP/HOLEP/UROLIFT who have waited 26 weeks                                                                                                                          |
|                            |                               | Patients waiting for TURBT >6 weeks                                                                                                                                                                   |
|                            |                               | Patients requiring rigid URS and laser to treat ureteric stones who have waited >8 weeks                                                                                                              |
|                            |                               | Patients waiting for FURS and laser or PCNL to treat renal stones who have waited >16 weeks                                                                                                           |
|                            |                               | Patients requiring a nephrectomy for cancer who have waited >6 weeks                                                                                                                                  |
|                            |                               | Patients requiring a change of suprapubic catheter under local anaesthetic who have waited >12 weeks                                                                                                  |
|                            |                               | Paediatric patients who have waited >18 weeks for orchidopexy                                                                                                                                         |
|                            |                               | Paediatric patients who have waited >12 weeks for urgent circumcision / bilateral testicular fixation                                                                                                 |
|                            |                               | Paediatric patients who have waited >26 weeks for routine surgery                                                                                                                                     |
|                            |                               |                                                                                                                                                                                                       |
| General Surgery            | Additional cohorts for review | Major bowel resection (not for cancer) who has waited longer than <b>18 weeks</b>                                                                                                                     |
|                            |                               | Restoration of continuity surgery (reversal of stoma); When the period of total time defunctioned exceeds <b>40 weeks</b> (for most patients this will not simply equate to the time on waiting list) |
|                            |                               | Biliary surgery; <b>&gt;18 weeks</b>                                                                                                                                                                  |
|                            |                               | Bariatric surgery; <b>&gt;18 weeks</b>                                                                                                                                                                |
|                            |                               | Hernia - groin / umbilical: <b>&gt;18 weeks</b>                                                                                                                                                       |
|                            |                               | Hernia – incisional / parastomal <b>&gt;18 weeks</b>                                                                                                                                                  |
|                            |                               | Hernia – hiatus; <b>&gt;18 weeks</b>                                                                                                                                                                  |
|                            |                               | Defunctioning procedures; <b>&gt;18 weeks</b>                                                                                                                                                         |

| General surgery and cancer |                               |                                                                |
|----------------------------|-------------------------------|----------------------------------------------------------------|
|                            |                               | Perineal procedures; <b>&gt;18 weeks</b>                       |
|                            |                               | Transanal work; <b>&gt;18 weeks</b>                            |
|                            |                               | Any work categorised as clinically urgent: <b>&gt;12 Weeks</b> |
|                            |                               | <b>Diagnostic patients over 18 weeks during COVID</b>          |
|                            |                               |                                                                |
| <b>Vascular Surgery</b>    | Additional cohorts for review | Patients listed as 'urgent' who have waited over 18 weeks      |
|                            |                               | Patients listed as 'routine' who have waited over 26 weeks     |
|                            |                               | Patients waiting for AAA more than 8 weeks                     |

| Specialist Services and Surgery |                               |                                                                                                                |
|---------------------------------|-------------------------------|----------------------------------------------------------------------------------------------------------------|
| <b>Oral Surgery</b>             | Additional cohorts for review | Co-efficient >1.5                                                                                              |
|                                 |                               |                                                                                                                |
| <b>Dermatology</b>              | Additional cohorts for review | Co-efficient >1.5                                                                                              |
|                                 |                               |                                                                                                                |
| <b>Ophthalmology</b>            | Additional cohorts for review | Co-efficient >1.5                                                                                              |
|                                 |                               |                                                                                                                |
| <b>Gastroenterology</b>         | Additional cohorts for review | Co-efficient >1.5                                                                                              |
|                                 |                               | Patients listed as 'urgent' for endoscopy who have waited >4 weeks                                             |
|                                 |                               | Patients listed as 'routine' for endoscopy who have waited >10 weeks                                           |
|                                 |                               | Surveillance and Barretts Oesophagus - in line with current BSG (British Society of Gastroenterology) Guidance |

| Specialist Services and Surgery |                               |                                                                                                                                                                             |
|---------------------------------|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>ENT</b>                      | Additional cohorts for review | Co-efficient >1.5                                                                                                                                                           |
|                                 |                               | Otology patients awaiting cholesteatoma surgery, if not had date by week 18, they are upgraded to urgent. Any case not having surgery by 28 weeks should have a harm review |
|                                 |                               | Head and Neck Pharyngeal pouch surgery and oesophageal dilatation: If surgery not done within 12 weeks of listing                                                           |
| <b>Rheumatology</b>             | Additional cohorts for review | Co-efficient >1.5                                                                                                                                                           |
|                                 |                               | Patient over 40 weeks flagged to consultant/doctor for review and recommend action where required                                                                           |

| Women, Children and Sexual Health |                               |                                                                                                                                                                         |
|-----------------------------------|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Gynaecology</b>                | Additional cohorts for review | Any patient awaiting a procedure for gynaecological cancer who has had their operation cancelled.                                                                       |
|                                   |                               | Any patient booked for 'urgent' gynaecological surgery who has not been booked and given a date for surgery 6 weeks after the day that the decision to operate was made |
|                                   |                               | Any patients waiting for a procedure on a planned waiting list who is past their to be seen by date                                                                     |
| <b>Acute Paediatrics</b>          | Additional cohorts for review | All non-admitted patient waiting over 18 weeks                                                                                                                          |
|                                   |                               | All non-admitted patients vetted as urgent over 6 weeks                                                                                                                 |
|                                   |                               | Follow-up patients waiting 1 month past their to be seen by date                                                                                                        |
|                                   |                               | New epilepsy patients waiting over 2 weeks                                                                                                                              |
|                                   | Exemptions                    | <i>From the retrospective cohorts - Open access patients</i>                                                                                                            |

