Mid Essex Hospital Services
NHS Trust

Non Cancer Clinical Harm Review	**Standing Operating Policy** **Register No: 18020** **Status: Public on ratification**

Developed in response to:	Mid Essex CCG
Contributes to CQC Outcome:	Good Governance

Consulted With	**Post/Committee/Group**	**Date**
Elizabeth Podd	Associate Director of Performance	May 2018
	Elective board	June 2018
Professionally Approved By **Dr Rebecca Martin** **Chris Partridge**	Deputy Trust Medical Director Head of Nursing Mid & South Essex STP Joint Cttee	16 August 2018 28 June 2018

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Author/Contact for Information	Dan Young, Performance Manager
Policy to be followed by (target staff)	All Trust Staff
Distribution Method	Intranet & Website
Related Trust Policies (to be read in conjunction with)	04055 Patient Access Policy

Document Review History

Version No	**Authored/Reviewed by**	**Issue Date**
1.0	Daniel Young	17 August 2018
1.1	Nicola Riches - Amendments to 2.2, 2.3, 3.1, 3.6, 3.8, 5.0, 6.7, 9.0, Appendix 3. Inclusion of 3.3, 7.3, Appendices 7, 8, 9	5th June 2019

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Appendices

1.0 Purpose

1.1 The purpose of this policy is to provide guidance and to outline the rules for the management of patients who have breached the national performance standard and have exceeded 52 weeks on an RTT pathway.

1.2 The policy will provide oversight and management of the process for undertaking a root cause analysis (RCA) and Clinical Harm Review (CHR) for any RTT pathway closed over 52 weeks where harm has been identified.

1.3 The Trust is committed to the provision of a service that is fair, accessible and meets the needs of all individuals. An Equality Impact Assessment is provided as Appendix 1.

1.4 To provide assurance that all avoidable patient pathway delays are reviewed and actions implemented to reduce the risk to future patients.

1.5 To ensure that when a case of clinical or psychological harm is found to have occurred, the Lead Consultant will follow the Trust Duty of Candour policy.

1.6 **For patients:**

This policy will ensure that patients who exceed 52 weeks on an RTT pathway will have their pathway reviewed at a weekly Divisional access meeting and escalated for a formal harm review depending on both the reasoning for their breach of the national RTT guidance and the outcome of their clinical pathway. The RCA will take into account that a patient may choose to wait longer or clinically be unable to be seen or treated within these time frames.

1.7 **For Clinical and Non Clinical staff:**

This policy will ensure that teams and individuals are aware of their responsibilities for moving patients along the agreed clinical pathway in accordance with the national RTT standards as set out in RTT national guidance.

2.0 Policy Statement

2.1 The patient's best interests are at the forefront of this policy**.**

2.2 Patients waiting longer than 52 weeks for treatment on an RTT pathway will have a harm review undertaken to ensure their delay in treatment had not caused any clinical or psychological harm.

2.3 Whilst there is an acknowledgement that there may be legitimate reasons for some waits, NHS England have set expectations that such long delays should be expected to trigger a review process, so that providers can understand the causes of these long waits and put in place processes to avoid them in future.

3.0 Roles and Responsibilities

3.1 Medical Director

Expected to co-chair the monthly, and in exceptional circumstances, twice weekly, non-cancer harm review meetings, until volumes of 52 week breaches are manageable.

Expected to sign off and confirm the breach report findings of the Patient Lead Clinician

3.2 Chief Operating Officer

Responsible for implementing Trust wide monitoring systems to ensure compliance with this policy and avoid breaches of the standards.

3.3 Director of Nursing

Expected to co-chair the monthly, and in exceptional circumstances, twice weekly, non-cancer harm review meetings, until volumes of 52 week breaches are manageable.

To support and ensure all harm reviews are delivered within the agreed timeframes

3.4 Associate Directors of Operations and Divisional Clinical Directors

Responsible for implementation and adherence to this policy, ensuring that all staff required are aware of their roles and responsibilities and receive training to enable them to meet the policy requirements.

3.5 Patient Lead Clinician

Expected to sign off and confirm the following on the breach report:

- Was the breach avoidable/unavoidable?
- What level of harm is associated with the breach?

