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Central Zone

Pathology and Laboratory Medicine Memorandum

To: Central Zone Healthcare Providers and Health Service Directors

From: Dr Manal Elnenaei, Chief of Service, Division of Clinical Chemistry, Central Zone
Cindy Andrews – Manager Core Lab, QEII sites, Central Zone
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Date: November 1 , 2021

Subject: Change in the Female Reference Range for HS-Troponin T Testing in Central Zone

As of November 17, 2021, Central Zone will begin participation in a national study (CODE-MI) that is investigating the question as to whether laboratory reporting of a female specific reference range for the high sensitivity cardiac troponin T test, will improve health care outcomes.

On November 17, 2021, Central Zone will begin reporting the normal reference range for females as:

< 9 ng/L (the 99th percentile for a female population)

Previously, the normal reference range was reported as < 14 ng/L (the 99th percentile for a mixed male / female population) for all patients. Aside from being triggered by a lower threshold in females, there will be no change to the interpretive comments that accompany HS-Troponin T results. There will be no change to the current reported male reference range (<14 ng/L).

The change to the female reference range will persist for at least one year. For further information regarding the purpose and motivation for the study, refer to the accompanying information sheet prepared by the principal investigator, Dr Karin Humphries.
Please contact any of the below , regarding this memo or other questions pertaining to the HS- troponin T test.

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Your hospital is participating in

CODE MI

Optimizing the Diagnosis of Acute Myocardial Infarction/Injury in Women

Can one simple change in how we diagnose myocardial infarction improve care for women and reduce their risk of cardiovascular events and death?

What is CODE-MI?

- CODE-MI is a multi-centre, stepped-wedge, cluster-randomized controlled trial funded by CIHR
- Focusing on the need for different standards of evaluation for women with ischemic symptoms
- The study is running in 30 hospitals across 8 provinces

Women with acute coronary syndrome = underdiagnosed and undertreated.

Therefore, women are at **higher risk of mortality** following their infarction.

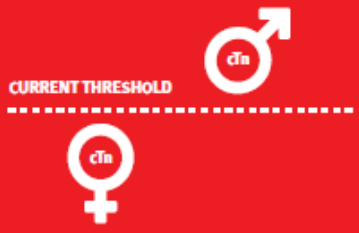
Why?

Using a single level high-sensitivity cTn (hs-cTn) threshold to identify patients with a myocardial infarction (MI) may contribute to the underdiagnosis of MI in women.

A single, overall cTn threshold is still used in most clinical settings, despite evidence and guidelines recommending sex-specific thresholds.

The importance of sex-specific thresholds

Women's levels of hs-cTn are lower than the overall threshold currently being used, and lower than the threshold in men, for all assays.



Women have different levels of cTn than men because of factors like:

- Unequal heart mass
- The protective role of estrogen
- Thrombotic activity
- Different mechanisms of ischemia

Starting September 15 , 2021:

The 99th percentile female threshold of 9 ng/L (hs-cTn T) will be implemented for the diagnosis of MI in women presenting to the ED with ischemic chest pain, instead of the currently used overall threshold of 14 ng/L.

CODE-MI will provide an opportunity to test the impact of sex-specific thresholds on the diagnosis, treatment, and outcomes of women presenting to ED with ischemic chest pain.