| Women, Children and Sexual Health |                               |                                                                                                                                                 |
|-----------------------------------|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|
| Community Paediatrics             | Additional cohorts for review | Patients with epilepsy not under the care of another RCHT paediatrician who holds responsibility for their epilepsy                             |
|                                   |                               | Patients with significant and complex motor difficulties (GMFCS IV and V) who need regular surveillance to prevent deformity                    |
|                                   |                               | Patients waiting over 2 weeks                                                                                                                   |
|                                   |                               |                                                                                                                                                 |
|                                   | Exemptions                    |                                                                                                                                                 |
|                                   |                               |                                                                                                                                                 |
| Paediatric neurology              | Additional cohorts for review | Frequent seizures with or without hospital admissions                                                                                           |
|                                   |                               | No diagnosis and/or awaiting tertiary neurology opinion for diagnostic ambiguity                                                                |
|                                   |                               | Local paediatrician and parents wanting to ensure all therapeutic options have been explored in a timely manner and seeking reassurance of this |
|                                   |                               | Patients waiting longer than 18 weeks for tertiary review                                                                                       |
|                                   |                               |                                                                                                                                                 |

| Specialist Medicine    |                               |                                                                         |
|------------------------|-------------------------------|-------------------------------------------------------------------------|
| Cardiology and CFS     | Additional cohorts for review | Overdue follow ups > 1-month past tbs date                              |
|                        |                               | Elective diagnostics waiting > 6 weeks without an appointment           |
|                        |                               | Elective procedures waiting > 10 weeks to receive treatment             |
|                        |                               |                                                                         |
| Endocrine and Diabetes | Additional cohorts for review | Coefficient >1.5 for prospective cohorts (replaces cohorts in main SOP) |
|                        |                               |                                                                         |
|                        | Exemptions                    | Obesity patients                                                        |
|                        |                               |                                                                         |
| Renal                  | Additional cohorts for review | Urgent new patients waiting > 4 weeks                                   |

| Specialist Medicine |                               |                                         |
|---------------------|-------------------------------|-----------------------------------------|
|                     |                               | Routine new patients waiting > 10 weeks |
|                     |                               | Follow ups > 1-month past tbs date      |
|                     |                               |                                         |
| <b>Neurology</b>    | Additional cohorts for review | Urgent new patients waiting > 4 weeks   |
|                     |                               | Routine new patients waiting > 10 weeks |
|                     |                               | Follow ups > 1-month past tbs date      |
|                     |                               |                                         |
| <b>Respiratory</b>  | Additional cohorts for review | Urgent new patients waiting > 2 weeks   |
|                     |                               | Routine new patients waiting > 7 weeks  |
|                     |                               | Follow ups > 1-month past tbs date      |
|                     |                               | Elective diagnostics > 6 weeks          |

| Trauma and Orthopaedics |                               |                                                                                                                     |
|-------------------------|-------------------------------|---------------------------------------------------------------------------------------------------------------------|
| <b>Trauma</b>           | Exemptions                    | All retrospective cohorts                                                                                           |
|                         |                               |                                                                                                                     |
| <b>Orthopaedics</b>     | Exemptions                    | Trust SOP Cohorts                                                                                                   |
|                         |                               |                                                                                                                     |
|                         | Additional cohorts for review | <b>Prospective categories:</b>                                                                                      |
|                         |                               | At 6 weeks:                                                                                                         |
|                         |                               | 1 <sup>st</sup> stage revision for infection of major joint replacement                                             |
|                         |                               | 2 <sup>nd</sup> stage revisions with spacer and Girdlestone (excluding Kiwi) from date of listing as infection free |
|                         |                               | Waiting over 6 weeks from date of listing as able to go ahead with surgery with second stage reimplantation surgery |
|                         |                               |                                                                                                                     |
|                         |                               | At 3 months:                                                                                                        |
|                         |                               | Neurological conditions such as median/ulnar nerve compressive neuropathies                                         |

| Trauma and Orthopaedics |  |                                                          |
|-------------------------|--|----------------------------------------------------------|
|                         |  | Major rotator cuff tears                                 |
|                         |  | Avascular necrosis hip review                            |
|                         |  | At 6 months:                                             |
|                         |  | Hip dysplasia waiting PAO                                |
|                         |  | Hip impingement patients                                 |
|                         |  | Knee ACL reconstruction or multi-ligament reconstruction |

UNDER REVIEW

## **Appendix 4. Standard Operating Procedure for Harm Review for Cancer Treatment Standard Breaches**

### **Objective:**

1. Retrospective: review patients on a 62-day GP referral to treatment pathway treated beyond 104 days to identify clinical harm where it has occurred and to comply with procedures for investigating serious untoward incidents and the duty of candour process
2. Prospective: categorise the daily Cancer PTL by patient cohort, identifying patients who are over day 62 with confirmed cancer, on their 62-day referral to treatment pathway, without a treatment date in place and therefore deemed to be at increased risk of coming to harm as a result of their waiting time. Follow the prescribed clinical harm review process for this group of patients and put processes in place to prevent them coming to harm.