3.6 Service Managers

- Ensure that clinical review is undertaken and clinical sign off takes place for each breach escalated for a harm review (See Appendix 4)
- If Low-Moderate harm is identified then the case will be managed internally by the Division.
- If Severe harm is identified, then a Datix incident report will be completed
- Expected to review the RCA for patients identified with severe harm within their specialty, ensuring it is a true and accurate representation of the patient journey (See Appendix 3)
- Share breach reports and learning outcomes with their specialty teams
- Return the completed RCA back to the Performance team

3.7 Performance and Validation Team

- Complete RCA timeline (see Appendix 3) for patients identified as severe harm following thematic review by the Divisions.
- Email out timelines and outstanding harm reviews from previous months to relevant service managers

- Update spreadsheet with WEB numbers and outcomes
- Performance team to support services will completion of outstanding tasks where required
- Prepare a quarterly thematic review report for the Clinical Quality Review Group (CQRG) and via the Trust governance structures.

3.8 **Elective Care Group**

The number of 52 week breaches by specialty will be a standing agenda item at the Elective Care Group. The Elective Care Group will receive and monitor the Divisional exception reports ensuring action is taken to mitigate avoidable delays.

4. Training

4.1 All clinical/nonclinical staff involved in RTT pathways will have specific local training in relation to the implementation of this policy.

5. Process

Step	Action	Purpose
Phase 1	Weekly access meetings will discuss all 52+ week pathways that have been closed in the previous week against the agreed questions as outlined in appendix 1. Clinicians will still be able to escalate the need for a harm review on any patient below 52 weeks that they feel requires one regardless of the stage they are in their pathway.	
Phase 2	The list of 52+ breach patients will be emailed to the relevant specialties, once the monthly 52 week breaches have been confirmed. The Divisions will report the breach on Datix and complete the harm review. The process will be coordinated by the Harm Review Coordinator	Ensures accurate pathway guide to review
Phase 3	Lead clinician and managerial leads through their own governance structure have 4 weeks to review timelines, assess and action counter measures for avoidable delays. Lead clinician to assess whether pathway delays have impacted on the patient's outcome and resulted in clinical and/or psychological harm. The forms will then be returned to the Performance team to catalogue the breach, and if severe harm has been documented, an RCA timeline (appendix 2) will be produced.	To prevent avoidable delay re-occurring

Phase 4	The Performance team will prepare a both a quarterly thematic review report for the Clinical Quality Review Group (CQRG) and Senior Management Group (SMG) The Performance team will prepare and distribute all completed harm reviews to the non-cancer harm review panel for discussion with both the Medical Director of MEHT and Head of Nursing for Mid & South Essex STP Joint Committee. This will occur only when potential harm is registered through Phase 1.	Any patient outcome found to have been impacted by the delays will result in the Trust declaring an SI and ensure duty of Candour is followed
Phase 5	The Performance team will prepare a quarterly thematic review report for the Clinical Quality Review Group (CQRG). All patients escalated from the harm review panel as having had or potentially had an instance of clinical or psychological harm will be escalated to the Clinical Quality Review Group (CQRG)	Share good practice and learning

6.0 Incident Reporting & Review

6.1 Every breach incident must be notified on Datix through a division wide Datix following the 52 week data submission to Unify.

6.2 The Service Managers of each specialty will be responsible for completing the review of each patient with the support of the lead Clinician for that patients care. The performance team will then close the Datix following review of the thematic report. Any patients found to have potential harm will then have a new Datix raised which will be closed by the Division following the formal harm review meeting outcome.

