British Society for Rheumatology

National Early Inflammatory Autoimmune Diseases Audit - Data Analysis Plan

Introduction

The National Early Inflammatory Autoimmune Diseases Audit aims to describe site-level performance and variation in the delivery of care to patients diagnosed with new-onset autoimmune rheumatic diseases. The audit focuses on early inflammatory arthritis and aligns with the NICE guideline NG 100, which provides recommendations on investigation, diagnosis, and treatment for patients with Rheumatoid Arthritis. Additionally, the audit collects information on referral timelines for rare rheumatic diseases(see table below for diseases included).

Systemic Vasculitis	Systemic Vasculitis Giant cell arteritis Large vessel vasculitis (not giant cell arteritis) Anti-neutrophil cytoplasmic antibody-associated vasculitis Small/medium vessel vasculitis (anti-neutrophil cytoplasmic antibody-negative) Behcet's syndrome
CTD	Systemic lupus erythematosus Primary Sjogren's syndrome Systemic sclerosis Idiopathic inflammatory myopathy Undifferentiated/other connective tissue disease or overlap syndrome

This data analysis plan outlines the methods used to calculate various performance measures and outcome measures for reporting in the annual Health Quality Improvement Partnership Publication.

Primary Objective

- To describe the proportion of patients with a new diagnosis of early inflammatory arthritis who are commenced on a disease-modifying anti-rheumatic drug (DMARD) within 6 weeks of the rheumatology department receiving a referral.

Secondary Objectives

- Describe the number of patients enrolled in the national audit overall and by disease type.
- Describe the proportion of patients seen within 3 weeks of referral.
- Describe average waiting times broken down by disease type.

- Describe the proportion of patients diagnosed with early inflammatory arthritis achieving disease remission by 3 months after diagnosis.
- Describe contextual data regarding patient characteristics and their symptom burden, captured through patient-reported outcome measures.

Study Design

The National Early Inflammatory Autoimmune Diseases Audit employs an observational prospective cohort design for patients with newly diagnosed early inflammatory arthritis and other rare rheumatic diseases.

Setting

The setting includes NHS healthcare providers in England, Wales and Jersey.

Population

The population consists of adults aged 16 and above who have not explicitly opted out of NHS data usage through the national opt-out system.

Eligibility

Only patients with new diagnoses are eligible for inclusion; those referred for a new opinion about an established diagnosis are excluded.

Data Collection

Data for the audit are collected through the audit data entry portal (www.arthritisaudit.org.uk). Local clinical departments enter the data, which are then processed for aggregate-level reporting by the analytics team at King's College London.

Definitions

Primary Metric of Interest: Delay in Initiating DMARD

NICE quality statement 33 recommends starting DMARD therapy within 6 weeks of referral. This is calculated as the number of days between the date a referral letter is received by the rheumatology department and the date the first DMARD is initiated. Compliance is achieved if this delay is 42 days or fewer for patients deemed eligible for early inflammatory arthritis follow-up.

If a patient has had a first visit more than 4 months prior to the data analysis cut point without any information on whether a DMARD has been initiated, it is assumed that the standard has not been met.

Secondary Outcomes

Primary Care Referral Delays: Clinicians will answer whether a patient was referred within 3 working days of presentation to primary care as a binary yes/no variable. These data will be reported without further processing.

First Appointment Delay: The delay between the referral letter being seen and the first appointment will be calculated in days (excluding weekends and bank holidays). A patient must be seen within 15 working days to meet the standard.

Calculating Site-Level Variability

For each site, an analysis will determine whether performance lies outside expected thresholds defined by the Health Quality Improvement Partnership recommendations:

- Alert levels = 2 standard deviations below expected performance
- Alarm levels = 3 standard deviations below expected performance

A multilevel logistic regression model is used to model unit performance, with the audit standard as the outcome of interest, adjusted for case mix variables (age, gender, ethnicity, and deprivation) with the hospital site included as a second level. Deprivation is estimated from the patient's postcode using the most recent Index of Multiple Deprivation translation for England and Wales.

Funnel plots will visualize the performance of different units and detect outlier performance of the predicted probabilities.

Benchmarking will be compared to national mean performance, as well as mean performance by country and region.

Analyses of other factors, including patient characteristics, patient-reported outcomes, and disease response, will be descriptive only.

Disease Activity Score

For patients with early inflammatory arthritis, the disease activity score will be calculated using the DAS28 formula, which can be derived from either ESR or CRP, depending on what has been provided by the clinical team. The calculations are as follows:

- **DAS28 ESR**:

$$DAS28 = 0.56 \times \sqrt{(\text{tender joint count})} + 0.28 \times \sqrt{(\text{swollen joint count})} + 0.7 \times \ln(\text{ESR}) + 0.014 \times \text{patient global}$$

- **DAS28 CRP**:

$$DAS28 = 0.56 \times \sqrt{(\text{tender joint count})} + 0.28 \times \sqrt{(\text{swollen joint count})} + 0.36 \times \ln(\text{CRP} + 1) + 0.014 \times \text{patient global} + 0.96$$

If both DAS28 ESR and CRP are provided, ESR will be used preferentially. Remission is defined as a DAS28 value of less than 2.6, low disease activity between 2.6 and 3.2, moderate disease activity between 3.2 and 5.1, and high disease activity as any DAS28 value of 5.1 or higher.

Patient-Reported Outcomes

Patient-reported outcomes include the MSKHQ score, which ranges from 0 to 56, with higher scores indicating better musculoskeletal health. The second patient-reported outcome measure includes mental health assessments using the PHQ2 and GAD2, scored as the sum of questionnaire components. A positive screen for mental health comorbidity is defined as a score greater than 2 out of 6 on the individual PHQ or GAD questionnaires.

Inferential analyses

No preplanned inferential analyses are included in this analysis plan.

Missing data

For missing data on ethnicity or deprivation, a missing variable category will be created to ensure patients are not excluded from analyses.

Ethical Considerations

The audit is conducted under the approval of a section 251 Clinical Advisory Group, allowing for analyses without explicit patient consent for the purpose of healthcare quality monitoring within the NHS.

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