

Health Technology Review

# **Troponin | Point of Care Testing in Rural and Remote Community Health Centres**

# Key Messages

## What Is the Issue?

- Acute coronary syndrome (ACS), including myocardial infarction (MI), is a leading cause of morbidity and mortality worldwide and survival rates for MI may be lower in rural and remote settings compared to urban settings.
- While chest pain is a common symptom of ACS, most patients with this symptom will ultimately not be diagnosed with MI and diagnosis can be challenging. Recommendations for diagnosis include many factors, one of which is serial blood sampling to test for cardiac troponin (cTn), a biomarker for cardiac injury. High sensitivity, laboratory-based assays are typically recommended for cTn testing ideally within 60 minutes of a patient's presentation.
- In many rural and remote community health centres, including in Canada, laboratory services are not easily accessible, and results may not be available for hours or days. The current clinical practice in many of these regions is to transfer patients presenting with suspected ACS to the nearest hospital or tertiary care centre, sometimes over long distances and by aeromedical transfer, and often at a high cost. Given many of these patients will not ultimately be diagnosed with MI or require hospital-based care, this poses a concern for patients, staff, and resources.
- Point-of-care tests (POCT) for cTn may offer an interesting opportunity in these settings. Efficient access to cTn results may potentially improve the ability for health care workers in community settings to more easily diagnose and triage patients at risk for MI and potentially avoid unnecessary patient transfers. However, cTn POCTs are generally less sensitive than laboratory-based assays with varied performance between devices and staff training is required for implementation and quality control. It is important to understand the clinical utility and recommendations regarding the use of cTn POCTs in remote and rural settings.

## What Did We Do?

- This rapid review has been conducted in response to a request from a jurisdictional service provider to help determine if implementation of POCTs for a cardiac biomarker, cardiac troponin I (cTnI), should be considered in rural and remote community health or primary care centres. The research questions were codeveloped in response to this request. We aimed to identify and summarize recent evidence on the

# Key Messages

current use, clinical utility, and guideline recommendations regarding cTnI POCTs to support patient diagnosis and triage in these settings, where access to laboratory-based cTn results may be limited.

- We searched key resources including journal citation databases and conducted a focused internet search for relevant evidence published since January 2009. No critical appraisal of identified information was conducted.

## What Did We Find?

- We identified 2 point-of-care testing programs implemented in rural jurisdictions that include cTnI POCTs, 1 in Australia and 1 in New Zealand; no records met our eligibility criteria regarding cTnI POCT use in rural and remote settings in Canada. The included reports describe program-related processes and experiences, including approaches to structured governance and oversight, training, and quality control. We also identified 2 surveys of general practitioners' (GPs) current and desired use of cTnI POCT, 1 from Germany and 1 from South Africa, with limited applicability to the setting in Canada.
- We identified 2 health technology assessments (HTAs (with 3 eligible studies in 4 reports) and 2 primary observational studies examining the clinical utility of cTnI POCT in community health centres in rural and remote settings. One HTA, including 2 studies, and 1 primary observational study assessed cTnI POCT as part of an accelerated diagnostic protocol (ADP), a clinical decision algorithm, incorporating cTnI POCT results with electrocardiogram (ECG) results, clinical assessment, and patient history. The results suggest that cTnI POCTs, when used within the context of an ACS-ADP, have the potential to identify low-risk patients (high sensitivity and negative predictive value), and reduce unnecessary referrals or transfers when there is limited or no efficient access to laboratory-based results.
- While the included HTAs appear to be well conducted, they identified few primary research studies, studies were focused primarily on 1 cTnI POCT used within specific ADPs, the studies lacked a control group, and no studies assessed high-sensitivity cTnI POCTs. The results cannot be translated to other cTnI POCT devices nor those used within other ADPs. We identified no studies conducted in rural or remote jurisdictions in Canada.
- While some existing guidelines provide specific recommendations on components of our questions, we did not identify evidence-based

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guideline recommendations on the use of cTnI POCT in rural or remote community health centres.

## What Does It Mean?

- The studies we identified suggest that cTnI POCTs may be useful in rural and remote community care settings to help identify patients presenting with symptoms of ACS who may be at low risk for MI, potentially avoiding unnecessary patient transfers to hospital.
- As the clinical utility of cTnI POCTs is dependent on the device used, patient-management protocols and contextual factors such as underlying community risk, social acceptability and resources — and we identified no studies conducted in rural and remote community care settings in Canada — the applicability of the results is unclear. To better understand their use, cTnI POCTs should be assessed within a suspected ACS-ADP in the context of interest to better understand their utility.
- The experiences published about rural or remote community POCT programs outside of Canada highlight various factors that may inform decision-making in Canada including the importance of governance and oversight structures; continuing resources for training, accreditation and quality control; and the challenges with high staff turnover in rural and remote regions.
- As high-sensitivity cTn POCTs become available, it will be important to assess their clinical utility in settings of interest.