6.3 Datix incidents to be reviewed by the Incident Review Group.

6.4 Breaches and action points/plans will be shared at Senior Management Group, Divisional performance meetings, Elective Care Group, Clinical Quality Review Group. Themes of causes and actions will be discussed at the Quarterly Harm review meeting with CCG colleagues

6.5 For breaches where patient harm has been identified then the Duty of Candour process must be followed.

6.6 A representative of the CCG will attend the harm review meetings at agreed intervals.

6.7 The number of 52 week breaches by specialty will be a standing agenda item at the Elective Care Group. The Elective Care Group will receive and monitor the Divisional exception reports as a standing agenda item, ensuring action is taken to mitigate avoidable delays

7.0 Equipment and System Access Requirements

7.1 RCA and clinical harm review template access for:

- Service Managers
- ADOs
- Performance Team
- Validation Team
- Consultants

7.2 Lorenzo access for:

- Service Managers
- ADOs
- Performance Team
- Validation Team
- Consultants

7.3 Weekly exception report for:

- Site Leadership team
- Programme Lead
- Harm Review Coordinator

8.0 Key Performance Indicators (KPI)

No	KPI	Target	Frequency
1.	Proportion of patients waiting longer than 52 weeks who had a clinical harm review	100%	Monthly
2.	Number of patients who had an avoidable delay in their pathway – identified through RCA process		Monthly
3.	Number of patients where there was an agreement that clinical harm had occurred due to long waits		Monthly

9.0 Monitoring and Dissemination

9.1 This policy will be professionally approved by Elective Care Group and ratified by the Document Ratification Group as per Trust procedure.

9.2 Compliance with this SOP will be monitored through the Elective Care Group, Clinical Quality Review Group (CQRG) and the Trust Board.

9.3 Alterations and amendments to this policy will be approved and endorsed by the Elective Care Group

9.4 Corporate Services will ensure that the policy is available on the Intranet and the Trust website following ratification.

Appendix 1: Initial Harm Review

Mid Essex Hospital Services NHS Trust

52 Weeks Clinical Harm Review

NHS Number	
Hospital Number	
Patients Name	
Speciality	
Diagnosis	
Date of Treatment	
Total Weeks Wait	
Form Completed By	
Was Physical harm sustained	
Date Form Completed	

1. Was the treatment different than the originally planned treatment due to the delay? If so please provide details

Yes / No

2. Is there any evidence of disease progression due to the delay?

Yes / No

3. Has the delay meant that the patient has had to have more radical surgery than first anticipated?

Yes / No

4. Has a delay meant that the condition has progressed to an extent that some treatment options that would have been applicable were no longer an option?

Yes / No

5. Has a delay in treatment meant that a patient has loss of functionality that is greater than anticipated, commensurate with their condition?

Yes / No

6. Do the patient's clinical notes indicate any prolonged (28 days or more) Psychological harm resulting from this delay? If so please annotate whether you consider this to be mild, moderate or severe psychological harm. Psychological Harm is a type of damage to the mind that occurs as a result of a severely distressing event. Harm could be the result of an overwhelming amount of stress that exceeds one's ability to cope, or integrate the emotions involved with that experience?

Yes / No

Name of Reviewer	
Reviewers Job Role	
Signed	
Date	

Mid Essex Hospital Services
NHS Trust

Harm Review Panel **Date**

Panellists

Kevin Beaton	**Medical Director**	**Print Name:**	**Signed:**
Dr. Rebecca Martin	**Deputy Medical Director**	**Print Name:**	**Signed:**
Wendy Matthews	**Director of Nursing**	**Print Name:**	**Signed:**
Dan Spooner	**Deputy Director of Nursing**	**Print Name:**	**Signed:**
	CCG Representative	**Print Name:**	**Signed:**

Patient Name:

Specialty:

Harm (Yes/No):

Agreed/Disagreed:

52 Week Clinical
Harm review Templat

Appendix 2: RCA template for potential Harm

NHS
Mid Essex Hospital Services
NHS Trust

52 Week Breach - Root Cause Analysis Report

To Be Completed By Access Team	
DATIX Web Number	
NHS Number	
Hospital Number	
Patient Name	
Speciality	
Pathway Type	
Referral Reason	
Total Weeks On Pathway	
Site	
Form Completed By	

Date	Role	Name	Signature
	Lead Clinician		
	Service Manager		
	Divisional Associate Director		

Chronology of events	Date (dd/mm/yyy)	Weeks on Pathway	No. weeks between events	RAG	Expected Wait	Outcome	Details / Comments
Date of Referral - CLOCK START							
		0					
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Actions To Be Taken

Problem / Issue	Action	Who	By When

Physical Harm Review

What was the patient originally referred for?	
What was the confirmed clinical diagnoses?	
Has the patient received treatment for their condition?	
Was the treatment different than the originally planned due to the delay? If so, please provide details	
Is there any evidence of disease progression due to the delay?	
Has a delay meant that patient has had to have more radical surgery than first anticipated?	
Has a delay meant that the condition has progressed to an extent that some treatment options that would have been applicable were no longer an option?	
Has a delay in treatment meant that a patient has loss of functionality that is greater than anticipated, commensurate with their condition?	

