NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

DIAGNOSTICS ASSESSMENT PROGRAMME

Equality impact assessment – Guidance development

High-sensitivity troponin tests for the early rule out of NSTEMI

Consultation

1. Have the potential equality issues identified during the scoping process been addressed by the committee, and, if so, how?

The following potential equality issues were identified during scoping:

- Consideration should be given to the use of sex-specific cut-offs which are recommended by the companies for some products
- Consideration may need to be given to certain subgroups which have chronically elevated troponin levels when exploring cutoffs/thresholds and early rule-out protocols which include delta change to define a positive or negative result. These subgroups include people who are older and people with comorbidities such as chronic kidney disease.

The committee made a recommendation to use sex-specific 99th percentile thresholds. Clinical experts explained that there was consistent evidence from reference range studies that the 99th percentile differs between men and women. Clinical experts noted that there was currently no evidence that using sex-specific 99th percentile thresholds affected clinical outcomes. But they noted that the ongoing CODE-MI study aims to evaluate the effect of using the sex-specific 99th percentile threshold for women for high-sensitivity cardiac troponin. This will be compared with the general (mixed) population 99th percentile threshold, on the diagnosis, treatment and outcomes of women presenting to the emergency department with cardiac chest pain. The committee noted that there was a wider equality issue because women with acute myocardial infarction are generally under-diagnosed and under-treated compared with men. The committee concluded that using sex-specific 99th percentile thresholds could be a step towards reducing this inequality. This is described in section 4.7 of the consultation document.

The committee discussed population subgroups and heard from clinical experts that there are much less data on the 99th percentile in subgroups such as older or younger people, people with or without renal disease, and black, Asian and minority ethnic groups. It considered that it would be very helpful to have a better understanding of any differences in the 99th percentile between these subgroups. This is described in section 4.18 of the consultation document.

2. Have any other potential equality issues been raised in the diagnostics assessment report, and, if so, how has the committee addressed these?

No other potential equality issues were raised in the diagnostics assessment report.

3. Have any other potential equality issues been identified by the committee, and, if so, how has the committee addressed these?

No other potential equality issues were identified by the committee.

4. Do the preliminary recommendations make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?

No

5. Is there potential for the preliminary recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?

No

6. Are there any recommendations or explanations that the committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 4 or 5, or otherwise fulfil NICE's obligations to promote equality?

No

7. Have the committee's considerations of equality issues been described in the diagnostics consultation document, and, if so, where?

Committee consideration about the use of sex specific thresholds is covered in sections 1.3, 4.7 and 5.2 of the diagnostics consultation document. Section 1.3 outlines the recommendation that sex specific thresholds at the 99th percentile should be used in clinical practice. Section 4.7 summarises the committee's discussion and consideration that using these thresholds could reduce inequality relating to the undertreatment of women with acute myocardial infarction. Section 5.2 outlines the committee's recommendation for further research into how the use of sex specific thresholds affects clinical outcomes in men and women.

Approved by Associate Director (name): Rebecca Albrow

Date: 23/04/2020

Diagnostics guidance document

1. Have any additional potential equality issues been raised during the consultation, and, if so, how has the committee addressed these?

No additional potential equality concerns were raised during the consultation

2. If the recommendations have changed after consultation, are there any recommendations that make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?

No

3. If the recommendations have changed after consultation, is there potential for the preliminary recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?

No

4. If the recommendations have changed after consultation, are there any recommendations or explanations that the committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 2 and 3, or otherwise fulfil NICE's obligations to promote equality?

No

5. Have the committee's considerations of equality issues been described in the diagnostics guidance document, and, if so, where?

Committee consideration about the use of sex specific thresholds is covered in sections 1.3, 4.7 and 5.2 of the diagnostics consultation document. Section 1.3 outlines the recommendation that the use of sex specific thresholds at the 99th percentile should be considered when NSTEMI is not ruled out using early rule-out test strategies. Section 4.7 summarises the committee's discussion and consideration that using these thresholds could reduce inequality relating to the under-treatment of women with acute myocardial infarction. Section 5.2 outlines the committee's recommendation for further research into how the use of sex specific thresholds affects clinical outcomes in men and women. The committee discussion on population subgroups such as older or younger people, people with or without renal disease, and black, Asian and minority ethnic groups is described in section 4.18.

Approved by Associate Director (name): Rebecca Albrow

Date: 23 June 2020