1 METHODS

Study advisory group

A multidisciplinary group of clinicians was convened to steer the study from design to completion, define the objectives of the study and advise on the key questions. The group comprised lay and patient representatives and healthcare professionals in vascular surgery, interventional radiology, vascular nursing, general nursing, anaesthesia, diabetes care, emergency medicine, haematology and general practice.

Study aims and objectives

The objectives of the study were to explore the current care pathways for patients with acute limb ischaemia (ALI) to allow the identification of the remediable clinical and organisational factors that would lead to improvements in the care of ALI.

Hospital participation

Data were included from NHS hospitals in England, Wales, and Northern Ireland.

Study population and case ascertainment

Inclusion criteria

Adults over the age of 18 years who were admitted to a vascular hub as an emergency, between 1st January 2023 and 31st March 2023 for treatment of ALI.

Exclusion criteria

Patients who received only anticoagulation or palliative care at a spoke hospital.

Identification of a sample population

The incidence of ALI is unknown as there is no ICD-10 code for ALI. The identification of ALI was made more challenging by its many modes of presentation and breadth of treatment options, which are often used to treat chronic limb-threatening ischaemia.

A pre-set spreadsheet was provided to every local reporter in vascular hub hospitals to populate with patients admitted as an emergency in the three months between 01/01/2023 and 31/03/2023, using a range of ICD-10 codes and mode of presentation as a surrogate initial marker for patients who may have ALI.

A local study contact (vascular surgeon or vascular radiologist) had to screen patient notes to identify those with acute limb ischaemia from those with chronic limb-threatening ischaemia. Patients were randomly selected from this sample.

Data collection

From the listed patients up to 10 per hub hospital were randomly selected to be included in the case review. For these patients data were collected from the following sources:

A clinical questionnaire was assigned to the named vascular surgeon for completion. This had questions detailing the care received following the pathway of care from pre-admission to discharge.

Case notes

Copies of the case notes from the hub hospital were requested for the included episode of care for each patient identified, for peer review.

Where transfer from a spoke hospital was identified, a request was sent to the spoke hospital for case note extracts from the emergency department presentation or episode of care if the patient was admitted to the spoke hospital.

For each patient identified, a request was also made to their GP for any case notes relating to the index admission to the hub hospital.

A list detailing the elements of the case notes that were required was provided to the NCEPOD local reporters who collated the notes from each participating trust/health board. For patients transferred from a spoke hospital, a request was made to the spoke hospital to return all notes for that attendance/admission.

Primary care questionnaires were disseminated to the listed GP surgery for each patient identified for the study. This short questionnaire had general organisational questions on the protocols and process of treating patients who have a suspected ALI and questions about what was done for the listed patient at the time of the hospital admission for ALI.

Hub or spoke organisational questionnaires were disseminated to the NCEPOD local reporter for completion, with assistance from relevant local clinical leads. These detailed the organisational structures in place in hub and spoke hospitals to deliver the service to patients who have an ALI.

Surveys

Our survey questionnaires were not linked to the data from patients selected for case review. They were designed using Microsoft Forms to be completed anonymously by patients who have had an ALI and clinicians treating these patients, respectively.

Patient survey

The patient survey (PS) was designed to collect data on the lived experience of patients regarding the care they have received in the treatment of ALI. The link to the patient survey was promoted online by the Vascular Society, the royal colleges and charities, including Legs Matter, and was also circulated to vascular consultants and nurses, who were involved in the study, to circulate to the patients they treat.

Clinician survey

This was designed using Microsoft Forms to collect the views of clinicians, particularly in emergency medicine, who may treat patients with ALI in spoke hospitals. The link to the online survey was promoted online with the help of the royal colleges and the Vascular Society.

Ambulance services survey

A short survey was disseminated to each ambulance service with questions on the service provided for patients with a suspected acute limb ischaemia.

Peer review of the case notes and questionnaire data

A multidisciplinary group of case reviewers comprised consultants and trainees from vascular surgery, interventional radiology, nursing, anaesthesia, acute medicine and emergency medicine.

Using a semi-structured electronic questionnaire **(reviewer assessment form)**, each set of case notes was reviewed by at least one reviewer within a multidisciplinary meeting. A discussion, chaired by an NCEPOD clinical co-ordinator, took place at regular intervals, allowing each reviewer to summarise their cases and ask for opinions from other specialties or raise aspects of the case for further discussion.

Data analysis

Following cleaning of the quantitative data, descriptive data summaries were produced. Qualitative data collected from the case reviewers' opinions and free-text answers in the clinician questionnaires were coded, where applicable, according to content to allow quantitative analysis. As the methodology provides a snapshot of care over a set point in time, with data collected from several sources to build a national picture, denominators will change depending on the data source, but each source is referenced throughout the document. This deep dive uses a qualitative method of peer review, and anonymised case studies have been used throughout this report to illustrate themes. The sampling method of this enquiry, unlike an audit, means that data cannot be displayed at a hospital/trust/health board/regional level.

Data analysis rules

- Small numbers have been suppressed if they risk identifying an individual (usually <3-5)
- Any percentage under 1% has been presented in the report as <1%
- Percentages were not calculated if the denominator was less than 100 so as not to inflate the findings, unless to compare groups within the same analysis
- There will be variation in the denominator for different data sources and for each individual question as it is based on the number of answers given.

Information governance

All data received and handled by NCEPOD complied with all relevant national requirements, including the General Data Protection Regulation 2016 (Z5442652), Section 251 of the NHS Act 2006 14 (PIAG 4-08(b)/2003, App No 007), and the Code of Practice on Confidential Information. Each patient was given a unique NCEPOD number.