British Society for Rheumatology

NEIAA Cause for Concern Policy

A cause for concern relates to the circumstance in which information submitted to the National Early Inflammatory Autoimmune Diseases Audit (NEIAA or British Society for Rheumatology (BSR) reasonably suggests the presence of very serious issues with clinical practice or system failure that presents a risk of harm to patients.
A cause for concern may be raised at any point during the audit, and by anyone involved in the audit (HQIP, ICBs, individual specialist units and/or clinicians, patients, BSR).

Examples where the BSR would raise a cause for concern include:

Patient concerns	Personal experience of care which: • Indicates patient is at significant risk of harm. • Indicates a dysfunctional or dangerous department or organisation. • Indicates a staff member displaying dangerous behaviour.
Commissioner concerns	• The BSR is contacted by Integrated Care Board regarding quality issues at a participating centre.
Clinical concerns	• Contact from within the department informs BSR of a cause for concern within the Trust/Health Board.

Operational	• A clinical unit fails to engage with the audit:
	  ○ No response to correspondence.
	  ○ No return of organisational data.

Initial treatment	• No DMARD use in any patient diagnosed with rheumatoid arthritis by 3 months. • Unusually high numbers (3 or more) of DMARDs used.
Disease response	• No patients achieve disease remission by 3 months.
Cluster of records	• Cluster of records suggest: • Significant risk of harm or actual harm has been caused to patients.

	• Dangerous individual or team behaviours.
Aggregate data trends	• Emerging data suggest a spike in mortality or morbidity significantly out of keeping with comparable healthcare providers.

The following actions are to be taken:

Stage	What action?	Who?	Within how many working days
1	Information is examined closely to determine its quality and completeness, the data handling and analyses performed to date, and the likely validity of the concern identified: • If no data are available, BSR staff and Clinical Lead, (Dr Elizabeth Price) to communicate directly with the clinical and audit leads at the unit concerned to assess whether there is a case to answer. 'No case to answer' • Data and results revised in NEIAA records if relevant. • Details formally recorded. 'Case to answer' • Contact HQIP Associate Director (AD) to discuss the nature of the cause for concern and agree next steps. HQIP AD to be kept appraised of the progress of the subsequent escalation process. *Proceed to stage 2*	BSR	10

2	The Healthcare Provider Lead Clinician informed about the potential cause for concern and requested to identify any data errors or justifiable explanation/s. All relevant data and analyses should be made available to the Lead Clinician. A copy of the request should be sent to the Healthcare Provider CEO and Medical Director.	BSR	5
3	Healthcare Provider Lead Clinician to provide written response to BSR.	Healthcare Provider Lead Clinician	25
4	Review of Lead Clinician's response to determine: **'No case to answer'** • It is confirmed that the data originally supplied by the provider contained inaccuracies. Re-analysis of accurate data no longer indicates significant cause for concern. • Data are not available but other investigations indicate that there is no case to answer. • Data and results should be revised in NEIAA records. Details of the provider's response and the review result recorded in Cause for Concern Log. • Lead Clinician notified in writing copying in Healthcare Provider CEO and Medical Director. *Process ends* **'Case to answer'** • It is confirmed that although the data originally supplied by the provider were inaccurate, analysis still indicates a significant cause for concern • It is confirmed that the originally supplied data were accurate, thus confirming the initial designation of cause for concern. • Data are not available but other investigations indicate that there is a case to answer. • No response from the Lead Clinician is forthcoming *Proceed to stage 5*	BSR	20

5	Contact Healthcare Provider Lead Clinician by telephone, prior to sending written confirmation of the persistence of the cause for concern to CEO copied to Lead Clinician and Medical Director. All relevant data and statistical analyses, including previous response from the Lead Clinician, made available to the Medical Director and CEO. The requirement for BSR to inform CQC and for the Provider CEO to inform commissioners, NHS England and relevant royal colleges to be determined jointly by the HQIP Associate Director and the BSR Clinical Lead.	BSR	5
6	Acknowledgement of receipt of the letter confirming that a local review will be undertaken, copying in the CQC, Welsh or Jersey Government as required.	Healthcare Provider CEO	10
7	If no acknowledgement is received, a reminder letter should be sent to the CEO, copied to CQC, Welsh or Jersey Government. If not received within 5 working days, CQC and NHS England, Welsh or Jersey Government notified of non-compliance.	BSR	5
8	Report recorded and presented at subsequent Senior Governance Group meeting.	BSR	n/a

Relevant Contact Details

Organisation	Email Address
CQC	clinicalaudits@cqc.org.uk
NHS England	england.clinical-audit@nhs.net
Welsh Government	wgclinicalaudit@gov.wales
Jersey Government	HssClinicalAuditdepartment@health.gov.je