Psychological Harm review

What was the outcome of the Psychological Harm review?	

RCA Assessment

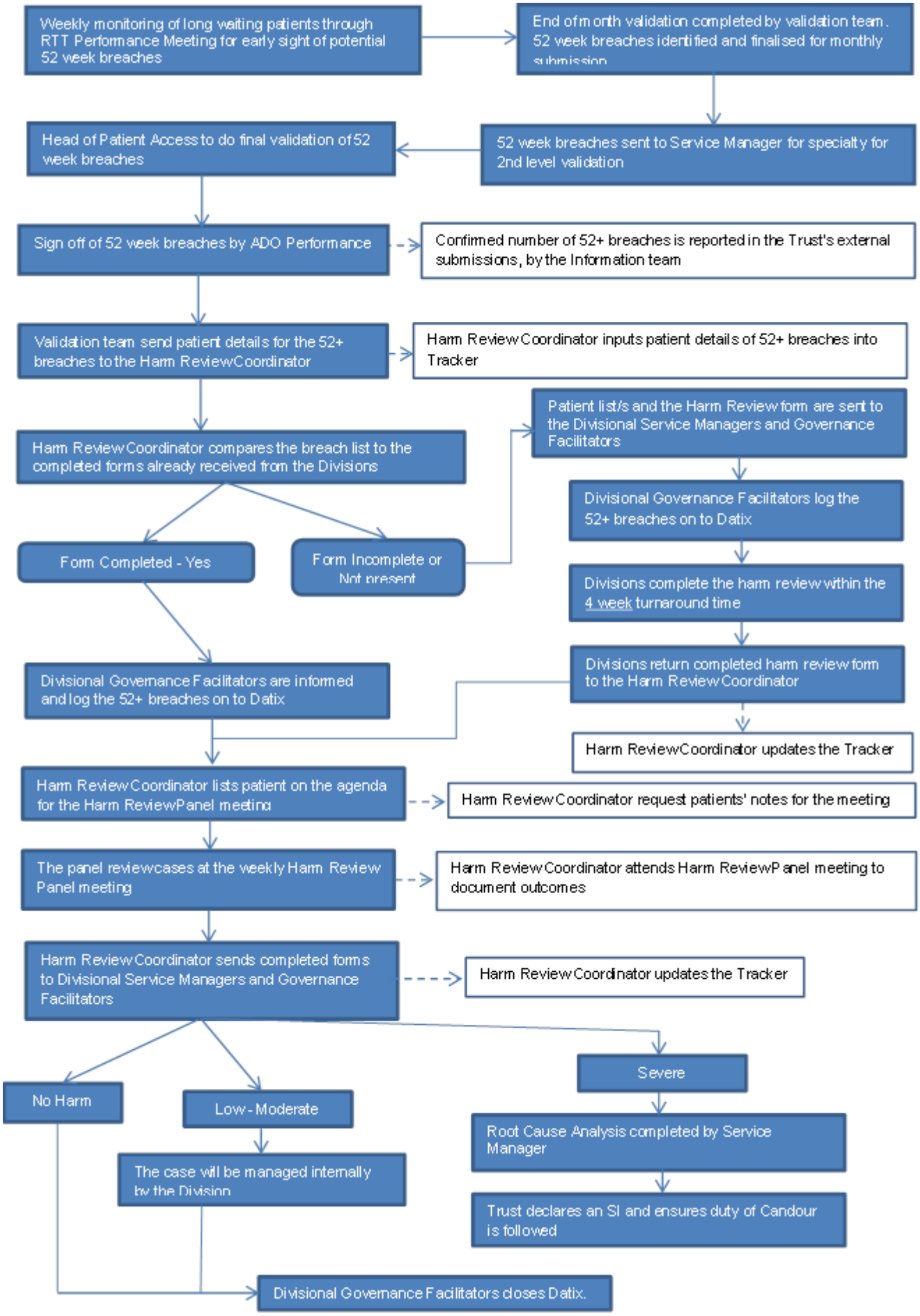
Physical Harm Impact	
Psychological Harm Impact	
Communication Impact	
Social / Work Impact	