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## Abbreviations

<b>ACS</b>	acute coronary syndrome
<b>ADP</b>	accelerated diagnostic protocol
<b>AIHTA</b>	Austrian Institute for Health Technology Assessment
<b>cTn</b>	cardiac troponin
<b>cTnI</b>	cardiac troponin I
<b>cTnT</b>	cardiac troponin T
<b>ECG</b>	electrocardiogram
<b>ED</b>	emergency department
<b>EUnetHTA</b>	European Network for Health Technology Assessment
<b>GP</b>	general practitioner
<b>HTA</b>	health technology assessment
<b>MACE</b>	major adverse cardiovascular events
<b>MI</b>	myocardial infarction
<b>NSTEMI</b>	non–ST-elevation myocardial infarction
<b>POCT</b>	point-of-care test
<b>QoL</b>	quality of life
<b>RACPP</b>	Rural Accelerated Chest Pain Pathway
<b>SR</b>	systematic review

## Context and Policy Issues

### Acute Coronary Syndrome

In Canada, approximately 2.6 million people live with heart disease<sup>1</sup> and it is the second leading cause of death.<sup>2</sup> ACS refers to multiple forms of coronary artery disease where blood flow to the heart is suddenly reduced and includes acute MI, heart attack, and unstable angina. ACS is one of the leading causes of morbidity and mortality worldwide; more than 63,000 adults in Canada are diagnosed with their first heart attack annually<sup>3</sup> and approximately 2% of patients have had a previous heart attack. In rural and remote settings, the risk of death due to MI may be higher than in urban settings.<sup>4</sup>

### Diagnosis of Acute Coronary Syndrome

Prompt recognition and treatment of ACS is critical. Patients experiencing ACS often present with chest pain and this is one of the top reasons for emergency department (ED) visits in Canada,<sup>5</sup> yet only a small proportion of patients presenting with chest pain will ultimately be diagnosed with ACS.<sup>6</sup> Symptoms of ACS can vary by sex and other factors, and chest pain is neither a necessary nor a specific symptom for diagnosis.<sup>6,7</sup> Diagnosis and triage of ACS includes multiple assessments, one of which is serial blood sampling to test and monitor levels of a cardiac injury biomarker, cTn — specifically cTnI or cardiac troponin T (cTnT). Other factors (e.g., injury) can also elevate or change cTn levels, thus triage and prompt diagnosis of ACS also includes relevant patient history, physical examination, and an ECG within 10 minutes of presentation. Patients with suspected ST-elevated MI (based on ECG results) require emergent intervention irrespective of cTn levels. For patients with suspected non-ST-segment elevation MI (NSTEMI), cTn testing is recommended as a component of a suspected ACS-ADP (i.e., a rapid MI rule in-rule out strategy).<sup>7-9</sup>

High-sensitivity laboratory assays are generally recommended for cTn measurement, with results recommended within 60 minutes of initial presentation.<sup>7-9</sup> However, regular and efficient access to laboratory services is not available for many community care centres in rural and remote settings, where more than one-third of the population in many of Canada's provinces and territories reside.<sup>10</sup> Wait times for results can range from hours to days, inhibiting the ability to efficiently diagnose and triage patients onsite. These centres also do not typically have cardiologists or other specialist services. As such, reported standard practice is to transfer patients with suspected ACS to the nearest hospital or tertiary care centre for assessments including repeated laboratory-based cTn measurements. Transportation can include long-distance travel, in some cases by air ambulance or helicopter. In the northern territories in Canada, for example, much of the population lives greater than 100 km from, and often without road access to, the nearest hospital; thus, there is a high reliance on expensive, aeromedical evacuations.<sup>11,12</sup> As many patients presenting with symptoms of possible ACS will not require hospital-based care, these potentially unnecessary patient transfers challenge finite health system and hospital resources; may cause avoidable hardship to patients; and may put patients, flight crews, and paramedics at risk in Canada's often challenging geographic and weather conditions.

