

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

NICE indicator validity assessment

Indicator IND260

The percentage of patients with a total cholesterol reading greater than 7.5 mmol/litre when aged 29 years or under, or greater than 9.0 mmol/litre when aged 30 years or over, who have been:

- diagnosed with secondary hyperlipidaemia or
- clinically assessed for familial hypercholesterolaemia or
- referred for assessment for familial hypercholesterolaemia or
- genetically diagnosed with familial hypercholesterolaemia.

Indicator type

General practice indicator suitable for use in the Quality and Outcomes Framework.

Importance

Considerations	Assessment
<p>The NHS Long Term Plan identifies cardiovascular disease as a clinical priority, and the single biggest condition where lives can be saved by the NHS over the next 10 years by improving the treatment of high-risk conditions. The plan commits to increasing the diagnosis of familial hypercholesterolaemia (FH) from 7% to 25% by 2024/25. FH affects at least 150,000 people in England (IIF guidance 2022/23).</p> <p>This indicator was included in the CVD prevention domain of the Investment and Impact Fund (IIF) 2022/23. It promotes systematically searching patient lists to identify those with possible FH and ensuring that appropriate action has been taken.</p>	<p>The indicator reflects a specific priority area identified by NHS England.</p>
<p>Public Health England (2018), report that most cases of FH remain undiagnosed, and only an estimated 8 to 15% of cases are known (based on prevalence estimates of 1:250 and 1:500).</p> <p>March 2023 Network contract directed enhanced service data show that:</p>	<p>The indicator relates to an area where there is known variation in practice.</p> <p>The indicator should help address under-diagnosis by improving the case-finding process.</p>

<ul style="list-style-type: none"> • 31% of people with cholesterol levels in the at-risk range for FH have a subsequent record of assessment, referral or diagnosis. • 10% of people with cholesterol levels in the at-risk range for FH have a relevant personalised care adjustment code. <p>CVDPREVENT audit data (December 2022) highlight:</p> <ul style="list-style-type: none"> • 0.15% of total registered patients have cholesterol levels indicating possible FH but no FH diagnosis or investigation. There was little difference between males and females and between deprivation quintiles. • The percentage with no diagnosis increased with age from 0.04% in those aged 18-39 years to 0.61% in those aged 80 and over. • Prevalence of GP recorded possible, probable and confirmed FH was 0.18% for all ages. • Prevalence increased with age, increased slightly from most to least deprived quintiles and was higher in females than males. 	
<p>Familial hypercholesterolaemia (FH) is a genetic disorder that causes a high cholesterol level. This increases the likelihood of coronary artery disease, heart attacks and sudden cardiac death. Early detection and genetic diagnosis will lead to provision of appropriate lipid-lowering treatment to lower these risks and improve outcomes.</p>	<p>The indicator will lead to a meaningful improvement in patient outcomes.</p>

Evidence base

Considerations	Assessment
<p>Familial hypercholesterolaemia: identification and management (NICE clinical guideline 71) recommendations:</p> <p>1.1.2 Systematically search primary care records for people:</p> <ul style="list-style-type: none"> • younger than 30 years, with a total cholesterol concentration greater than 7.5 mmol/l and • 30 years or older, with a total cholesterol concentration greater than 9.0 mmol/l <p>as these are the people who are at highest risk of FH.</p> <p>1.1.5 Use the Simon Broome criteria (see appendix F of the full guideline) or Dutch Lipid Clinic Network (DLCN) criteria to make a clinical diagnosis of FH in primary care settings. This should be done by a healthcare professional competent in using the criteria.</p>	<p>The indicator is derived from a high-quality evidence base.</p> <p>The indicator aligns with the evidence base.</p>

1.1.6 Refer the person to an FH specialist service for DNA testing if they meet the Simon Broome criteria for possible or definite FH, or they have a DLCN score greater than 5.