### **Patient cohort:**

1. Review of patients each month and perform clinical harm reviews on the following groups of patients;
  - i. Patients treated beyond 104 days.
  - ii. Patients with confirmed cancer diagnosis who died prior to receiving any treatment.
2. Prospective review of the Cancer PTL patients: Patients who are over day 62 with confirmed cancer, on their 62-day referral to treatment pathway, without a treatment date in place and therefore at increased risk of harm. Full RCA if patients are treated beyond 104 days.

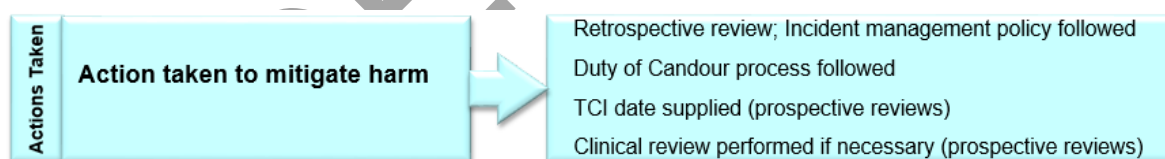
### **Process:**

1. Phasing:
  - a. Phase 1 all patients treated over 104 days, reported monthly in line with national cancer waiting times submissions. (25 working days after the end of the month)
  - b. Phase 2 all patients over 104 days not treated, reported monthly in line with NHS England return, (1<sup>st</sup> Friday of the month for all patients currently on a 62-day pathway)
  - c. Retrospective harm review of any patient over 104 days who died before treatment commenced.
  - d. Phase 4 all patients waiting over 62 days for treatment, reported monthly in line with national cancer waiting times submissions. (25 working days after the end of the month)

2. Cancer Services will identify the patients defined by:
  - i. Patients treated beyond 104 days.
  - ii. Patients with confirmed cancer diagnosis who died prior to receiving any treatment.

and identify this patient group on a monthly basis. They will then communicate to the clinical director, responsible clinician(s), Governance Leads and Associate Director how many patients require a harm review to be completed.

3. Cancer Services will identify the patients who are over day 62 with confirmed cancer, on their 62-day referral to treatment pathway, without a treatment date in place on a monthly basis. They will then communicate to the clinical director, responsible clinician(s), Governance Leads and Associate Director how many patients require a harm review to be completed. Patients under the care of tertiary centres will be excluded from harm reviews as these will be provided by the responsible trust.
4. The lead clinician responsible for a patient who fits into one of the above categories will carry out a desktop-based harm review using information on Maxims and the patient's notes.
5. The Clinical Director of Cancer Services will review the case.
6. A final decision on the level of harm the patient has suffered (or not suffered) will be decided.
7. As a result of the clinical harm review, a plan will be put in to place to mitigate the risk for the patient. The processes that should be followed will vary depending on whether the patient has had a prospective or a retrospective harm review. These processes are summarised below.



8. Results of clinical harm reviews will be discussed at specialty governance meetings where duty of candour processes will be put in place by the specialty.
9. Results of clinical harm reviews will be summarised by specialty and available for review at patient level by the Clinical Harm Review Panel.
10. The Clinical Harm Review Panel will review results of clinical harm reviews and report to the Trust's Quality Assurance Committee.
11. Any need for change identified will be discussed at the Cancer Operational Board and built into pathways and processes as part of the team work plan.

**Stake holders:**

Clinical Director for Cancer Services

Associate Director for Cancer Services

Specialty Manager for Cancer Services

Clinical Directors for each specialty

Associate Director for each Specialty

Agreed at specialty meeting/Cancer meeting/ CSCS Div Gov Meeting

UNDER REVIEW

## Appendix 5. Harm Review Handover

### Background

NHSE Harm Review Guidance produced in 2016, formed basis of harm review process in acute Trusts. Aim of the reviews is to minimise harm to patients who are waiting for treatment, and to ensure where harm is identified, appropriate steps are taken to address harms including fulfilling Duty of Candour obligations.

Whilst waiting times for treatment had seen an improvement in 2019, COVID caused and continues to cause significant disruption to normal provision of care and waiting times are ever increasing. As a result, the focus returned to the harm review process. There is a requirement to be able to provide assurance to the Board and to NHSE that the Trust has a robust process in place and to report on harm review outcomes.

### RADAR

#### Potential patient harm report

This report identifies the patients falling into the Trust SOP categories for review. Some issues with the quality of data:

- The search relies on data in PAS, so any inaccuracies lead to the wrong patients being on the list or missed off the list. Latter mitigated by RTT discussion identifying additional patients for review.
- Limited extent of filtering that is possible. Therefore, within the identified cohorts there will be patients who on further review do not fall into the categories and therefore do not need harm review. For example, where a patient is waiting for hand surgery and attends the ED with a traumatic knee injury, there is no link but because trauma and orthopaedics are not recorded separately, they will appear on list for review.
- Duplication in different cohorts appears where a patient may have more than one appointment/procedure planned.

#### Ways to address this:

- Clinicians when carrying out reviews will quickly see where not needed and can enter no harm in CHiRP (may be onerous for some specialties where numbers high and frequently have more than one pending apt). Appreciate that where harm review numbers are large, clinicians may feel disinclined to do this.
- Administrator reviews lists prior to distributing to clinicians to remove those cases clearly not requiring harm review and where duplications, indicates to clinicians that need to review with all categories in mind, but only complete one and admin will duplicate entry for other cohorts.
- Combination of above – clinicians can notify admin where duplication and administrator can input review on their behalf (clearly stating this in the additional comments section on CHiRP).

