Northern Cancer Alliance

NHS North East and North Cumbria

The Northern Cancer Alliance

Guideline to Manage Long Wait Cancer Patients +104 days Harm Review Process

Version No:	Draft 1
Effective From:	June 2025
Review Date:	June 2027
Date Ratified:	5 June 2025
Ratified By:	NCA Board

1 Introduction

This paper outlines the NCA agreed guidance for completing a Harm Review on cancer patients waiting beyond which patients should be assessed for harm – for cancer waiting times this is beyond 104 days. Delays in diagnosis and surgery cause exponential burden of attributable mortality (Sud et al; 2020). The NHS Delivery plan for tackling the Covid backlog (February 2022) identified the need to ensure robust accuracy and tracking of patients and the importance to focus on clinical need and not solely numbers on the waiting list. The review process should take place as a minimum for any cancer patients waiting 104 days (6 weeks after reaching 62 days) or more from referral to the first definitive treatment.

This document provides further guidance to support best practice processes in Trusts across NENC to identify and reduce the risk of harm to our patients across all pathways. The guidance is based on extensive work with Newcastle upon Tyne Hospitals to improve their processes and embed reviews within a treatment organisation and referring Trusts (where applicable) through shared learning and best practice. It includes harm review criteria and measured definitions of harm, and a suggested internal escalation approach to report delays that may have direct clinical significance and/or have resulted in a harm event for the delayed patient.

2 Guideline scope

The NHS has set maximum waiting time standards for patients with a potential cancer diagnosis. Patients consider achievement of these national cancer waiting times (CWT) standards and the public to be an indicator of the quality of cancer diagnosis,

treatment and care NHS organisations deliver. Patients on a cancer pathway can face many obstacles that can cause delays and therefore influence their potential outcome.

Individual Trust cancer operational standards, performance management and reporting arrangements aim to act as a tool to improving access times for all cancer patients. This guideline details a process by which patient pathways with significantly long waiting times are reviewed on a patient specific and thematic basis. It aims to join up these reviews and processes for effective clinical governance and risk management within organisations and give assurance that any delays are not impacting on patient safety.

All patients at 104 days with a confirmed cancer diagnosis irrespective of whether treatment is planned, need to have any harm or potential of harm assessed and documented. This could be done at a sooner date with **104 days as a minimum**. Several organisations are doing reviews at approximately 84 days which would support best practice.

The aims for the cancer harm review process are:

- To identify any avoidable harm and mitigate this moving forward.
- To provide assurance that all avoidable patient pathway delays are reviewed, and actions implemented to reduce the risk to future patients.
- To provide oversight and management of the process where harm has been identified by following trust protocols including Duty of Candour considerations.

3 Complete a Harm Review

Each Trust should have an internal process to produce a weekly ‘Cancer waiting 104 days/long waits report’. The report should show the number of cancer patients on a pathway who are at 104 days (or at the Providers agreed threshold <104 days) with or without a cancer diagnosis. Each cancer services team or pathway team should have incorporated into their operational delivery, methods that include a minimum of weekly cancer patient review, with the oversight from a senior manager responsible for the delivery of the cancer operational standards.

The senior operational manager or identified person should ensure the report is reviewed to identify any patients who have reached 104 days (or at the Providers agreed threshold <104 days) with a cancer diagnosis (with or without a decision to treat). They should initiate a clinical harm review. It is further recommended that patients identified as 104 days (or at the Providers agreed threshold <104 days) requiring a harm review should also be discussed at the weekly PTL meeting to further highlight the need for harm assessment.

A clinician should review the patient pathway and complete a clinical harm review assessment recording this in The Trust system for example eRecord using the agreed 6-point criteria “assessing for harm” (see point 3.2).

Where a patient has had different members of the MDT or other service involvement (such as radiology and pathology, or the chemotherapy, surgical and radiotherapy service) those clinical teams should support the process and there is an option to include them in the harm review, harm assessment and have input to reach a conclusion.

3.1 What is harm?

Clinicians who have been involved in the patient pathway will review each individual case and ascertain if avoidable or non-avoidable harm has occurred (examples shown below but not exclusive).

Non-Avoidable

1. Patient choice has had impact on delays in pathway, diagnostic or treatment related.
2. Medical reasons have delayed diagnostics or start of treatment.
3. Multiple and complex diagnostics have influenced delays, including investigations across two or more tumour groups.

Avoidable

1. Diagnostic delays not associated with complex or non-diagnostic results.
2. Treatment delays due to capacity/equipment failure.