Review Panels Decision

What level of harm should be attributed to this case?	No Harm		Date:	
	Low Harm		Name of person signing on behalf of panel	
	Moderate Harm		Role of person signing on behalf of panel	
	Severe Harm		Signature	
Is this case to be refered to the SIMG?				

Comments

Appendix 3: Standard Operating Procedure for Reporting 52 Week Breaches



Appendix 4: Degree of Harm RAG Rating Guidance Table

Level of Harm	Definition*	Examples
No Harm (GREEN)	There are two types of no harm incident: *a) Impact prevented (i.e. a near miss): any adverse incident that had the potential to cause harm but was prevented, resulting in no harm to anyone* b) *Impact not prevented: any adverse incident that ran to completion but caused no harm to anyone*.	• Pathway found to be an administrative failing with no delay to patient • Patient waited excessively for treatment but no harm was caused as a result of the wait • Patient died of a different condition to that for which they were referred.
Minor harm (YELLOW)	Defined as: *Any event or circumstance resulting in minor changes to the original treatment plan and caused minimal harm.*	• Additional treatment and/or pain relief required • Psychological impact of delayed treatment on the patient.
Moderate Harm (AMBER)	Defined as: *(a) harm that requires a moderate increase in treatment, and;* *(b) significant, but not permanent, harm;* *A "moderate increase in treatment" means an unplanned change to the original treatment plan, an emergency admission for the same condition prior to treatment, extra time in hospital or as an outpatient, cancelling of treatment, transfer to another treatment area (such as intensive care), or prolonged psychological harm (prolonged in this context means waiting for treatment in excess of 52 weeks).*	• Attendance to ED for the same condition (not admitted) • Admitted via ED for the same condition • Where the treatment plan is significantly different to the original treatment plan, requiring more recovery or protracted length of stay as a result.
Severe / Catastrophic Harm or Death **(RED)**	Defined as: *A permanent lessening of physiologic or intellectual functions, including organ or brain damage, that is related directly to the delay in managing the patient and not related to the condition for which the patient was referred.*	• Patient died of the same condition prior to receiving treatment • Missed opportunity to treat cancer as a result of the delay • Patient has had life changing injury as a result of the delay.

Appendix 5: Psychological Harm Review Document

PSYCHOLOGICAL HARM REVIEW

NHS Number	
Hospital Number	
Patients Name	
Speciality	
Total Weeks Wait	
Form Completed By	
Was Psychological harm sustained	

1. Did the patient sustain physical harm as a result of the delay?

Yes / No

2. Did the patient experience multiple cancellations during phases 1-3 of their pathway caused by the hospital, or conflicting messages from hospital staff?

Yes / No

3. Did the patient experience multiple cancellations during phases 4-5 of their pathway caused by the hospital, or conflicting messages from hospital staff?

Yes / No

If the answer was 'Yes' to any of these questions, then probable additional psychological harm has been sustained and actions should be completed, If not move to question 4.

4. Is their evidence in the notes that the patient received clear and accurate information from their clinician about their treatment plan?

Yes / No

5. Is their evidence in the notes that the patient was given information about what to do if they experienced delays?

Yes / No

If yes, was this information acted on in keeping with the trusts policies?

Yes/No

6. Did the patient inform the hospital in the inpatient nursing or holistic assessment that they would require support to manage their feelings?

Yes/No

If yes, was this information acted on in keeping with the trusts policies?

Yes/No

7. At 48 weeks into their pathway, was a phone call made to explain the situation and assess their wellbeing, if so was appropriate support offered or a referral made?