Provides basis for the harm review process at RCHT. Has been updated but will require further updates in the post covid era.

The updated Trust SOP at appendix 3 outlines the specialty specific cohorts for review and those which are exempt. These are all prospective cohorts. However, as a result of the pandemic, the numbers of patients requiring review within the Trust prospective cohorts and the specialty cohorts has increased to such an extent that there is not enough clinical resource to do this within the available time. In addition, analysis of the data from carrying out the prospective reviews in RCHT has shown a disproportionate amount of time being spent with very limited benefit (see Review of Harm Review Process at RCHT paper). At the same time, questions were asked across the country to NHSE about the feasibility of doing these reviews at the current time – recommendations were made:

Suspend Harm Reviews according to usual guidance:

- Adopt a risk-based approach to the issue of harm.
- Use the RCS patient groups (P1-P4) to prioritise treatments.
- Pull forward patients for earlier treatment if evidence of harm comes to light.
- Where harm is identified in the course of pathway/treatment ensure that Duty of Candour and other appropriate actions are taken
- Inform your respective Boards of your approach.

The Board will be reviewing the Paper in January to confirm the approach to be taken to harm reviews at RCHT at the current time. Whilst waiting for Board approval, care groups have been asked to prioritise completion of retrospective reviews.

At present, prospective reviews will be carried out where identified by clinicians as being of particular concern, or as a result of discussions at the weekly RTT meetings.

#### **Distributing cases for review:**

##### **RETROSPECTIVE**

1. Use the 'Potential patient harm' report on RADAR.
2. Select the month for review, and the specialty in the drop-down boxes on the right-hand side.
3. Click apply.
4. Screen (See notes below) and distribute the cases to the clinicians which fall into categories 1-5. These are the retrospective cases – emergency admissions whilst on the in-patient pending/out-patient pending/future booked appointment, and deaths on the in/out patient waiting lists.
5. Provide the clinicians with the cohort ID and the patient CR (these are used to record the reviews in CHiRP).

## Screening –

It is important to try and ensure that only the cases that require clinician review are distributed to the clinicians. Given the inherent problems with the RADAR report noted above, the following guidance needs to be considered:

Where a patient has an emergency admission and they have not been waiting for a period of time considered excessive, a review will not be required. For example, if a patient's appointment was made in September for November which would be considered a reasonable time to wait, but they were admitted in October, this arguably does not require review. However, if the appointment was made in March, the date given was November when it would have been May if Covid had not caused delay, if they then presented as an emergency in September, this would require review as it is possible the admission could have been prevented if they had been seen more quickly.

Where a patient appears in more than one cohort because for example, they are on the inpatient waiting list but are also on the outpatient pending list, only one review is needed but it will need to be recorded on CHiRP against both cohort IDs. Either the clinician can enter both, or the administrator can put on the duplicate entries for the clinician. The latter preferable particularly where numbers are large to reduce clinician time spent.

Where a patient has had more than one admission in the same month, only one review is needed on CHiRP although the review may be more complex for the clinician as they will have more notes etc to consider.

Because the data used to create the report is high level, there will be cases picked up which do not require review. For example, a patient admitted with a knee injury who appears on the ortho report because they are waiting for an outpatient shoulder consultation does not need to be reviewed. Where possible, any cases where it is clear that the admission is unrelated to the procedure/apt they are waiting for should be screened out before they reach the clinician. CHiRP can be completed by the administrator to show no harm with 'unrelated – no review required' entered into the additional comments box.

## PROSPECTIVE

1. Patients in the prospective harm categories 6-8 of the potential patient harm report on RADAR. **This category is currently under review and at present does not need to be prioritised, instead focus on the retrospective (above) and any additional cases identified through steps 2 and 3 below.**
2. Any patients identified in RTT as requiring harm review.
3. Any cohorts/patients identified by the specialty identified by the clinicians as requiring review.
4. Create a cohort ID for these patients, by prefacing the pathway ID with PP.
5. Provide the clinicians with the cohort ID and the patient CR to enable them to record the review on CHiRP.

## OTHER

1. Where a GP has contacted with concerns about a patient waiting, a harm review should be undertaken. This will be a retrospective review as the clinician will be considering whether or not the information provided suggests that the patient is coming to harm due to delay in treatment.
2. Create a cohort ID for these patients by prefacing the pathway ID with RR.
3. Provide the clinician with the cohort ID and patient CR to enable them to record the review on CHiRP.

## CHiRP

This is RCHT's tool for recording harm reviews. All clinicians undertaking harm reviews should be completing the reviews and recording in CHiRP.

The 10-minute training video can be found here:

<https://elearning.cornwall.nhs.uk/index.html?emod=chirp>

see also guidance document (How to record a clinical harm review using the CHiRP tool).

## Reporting

Monitoring and reporting reviews is done directly from the RADAR potential patient harm report (shows completion date and actions), and by using the CHiRP pivot (full review detail available) which is also on RADAR (enter 'CHiRP' in search bar).

All reviews on cases which are within the potential patient harm report on RADAR which are completed on CHiRP pull back through onto RADAR so you can see the date completed, the date any further review is required, and what actions were taken. If in the action column it states, 'Escalation required...', this tells you that the reviewer considers that there may have been harm as a result of delay. You can then look up the case in CHiRP to see what level of harm has been assigned. Any cases of harm should be discussed within the care group and once that discussion has taken place, a subsequent review is added to CHiRP to update on any actions. It may be that the discussion results in agreement of no harm, in which case, the subsequent review will be entered, and no further actions are required. If the discussion concludes harm, then a datix should be done, the subsequent review then entered into CHiRP with the datix ID, and any actions required. Any cases of agreed harm should be discussed in the Clinical Harm Review Panel meetings (currently held fortnightly on a Wednesday morning) and then reported to QAC/Board (see templates for reporting).