POCT for cTn pose an interesting opportunity to triage patients presenting with potential ACS in remote and rural community health care centres. These tests can be conducted close to the patient, often with handheld



or desktop devices, provide results quickly (typically within 10 to 20 minutes),<sup>13</sup> can be used without need for extensive medical-technical training, and many are approved for use in Canada.<sup>14</sup> However, POCTs for cTn have been found to be less sensitive compared to laboratory-based assays,<sup>14</sup> performance varies between devices, and staff training is required for implementation and quality control. A 2016 CADTH HTA<sup>14</sup> of cTn POCTs in patients with symptoms suggestive of ACS in any setting concluded that cTn POCTs are not recommended when immediate access to central laboratory testing is available, but, in settings without immediate access to central laboratory testing, including rural or remote settings, cTn POCTs can be considered. A CADTH rapid response update (search date up to 2020),<sup>15</sup> specific to cTn POCTs, identified no new evidence.<sup>15</sup>

## Why Is It Important to Do This Review?

Research and development in this field is rapidly evolving, including the availability of high-sensitivity cTn POCTs. As testing evolves, decision-makers are interested in understanding how cTn POCTs may be used in community health care in rural and remote settings in Canada. Previous HTAs have identified limited research conducted in rural or remote settings. Most evidence and guideline recommendations have focused on cTn POCT use in EDs or hospitals in urban centres which differ in important ways in terms of patient demographics and efficient access to subsequent care. The 2023 European Society of Cardiology guidelines acknowledges that the clinical availability of validated high-sensitivity POCTs may alter the clinical utility of cTn POCT devices.<sup>7</sup> As cTn testing is recommended as a component of suspected ACS-ADPs,<sup>7-9</sup> and guidelines recommend validating ADPs within their intended context,<sup>9</sup> reviewing the current research on clinical utility of these devices in community health care in rural and remote settings is important.

## Objective

The objective of this rapid review is to examine recent research and evidence-based guidance on the use of cTn POCTs within community health and primary care centres in rural and remote settings, where there may be limited or no efficient access to laboratory-based cTn measurements. Of particular interest for this review is whether and how cTn POCTs can be used to help identify, in people presenting with symptoms of possible ACS, those who are likely to be at low risk for MI and for whom community care may be safe and effective.

## Research Questions

1. What is the available information regarding the current use of point-of-care testing for cTn in community health centres in rural or remote settings?
2. What is the clinical utility of point-of-care tests for cTn when used in community health centres in rural or remote settings?
3. What are the evidence-based guidelines and best practices regarding the use of point of care tests for cTn in community health centres in rural or remote settings?

## Methods

An information specialist conducted a customized literature search of multiple sources and grey literature on November 28, 2024, balancing comprehensiveness with relevancy and limited to English-language documents published since January 1, 2009.

One reviewer screened citations, selected studies based on the inclusion criteria presented in [Table 1](#), and extracted data from the included studies. We did not predefine the terms *rural* or *remote* and accepted definitions as employed by the study authors. This rapid review did not include a formal critical appraisal of included studies; if the results of such assessments were presented in included HTAs, this has been noted.

[Appendix 1](#) presents a detailed description of methods.

**Table 1: Selection Criteria**

Criteria	Description
<b>Population</b>	Patients presenting with symptoms of a myocardial infarction at community or primary health centres in a rural or remote setting
<b>Intervention</b>	Point-of-care testing for troponin I
<b>Comparator</b>	NA
<b>Outcomes</b>	Q1: Current use of point of care for troponin I including jurisdictions using it in rural or remote community settings; how patients are transported to tertiary care (e.g., ambulance, medical evacuation), distance to tertiary care Q2: Clinical outcomes (e.g., mortality), patient acceptability and satisfaction with care Q3: Recommendations, best practices and practice standards regarding the appropriate use of point of care for troponin I in rural or remote community health care settings (e.g., decision-making criteria for transport to a tertiary care centre, how care is provided following testing)
<b>Study designs</b>	HTAs, SRs, RCTs, nonrandomized studies, evidence-based guidelines, institutional guidelines, program evaluations

HTA = health technology assessment; RCT = randomized controlled trial; SR = systematic review.

## Summary of Evidence

### Quantity of Research Available

A total of 249 citations were identified in the literature search. Following screening of titles and abstracts, 205 citations were excluded and 44 potentially relevant reports from the electronic search were retrieved for full-text review. In addition, 8 potentially relevant publications were identified from the grey literature search and, 1 record referenced in a study. Of these potentially relevant articles, 46 publications were excluded. [Appendix 1](#) presents the PRISMA<sup>16</sup> flow chart of study selection.