3. Cancellation of diagnostic tests or treatment not associated with medical reasons.
4. Appointment delays and/or admin delays (e.g. delay for letters/outcomes, onward referrals, requests for imaging, follow up)

3.2 Harm Review Criteria (see flow diagram page 7)

To define harm the following criteria should be used:

1) Has the delay caused a change of stage of the disease? (Usually need CT / imaging report to confirm this).

2) Has the modality of treatment changed i.e., from radical surgery to radiotherapy, chemotherapy, or best supportive care?

3) Has the intent of the treatment changed i.e., from curative to palliative?

4) Has the delay caused the patient to need additional treatment, such as adjuvant chemotherapy, radiotherapy or additional resection/ mastectomy?

5) Has the delay resulted in a change in performance status that now precludes treatment options that would have been possible at time of referral? (If comorbidities from the beginning precluded curative treatment, then this does not count as harm)

6) Has the delay resulted in psychological harm that has lasted, or is likely to last, for a continuous period of at least 28 days?

Psychological Harm

There is no evidence that supports a process to assess if a patient has experienced psychological harm because of a long diagnostic pathway, however it is recognised that emotional distress can be significant for patients with a cancer diagnosis. Patients should have access, usually via their specialist nurse, to a comprehensive holistic needs assessment that can support addressing any identified psychological care needs and signposting to appropriate services.

No Harm

If the clinical assessment shows no harm has occurred, a member of the service management team should review the patient pathway and any trends in delays that

could identify service improvement must be added to the cancer teams service improvement plans.

The assessment must be completed in a timely manner and Trusts should use regular forums to highlight any themes or trends such as internal cancer steering groups, PTL meetings or other regular touchpoints where senior managers can have oversight and can escalate any outstanding issues.

Shared care 104+ days

For patients who have received care across two or more organisations, the responsibility of the harm review will be allocated as per the breach allocation rules. Where there is a shared breach, it is the overarching responsibility of the treating trust to complete the harm review. The providers must communicate with each other at an early stage to agree which trust will lead on the investigation.

If there is a need to have input from another trust discussion should be held within the Multi-Disciplinary Team with support from the Trust Cancer Lead, Cancer Services Manager or Cancer Governance and Risk Lead to discuss the patient and their pathway fully. Collaboration between trusts is essential to share responsibility for problem solving and improving patient care and outcomes.

3.3 If Harm has occurred.

All 104+-day patients where harm has been identified will require completion of an Incident Report onto the Trust Risk Management System such as Datix, this should be completed by an appropriate clinical member of the team and managed via the Trust protocol for Incident Reporting, to meet the standards required of the Serious Incident Framework and the compliance with Duty of Candour Process.

3.4 Duty of Candour

Promoting a culture of openness is a prerequisite to improving patient safety and the quality of healthcare systems. It involves explaining and apologising for what happened to patients who have been harmed or involved in an incident because of their healthcare treatment. It ensures communication is open, honest and occurs as

soon as possible following an incident. Duty of candour policy has a measurement of 10 days for informing patients where harm has occurred. It encompasses communication between healthcare organisations, healthcare teams and patients and/or their carers'.

The consultant responsible for the patient's care will contact the patient and/or carers acting on duty of candour. The case should be discussed at the Clinical Governance meeting, and actions agreed and documented. Discussion at the Governance meeting, the route cause analysis and incident report outcome should be discussed to determine if the incident should also be reported to commissioners as a Serious Incident via established reporting routes.

The outcomes of this process should be shared with the wider members of the clinical team and where there are recurring themes the MDT annual work programme should include actions to address these issues.