Each care group should be able to provide the data required to the individual overseeing the harm review reporting to Allister Grant (or his delegate) in advance of the reporting deadline for QAC. This includes the numbers of reviews carried out (as per template) and a brief narrative on any cases of harm.

## Appendix 6. Harm review quick guide

### Distributing cases for review:

#### RETROSPECTIVE

1. Use the 'Potential patient harm' report on RADAR.
2. Select the month for review, and the specialty in the drop-down boxes on the right-hand side.
3. Click apply.
4. Distribute the cases to the clinicians which fall into categories 1-5. These are the retrospective cases – emergency admissions whilst on the inpatient pending/outpatient pending/future booked appointment, and deaths on the in/out patient waiting lists.
5. Provide the clinicians with the cohort ID and the patient CR (these are used to record the reviews in CHiRP).

#### PROSPECTIVE

1. Patients in the prospective harm categories 6-8 of the potential patient harm report on RADAR. **This category is currently under review and at present does not need to be prioritised, instead focus on the retrospective (above) and any additional cases identified through steps 2 and 3 below.**
2. Any patients identified in RTT as requiring harm review.
3. Any cohorts/patients identified by the specialty identified by the clinicians as requiring review.
4. Create a cohort ID for these patients, by prefacing the pathway ID with PP.
5. Provide the clinicians with the cohort ID and the patient CR to enable them to record the review on CHiRP.

#### OTHER

1. Where a GP has contacted with concerns about a patient waiting, a harm review should be undertaken. This will be a retrospective review as the clinician will be considering whether or not the information provided suggests that the patient is coming to harm due to delay in treatment.
2. Create a cohort ID for these patients by prefacing the pathway ID with RR.
3. Provide the clinician with the cohort ID and patient CR to enable them to record the review on CHiRP.

## **For Reviewers:**

If on a first review of a case, you consider that there may be harm, the case must be escalated. The Trust SOP requires the case to be discussed with either the governance or specialty lead, or the clinical lead. If harm is confirmed, a datix should be raised. A subsequent review should then be added to CHiRP which will either confirm harm (and include adding the datix number) or record no harm.

## **Reporting:**

### **RETROSPECTIVE**

CHiRP automatically feeds back into RADAR for the cases on the potential harm report. You will therefore be able to see the date on which a harm review has been carried out, the date for any future review, and any actions. For those cases where harm was initially identified, you will see in the actions: '[date] Escalation Required – Internal Review'. This allows you to track which cases should be discussed to decide if harm is agreed and the need for datix and any other actions arises (e.g. duty of candour if moderate or severe harm).

For reviews where the cohort ID was manually created, these do not as yet feedback into RADAR.

The CHiRP pivot is now available in RADAR – enter 'CHiRP' into the RADAR search box to locate.

## Appendix 7. How to Record Clinical Harm Reviews using the Chirp Tool

| Purpose                 | To standardise the way we record clinical harm                                     |
|-------------------------|------------------------------------------------------------------------------------|
| Scope                   | This document applies to anyone who has responsibility for recording clinical harm |
| Effective date          | October 2020                                                                       |
| Sign off by             | Standard administration guideline group                                            |
| Sign off date           | October 2020                                                                       |
| Version                 | 1.3                                                                                |
| Primary source document | Patient Access Policy                                                              |
| Access policy reference | 11 General waiting list management<br>17.5 data collection                         |
| Review date             | April 2021                                                                         |
| Author                  | Nicola Robbins – Access Manager                                                    |

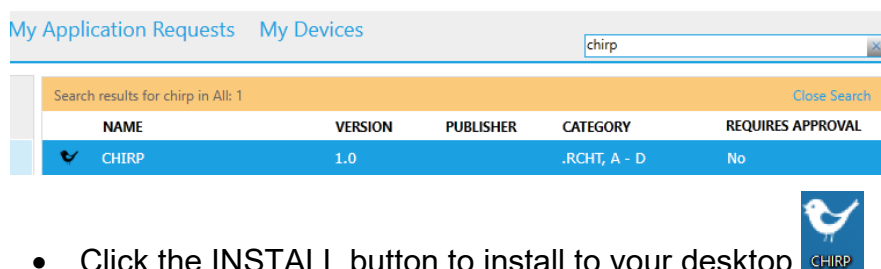
Harm Reviews give assurance to patients, patient groups, commissioners, and the public as to whether patients have been harmed, or are at risk of harm, as well as helping to avoid future harm to patients.

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.

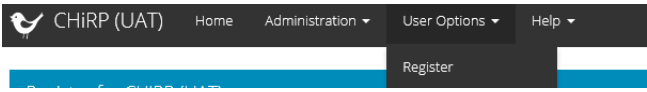
Definitions of harm will differ according to the circumstances which are being reviewed, e.g. Referral to Treatment (RTT) pathway, or Cancer pathway. However, NHSE have suggested definitions for the different levels of patient harm that may occur in for these pathways appendix 1. There will be other condition-specific factors that could be used to contribute to the definition of harm at a specialty level.