Yes/No

Actions to be taken based on outcome

Action to take	By Who?	By When

Guidance
If the answer was 'No' to 1-2 of the secondary questions, then the Matron for the service will need to contact the patient to ensure they have not received any significant and preventable psychological distress and harm contributed by MEHT care. Following this phone call, if the matron believes the patient has suffered significant and preventable psychological distress, they should offer a referral to the psychotherapy and counselling team.

If the answer was 'No' to 3-4 of the secondary questions, then the Matron for the service will need to contact the patient as it is assumed MEHT care contributed to significant and preventable psychological distress. During this phone call, the Matron will offer a referral to the psychotherapy and counselling team.

Appendix 6: 52 week Breach RCA Quality Assurance Checklist

Web No	
NHS No	
Hospital No	
Patient Name	
Speciality	
RCA Owner	

- □ Is all patient detail included on the RCA?
- □ Are the lead clinician, service manager and divisional manager identifiable?
- □ Is the timeline complete with no gaps in events?
- □ Have the auto-complete fields populated correctly?
- □ Are the outcomes and comments fields completed to a sufficient standard?
- □ Is there an action for each red and amber light on the timeline?
- □ Are the actions relevant to the light and detailed?
- □ Has the physical harm assessment been completed and agreed?
- □ Has a psychological harm review been completed and attached?
- □ Is the RCA complete to a standard ready to be presented?

Name of Reviewer	
Reviewers Job Role	
Signed	
Date	

GUIDANCE NOTES:

This document is designed to be a failsafe check on the RCA before it is presented to the panel.

This document is to be completed by the Performance Manager or another suitable independent manager not associated with the speciality listed.

This document must be completed and signed off for each RCA before it is presented to the Harm review Panel.

All actions must be reviewed to ensure they are of an adequate standard to remove the risk of the red/amber light repeating.

If one of these checks is not complete, the RCA must be returned back to the Service Manager with detail of why the RCA was rejected.

It is the Service Managers responsibility to ensure that the RCA is completed correctly and on time.