1.1.8 Healthcare professionals should consider a clinical diagnosis of homozygous FH in adults with a low-density lipoprotein cholesterol (LDL-C) concentration greater than 13 mmol/l and in children/young people with an LDL-C concentration greater than 11 mmol/l. All people with a clinical diagnosis of homozygous FH should be offered referral to a specialist centre.

Specification

Considerations	Assessment
<p>Numerator: The number in the denominator who have been:</p> <ul style="list-style-type: none"> • diagnosed with secondary hyperlipidaemia after the earliest high cholesterol reading; or • clinically assessed for familial hypercholesterolaemia at any time; or • referred for assessment for familial hypercholesterolaemia at any time; or • genetically diagnosed with familial hypercholesterolaemia at any time. <p>Denominator: The number of patients with a total cholesterol reading greater than 7.5 mmol/litre when aged 29 years or under, or a total cholesterol reading greater than 9.0 mmol/litre when aged 30 years or over.</p> <p>Personalised care adjustments or exception reporting should be considered to account for situations where the patient is receiving palliative care, declines assessment, or if further assessment is not appropriate.</p> <p>The construction searches for the earliest total cholesterol reading that would indicate a risk of FH as per NICE guidance. It does not include a specific time period.</p> <p>(IIF Guidance 2022/23 and NHS Digital Business rules for network contract DES (NCD) - Cardiovascular Disease Prevention)</p>	<p>The indicator has defined components necessary to construct the indicator, including numerator, denominator and exclusions.</p>
<p>The indicator would be appropriate to assess performance at individual general practice level. To be classified as suitable for use in QOF, there should be an average minimum population of more than 20 patients per practice eligible for inclusion in the denominator prior to application of personalised care adjustments.</p> <p>IIF CVD-04 data for March 2023 show that 0.6% of people in England had cholesterol levels in the at-risk range for familial hypercholesterolemia: 62 patients for an average practice with 10,000 patients.</p>	<p>The indicator does outline minimum numbers of patients needed to be confident in the assessment of variation.</p> <p>Available data does suggest that the number of eligible patients per average practice would be above this minimum number.</p>

Feasibility

Considerations	Assessment
A similar indicator was previously included in the IIF and the data published monthly by NHS digital as part of the network contract directed enhanced service .	The indicator is repeatable.
Business rules could be adapted from the Network Contract DES 2022/23.	The indicator is measuring what it is designed to measure. The indicator uses existing data fields.

Acceptability

Considerations	Assessment
No concerns were raised during testing and consultation about the attribution of responsibility. It was felt that ensuring appropriate action is taken was within the control of general practice.	The indicator assesses performance that is attributable to or within the control of the audience.
The results can be used to understand if appropriate action is taking place for people with cholesterol readings above the at-risk threshold and performance compared to previous years. Feedback at consultation and testing for IND260 supported the opportunity to increase FH diagnosis.	The results of the indicator can be used to improve practice

Risk

Considerations	Assessment
<p>The construction searches for the earliest total cholesterol reading that would indicate a risk of FH as per NICE guidance. This could result in an increased workload for practices to recall patients with historical high cholesterol readings and increased referral to specialist services. Consideration should be given the potential increase in workload during the early periods of implementation.</p> <p>As currently constructed, the indicator denominator will include some of the same patients for the same high reading each time data is extracted, with potentially no need for action in the current reporting period. A 'success' in year one of implementation, will be a success in year 2 as the indicator does not only look for newer or more</p>	<p>The indicator has an acceptable risk of unintended consequences.</p> <p>Achievement thresholds could be used to mitigate some risks in potential increased workload for primary care and specialist services.</p> <p>The indicator should be reviewed once diagnosis rates have improved.</p>

recent cholesterol readings (for example, within the preceding 12 months only).

The denominator would include patients with a single historical high reading even with multiple subsequent readings below the threshold.

Personalised care adjustments could be used to account for situations where recall of the patient for assessment or referral is not considered appropriate.