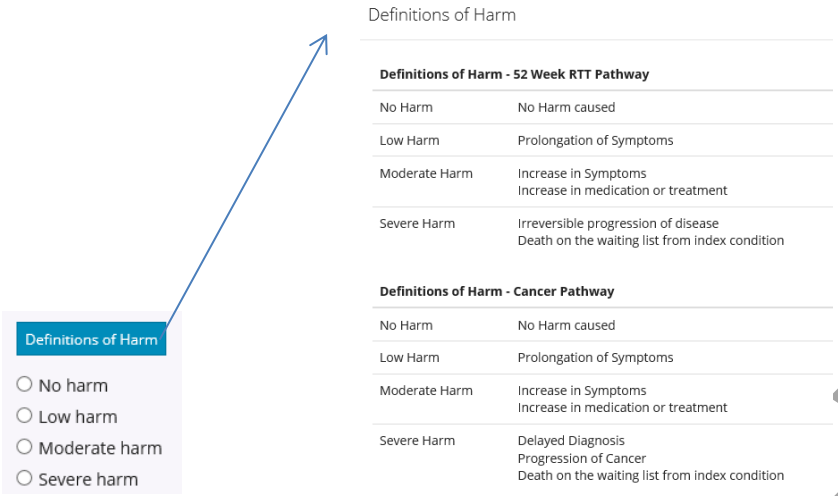
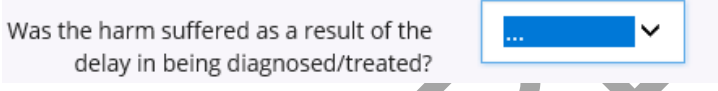
### 1. Add CHiRP to your desk top:

- Click on the Application catalogue icon on your desktop to search for CHiRP.



- Click the INSTALL button to install to your desktop

|    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2. | Open CHiRP using the icon on your desktop                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 3. | <p>Register to use CHiRP by clicking on the arrow to the right of 'User options' and selecting Register.</p>  <p>Tick Harm Reviewer and click submit:</p> <p>Select the group(s) you require access to:</p> <p><input type="checkbox"/> HarmReviewer</p> <p>Please enter a brief reason for accessing the system</p> <p>Submit</p> <p>You will then receive an email confirming access to the CHiRP harm review tool.</p>                                                                                                                                                                                                                                          |
| 4. | Enter the CR number of the patient requiring review                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 5. | Click the 'Add Harm Review' button to record the initial harm review. Click the 'Add Subsequent Review' button to record any subsequent harm review for a cohort ID.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 6. | <p>The cohort ID number is found on the Potential Patient Harm report on the inpatient module of RADAR. The Potential Patient Harm report cohorts patients most at risk of potential harm using agreed pre-defined criteria.</p>  <p>NB The cohort ID prefix identifies prospective and retrospective harm review. For example:</p> <ul style="list-style-type: none"> <li>• R112112 – Retrospective</li> <li>• P125235 – Prospective</li> </ul> <p>NB. For patients not included in the Potential Patient Harm report on Radar you must create the cohort ID manually using a prefix of PP (prospective) or RR (retrospective) followed by the pathway ID.</p> |
| 7. | Select specialty from the dropdown list.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 8. | <p>Enter the date of the harm review using the calendar icon</p> <p>Date of Review <input type="text"/> </p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 9. | Review clinical information using Maxims, Bluespier, hospital notes etc to establish what level of harm was suffered. Summarise your findings in the additional comments field.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |

|     |                                                                                                                                                                                                                   |
|-----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10. | <p>Select the level of harm, using the 'Definitions of harm' button to display further explanation on the harm categories:</p>  |
| 11. | For prospective harm review where potential harm is recorded the actions will automatically pre-fill with escalation required.                                                                                    |
| 12. | <p>For retrospective harm review you will need to record if the harm was as a result of delay, use the drop-down box:</p>      |
| 13. | If you are completing a subsequent review, you will need to enter the Datix ID                                                                                                                                    |
| 14. | Enter a re-review date (date by which you consider a further harm review should be undertaken if patient still not seen).                                                                                         |
| 15. | <p>Enter action category and type if appropriate, for example:</p> <p>Action category- Requires outpatient appointment.</p> <p>Action type – Book face to face</p>                                                |
| 16. | <p>Enter the date the action is required to be completed and click the Add action button to add the action.</p>               |
| 17. | Click submit review                                                                                                                                                                                               |