Appendix 7: 52 week Harm Review Backlog Completion Tracker

										Degree of Harm					Audits	
January to December 2018 >52 week complete breaches	Total in Breach	CHR Undertaken	Data Quality Error	CHR Outstanding	Harm Review paperwork given to S/M	Harm review paperwork in notes	Harm review completed by consultant	Harm review presented at panel	Decision of harm completed	None	Low	Moderate	Severe	Outstanding	Number Audited	% Audited
ALLERGY	65	53	7	5	65	0	53	53	53	51	2	0	0	0	10	19%
ANAESTHETICS	1	0	0	1	1	0	0	0	0	0	0	0	0	0	0	#DIV/0!
ANTICOAGULANT	1	0	1	0	1	0	0	0	0	0	0	0	0	0	0	#DIV/0!
AUDIOLOGY	3	2	0	1	3	0	2	2	2	2	0	0	0	0	0	0%
BREAST	1	1	0	0	1	0	1	1	1	1	0	0	0	0	0	0%
CARDIOLOGY	131	93	21	17	131	0	93	93	93	88	5	0	0	0	80	86%
CLINICAL HAEMATOLOGY	2	0	1	1	2	0	0	0	0	0	0	0	0	0	0	#DIV/0!
CLINICAL NEUROPHYSIOLOGY	23	0	23	0	23	0	0	0	0	0	0	0	0	0	0	#DIV/0!
COLORECTAL SURGERY	72	60	10	2	72	0	60	60	60	56	4	0	0	0	22	37%
DERMATOLOGY	24	10	5	9	24	0	10	10	10	9	1	0	0	0	3	30%
PAEDIATRIC DERMATOLOGY	10	10	0	0	10	0	10	10	10	10	0	0	0	0	1	10%
DIABETIC MEDICINE	1	1	0	0	1	0	1	1	1	1	0	0	0	0	1	100%
DIETETICS	4	4	0	0	4	0	4	4	4	4	0	0	0	0	4	100%
ENDOCRINOLOGY	18	14	1	3	18	0	14	14	14	12	2	0	0	0	2	14%
ENT	147	141	4	2	147	0	141	141	141	140	1	0	0	0	17	12%
PAEDIATRIC EAR NOSE AND THROAT	36	35	1	0	36	0	35	35	35	34	1	0	0	0	7	20%
GASTROENTEROLOGY	71	54	4	13	71	6	54	54	54	53	1	0	0	0	15	28%
GENERAL MEDICINE	56	44	1	11	56	0	44	44	44	41	3	0	0	0	13	30%
GENERAL SURGERY	43	37	5	1	43	0	37	37	37	31	6	0	0	0	20	54%
PAEDIATRIC SURGERY	35	30	0	5	35	0	30	30	30	26	4	0	0	0	15	50%
GERIATRIC MEDICINE	2	2	0	0	2	0	2	2	2	2	0	0	0	0	1	50%
GYNAECOLOGY	4	0	4	0	4	0	0	0	0	0	0	0	0	0	0	#DIV/0!
MAXILLO-FACIAL SURGERY	52	30	0	22	52	0	30	30	30	30	0	0	0	0	1	3%
PAED MAXILLO-FACIAL SURGERY	1	1	0	0	1	0	1	1	1	1	0	0	0	0	0	0%
ORAL SURGERY	65	65	0	0	65	0	65	65	65	65	0	0	0	0	0	0%
ORTHODONTICS	2	2	0	0	2	0	2	2	2	2	0	0	0	0	2	100%
MEDICAL ONCOLOGY	1	1	0	0	1	0	1	1	1	1	0	0	0	0	1	100%
NEPHROLOGY	1	1	0	0	1	0	1	1	1	1	0	0	0	0	1	100%
NEUROLOGY	65	41	0	24	65	0	41	41	41	38	3	0	0	0	7	17%
NEUROSURGERY	5	2	0	3	5	0	2	2	2	2	0	0	0	0	0	0%
OPHTHALMOLOGY	129	96	4	29	129	0	96	96	96	96	0	0	0	0	13	14%
PAEDIATRIC OPHTHALMOLOGY	2	0	0	2	2	0	0	0	0	0	0	0	0	0	0	#DIV/0!
PLASTIC SURGERY	271	250	0	21	271	0	250	250	250	249	1	0	0	0	37	15%
PAEDIATRIC PLASTIC SURGERY	3	0	1	2	3	0	0	0	0	0	0	0	0	0	0	#DIV/0!
PAEDIATRICS	7	4	3	0	7	0	4	4	4	4	0	0	0	0	0	0%
PAIN	3	1	0	2	3	0	1	1	1	0	1	0	0	0	1	100%
PHYSIO	7	0	7	0	7	0	0	0	0	0	0	0	0	0	0	#DIV/0!
RESPIRATORY MEDICINE	37	21	14	2	37	0	21	21	21	20	1	0	0	0	8	38%
RHEUMATOLOGY	109	94	0	15	109	0	94	94	94	94	0	0	0	0	7	7%
STROKE/Transient Ischaemic Attack	3	2	0	1	3	0	2	2	2	2	0	0	0	0	1	50%
TRAUMA AND ORTHOPAEDICS	159	137	1	21	159	0	137	137	137	135	2	0	0	0	17	12%
PAEDIATRIC TRAUMA AND ORTHOPAEDICS	4	0	1	3	4	0	0	0	0	0	0	0	0	0	0	#DIV/0!
UROLOGY	8	8	0	0	8	0	8	8	8	8	0	0	0	0	8	100%
PAEDIATRIC UROLOGY	1	1	0	0	1	0	1	1	1	1	0	0	0	0	1	100%
UPPER GASTROINTESTINAL SURGERY	62	57	5	0	62	0	57	57	57	49	8	0	0	0	29	51%
VASCULAR SURGERY	12	7	5	0	12	0	7	7	7	7	0	0	0	0	6	86%
TOTAL	1759	1412	129	218	1759	6	1412	1412	1412	1366	46	0	0	0	351	25%

As of 17/05/2019

Appendix 8: RTT 52 Week Harm Review Process Outpatients

RTT HARM REVIEW PROCESS OPD.doc

Appendix 9: RTT 52 Week Harm Review Process Inpatients

RTT HARM REVIEW PROCESS IP - V3 201