4 Data Analysis

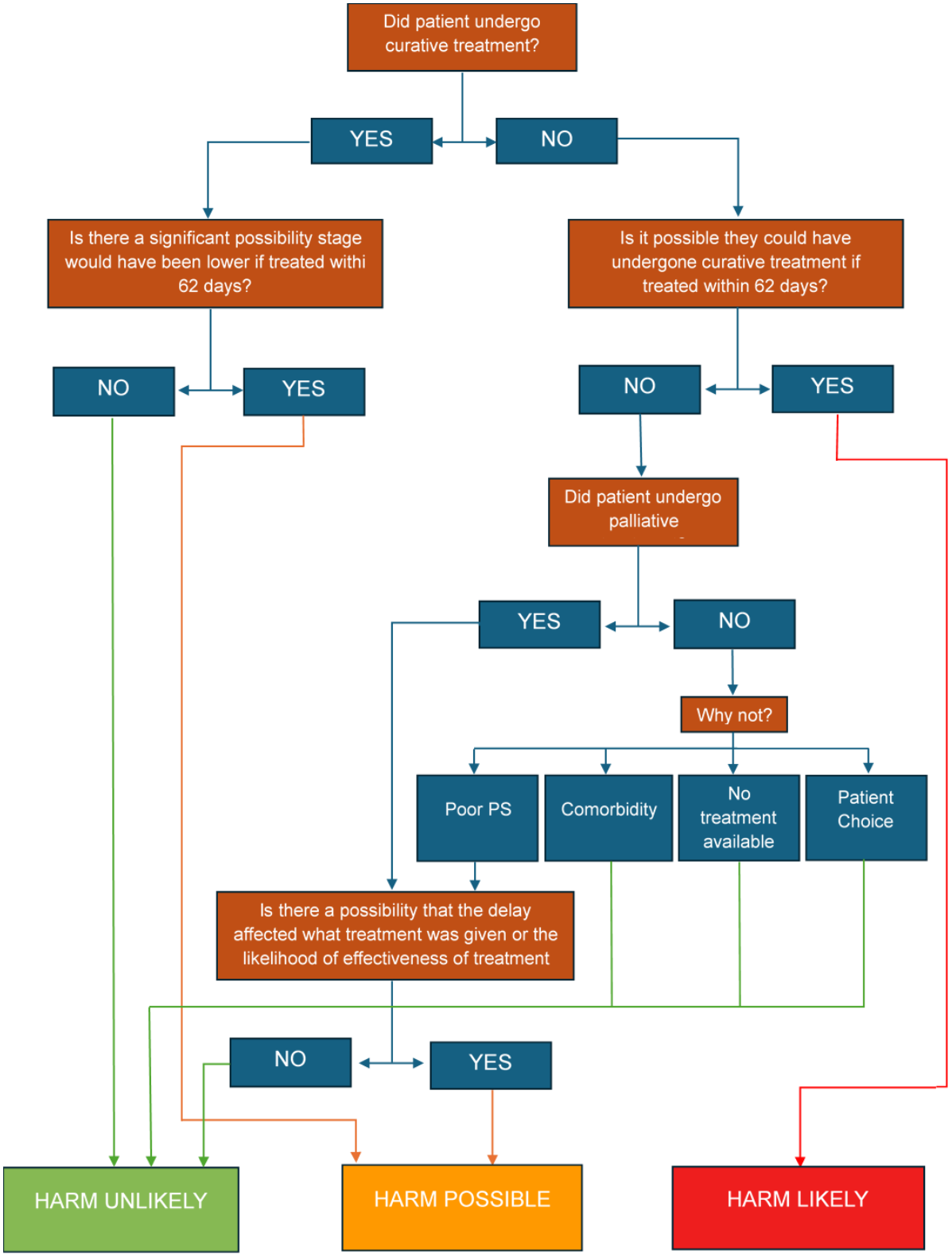
Clinical quality review assurance meetings should maintain a focus on patients who breach 104 days (or the Providers agreed threshold <104 days) and themes and trends should be reviewed, and improvement plans agreed within the clinical teams. The data should be used to inform commissioning decisions as part of system improvements. Individual Trust's patient quality and cancer teams will oversee and seek assurance that the clinical and operational teams identify underlying causes as to the delays in these pathways, develop action plans and make changes to practice and processes and ensure lessons are learned and shared.

Reporting internally and externally takes place to assure that Trusts have a robust governance process in place to drive to improving performance relating to harm to patients and supporting the quality and safety agenda.

Cancer Alliance Tumour Site Specific Learn and Share events or pathway meetings provide an opportunity for system learning from such events.

5 Governance structure

The outcomes from the harm review should be shared with the Trust Cancer Services Team. An anonymised harm summary should be discussed within Trust governance structures.



References

Managing long waiting cancer patients – policy on "backstop" measures NHS England (2015)https://www.england.nhs.uk/wp-content/uploads/2015/11/managing-long-waiting-cancer-patients.pdf

Openness and honesty when things go wrong: The professional duty of candour GMC (2022)http://policies.app/launchtext.asp?launchit=6232

Patient Safety Incident Response Framework NHSE (2022)https://www.england.nhs.uk/patient-safety/incident-response-framework/

Holistic Needs Assessment Macmillan Cancer Support https://www.macmillan.org.uk/healthcare-professionals/innovation-in-cancer-care/holistic-needs-assessment

Sud, A., Jones, M.E., Broggio, J., Loveday, C., Torr, B., Garrett, A., Nicol, D.L., Jhanji, S., Boyce, S.A., Gronthoud, F. and Ward, P., 2020. Collateral damage: the impact on outcomes from cancer surgery of the COVID-19 pandemic. *Annals of Oncology*, *31*(8), pp.1065-1074.

NHS Delivery Plan for tackling the COVID backlog (Feb 2022) https://www.england.nhs.uk/coronavirus/publication/delivery-plan-for-tackling-the-covid-19-backlog-of-elective-care/