**NB. All cases where harm has been identified must be discussed with the Governance lead.**

## Definition of harm table

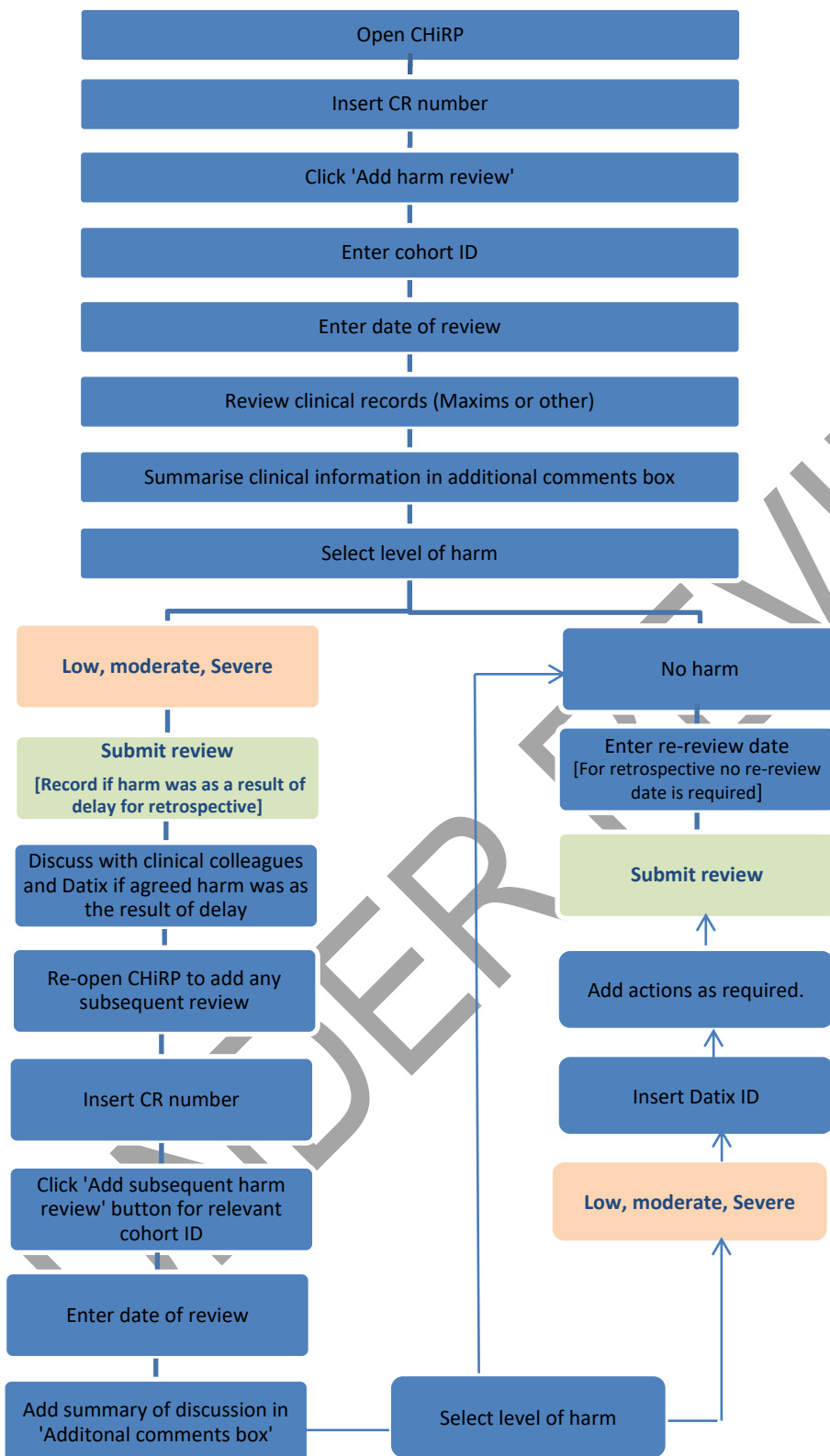
### Definitions of Harm –52-week RTT pathway

|          |                                                                                       |
|----------|---------------------------------------------------------------------------------------|
| Severe   | Irreversible progression of disease<br>Death on the waiting list from index condition |
| Moderate | Increase in symptoms.<br>Increase in medication or treatment                          |
| Low      | Prolongation of symptoms                                                              |

### Definitions of Harm – Cancer pathway

|          |                                                                                              |
|----------|----------------------------------------------------------------------------------------------|
| Severe   | Delayed diagnosis<br>Progression of cancer<br>Death on the waiting list from index condition |
| Moderate | Increase in symptoms.<br>Increase in medication or treatment                                 |
| Low      | Prolongation of symptoms                                                                     |

## Appendix 8. CHiRP – Clinical Harm Review Pathway Tool



**NB. All cases where harm has been identified must be discussed with the Governance lead.**

## Appendix 9. Harm Review Dashboard Template

### Prospective Harm Reviews

| [Month]                                | New patients waiting >24 weeks |                              |                                                            |     |          |        |
|----------------------------------------|--------------------------------|------------------------------|------------------------------------------------------------|-----|----------|--------|
| Care Group                             | No of patients                 | No of harm reviews completed | No. of patients where risk of coming to harm is identified |     |          |        |
|                                        |                                |                              | No harm                                                    | Low | Moderate | Severe |
| General Surgery & Cancer               |                                |                              |                                                            |     |          |        |
| Specialist Services & Surgery          |                                |                              |                                                            |     |          |        |
| Women, Children & Sexual Health        |                                |                              |                                                            |     |          |        |
| Anaesthetics, Critical Care & Theatres |                                |                              |                                                            |     |          |        |
| Specialist Medicine                    |                                |                              |                                                            |     |          |        |
| Urgent, Emergency & Trauma             |                                |                              |                                                            |     |          |        |
| Clinical Support                       |                                |                              |                                                            |     |          |        |
| Ortho                                  |                                |                              |                                                            |     |          |        |
| Total                                  | 0                              | 0                            | 0                                                          | 0   | 0        | 0      |

| Follow ups greater than 6 months |                              |                                                            |     |          |        |
|----------------------------------|------------------------------|------------------------------------------------------------|-----|----------|--------|
| No of patients                   | No of harm reviews completed | No. of patients where risk of coming to harm is identified |     |          |        |
|                                  |                              | No harm                                                    | Low | Moderate | Severe |
|                                  |                              |                                                            |     |          |        |
|                                  |                              |                                                            |     |          |        |

| Follow ups greater than 6 months |   |   |   |   |   |
|----------------------------------|---|---|---|---|---|
|                                  |   |   |   |   |   |
|                                  |   |   |   |   |   |
|                                  |   |   |   |   |   |
|                                  |   |   |   |   |   |
|                                  |   |   |   |   |   |
| 0                                | 0 | 0 | 0 | 0 | 0 |

| Patients waiting > 52 weeks |                              |                                                            |     |          |        |
|-----------------------------|------------------------------|------------------------------------------------------------|-----|----------|--------|
| No of patients              | No of harm reviews completed | No. of patients where risk of coming to harm is identified |     |          |        |
|                             |                              | No harm                                                    | Low | Moderate | Severe |
|                             |                              |                                                            |     |          |        |
|                             |                              |                                                            |     |          |        |
|                             |                              |                                                            |     |          |        |
|                             |                              |                                                            |     |          |        |
|                             |                              |                                                            |     |          |        |
|                             |                              |                                                            |     |          |        |
|                             |                              |                                                            |     |          |        |

| Patients waiting > 52 weeks |   |   |   |   |   |
|-----------------------------|---|---|---|---|---|
| 0                           | 0 | 0 | 0 | 0 | 0 |

## Retrospective Harm Reviews

| [Month]                                | Patients admitted as an emergency whilst on the inpatient waiting list, under the same or linked treatment function |                              |                                               |     |          |        |
|----------------------------------------|---------------------------------------------------------------------------------------------------------------------|------------------------------|-----------------------------------------------|-----|----------|--------|
| Care Group                             | No. of patients admitted                                                                                            | No of harm reviews completed | No. where harm been assessed to have happened |     |          |        |
|                                        |                                                                                                                     |                              | No harm                                       | Low | Moderate | Severe |
| General Surgery & Cancer               |                                                                                                                     |                              |                                               |     |          |        |
| Specialist Services & Surgery          |                                                                                                                     |                              |                                               |     |          |        |
| Women, Children & Sexual Health        |                                                                                                                     |                              |                                               |     |          |        |
| Anaesthetics, Critical Care & Theatres |                                                                                                                     |                              |                                               |     |          |        |
| Specialist Medicine                    |                                                                                                                     |                              |                                               |     |          |        |
| Urgent, Emergency & Trauma             |                                                                                                                     |                              |                                               |     |          |        |
| Clinical Support                       |                                                                                                                     |                              |                                               |     |          |        |
| Orthopaedics                           |                                                                                                                     |                              |                                               |     |          |        |
| Total                                  | 0                                                                                                                   | 0                            | 0                                             | 0   | 0        | 0      |

| Patients admitted as an emergency whilst on the outpatient pending list, under the same or linked treatment function |                              |                                               |     |          |        |
|----------------------------------------------------------------------------------------------------------------------|------------------------------|-----------------------------------------------|-----|----------|--------|
| No. of patients admitted                                                                                             | No of harm reviews completed | No. where harm been assessed to have happened |     |          |        |
|                                                                                                                      |                              | No harm                                       | Low | Moderate | Severe |

| Patients admitted as an emergency whilst on the outpatient pending list, under the same or linked treatment function |   |   |   |   |   |
|----------------------------------------------------------------------------------------------------------------------|---|---|---|---|---|
|                                                                                                                      |   |   |   |   |   |
|                                                                                                                      |   |   |   |   |   |
|                                                                                                                      |   |   |   |   |   |
|                                                                                                                      |   |   |   |   |   |
|                                                                                                                      |   |   |   |   |   |
|                                                                                                                      |   |   |   |   |   |
|                                                                                                                      |   |   |   |   |   |
| 0                                                                                                                    | 0 | 0 | 0 | 0 | 0 |

| Patients admitted as an emergency with a future booked appointment under the same or linked treatment function |                              |                                               |     |          |        |
|----------------------------------------------------------------------------------------------------------------|------------------------------|-----------------------------------------------|-----|----------|--------|
| No. of patients admitted                                                                                       | No of harm reviews completed | No. where harm been assessed to have happened |     |          |        |
|                                                                                                                |                              | No harm                                       | Low | Moderate | Severe |
|                                                                                                                |                              |                                               |     |          |        |
|                                                                                                                |                              |                                               |     |          |        |
|                                                                                                                |                              |                                               |     |          |        |
|                                                                                                                |                              |                                               |     |          |        |

| Patients admitted as an emergency with a future booked appointment under the same or linked treatment function |   |   |   |   |   |
|----------------------------------------------------------------------------------------------------------------|---|---|---|---|---|
|                                                                                                                |   |   |   |   |   |
|                                                                                                                |   |   |   |   |   |
|                                                                                                                |   |   |   |   |   |
|                                                                                                                |   |   |   |   |   |
| 0                                                                                                              | 0 | 0 | 0 | 0 | 0 |

| Deaths on the inpatient wait list |            |  | Deaths on outpatient wait list |            |
|-----------------------------------|------------|--|--------------------------------|------------|
| Linked                            | Not linked |  | Linked                         | Not linked |
|                                   |            |  |                                |            |
|                                   |            |  |                                |            |
|                                   |            |  |                                |            |
|                                   |            |  |                                |            |
|                                   |            |  |                                |            |
|                                   |            |  |                                |            |
|                                   |            |  |                                |            |
|                                   |            |  |                                |            |
|                                   |            |  |                                |            |
| 0                                 | 0          |  | 0                              | 0          |