This review includes 7 publications: 2 HTAs,<sup>17,18</sup> 4 primary studies including 2 surveys of current practice,<sup>19-22</sup> and 1 report describing experiences with POCT programs.<sup>23</sup> Other relevant records were identified in the search but were excluded as they were either included in 1 of the HTAs (<sup>24,25</sup>) or were systematic reviews

(SRs) that did not provide additional relevant information.<sup>14,26,27</sup> No evidence-based guidelines that provided recommendations on the use of cTnI POCT in rural or remote community health centres were identified within our search period.

## Summary of Study Characteristics

[Appendix 2](#) contains detailed characteristics of the included studies

### Research Question 1: Current Use of cTnI Point-of-Care Testing in Community or Primary Health Centres in Rural and Remote Settings

Our search identified no information on the current use of cTnI POCT in rural or remote community health care settings in Canada. We identified 2 point-of-care testing programs that include cTnI POCT in rural and remote settings – 1 in Australia and 1 in New Zealand.<sup>19,20,23</sup> [Appendix 3](#) includes details of these programs extracted from the identified literature serve as examples of relevant programs. We also identified 2 surveys that assessed GPs' current and desired use of cTnI POCT: 1 surveyed GPs from primary practices in 3 German federal states (n = 292 responses of 2,052 surveyed)<sup>21</sup> with subgroup data for GPs from rural community practices (n = 84), and the other surveyed staff members (1 per site) from each one of 100 randomly selected primary health care clinics in KwaZulu-Natal, South Africa (100% response rate).<sup>23</sup> Some respondent demographic information was provided in the publications yet is not detailed here due to the low applicability of these studies for this review.

### Research Question 2: Clinical Use of cTnI Point-of-Care Testing in Community or Primary Health Centres in Rural and Remote Settings

#### *Study Designs, Populations, and Settings*

Two HTAs<sup>17,18</sup> reporting 4 studies relevant to this review,<sup>24,25,28,29</sup> and 2 primary observational studies<sup>19,20</sup> examined the clinical utility of cTnI POCT in the settings of interest.

One HTA was conducted by the European Network for Health Technology Assessments (EUnetHTA)<sup>18</sup> and the second, an update of the first with narrower eligibility criteria, was conducted by the Austrian Institute for Health Technology Assessment GmbH (AIHTA).<sup>17</sup> Both had broader inclusion criteria than our rapid review: they assessed questions related to both cTn and another POCT (D-dimer to help rule-out deep vein thrombosis and pulmonary embolism); they included studies examining cTnT as well as cTnI, and they included settings beyond community care in rural and remote locations. Both searched for studies including adult patients with suspected non–ST-elevation acute MI. The EUnetHTA report included studies in both ambulatory and emergency settings, while the AIHTA report was limited to studies conducted in primary and community care. Both HTA teams used a stepwise approach to identify relevant evidence — first searching for SRs, HTAs, and clinical or diagnostic guidelines (published in English or German between 2009 and 2019,<sup>18</sup> or 2019 and 2024<sup>14</sup>), then supplementing the search, as needed, to identify primary studies. The EUnetHTA report<sup>18</sup> identified 2 SRs, 1 of which was the 2016 CADTH HTA,<sup>14</sup> and 8 guidelines that contributed to their assessment of cTn POCT. The AIHTA<sup>17</sup> update identified no new relevant SRs or guidelines and included 3 primary studies in 4 publications. Only studies relevant to this rapid review, 2 from each HTA,<sup>24,25,28,29</sup> will be described in this report.

The EUnetHTA report<sup>18</sup> included 1 study reported in 2 publications assessing a POCT program implemented in 36 remote health or community service centres in Australia's Northern Territory.<sup>25,29</sup> Staff at the relevant health centres were invited to participate in a satisfaction survey (n = 127) regarding their perceptions before and after implementation of the POCT program.

The other 2 included primary observational studies<sup>19,20</sup> also assessed Australia's Northern Territory POCT Program, auditing clinical outcomes. Matthews et al. (2020)<sup>19</sup> included data from up to 80 remote sites within this region, while Spaeth et al. (2017)<sup>20</sup> included data from 6 remote health centres and limited participants to those with a primary presentation of chest pain, normal ECG, and clinical symptoms suggestive of NSTEMI. Time from onset of symptoms to presentation was not reported in either publication. In this region, patients can be transferred to 1 of 2 hospitals, typically by airplane or helicopter, and the average distance from practice to the hospital is 275 km (range, 100 to 700 km).

The AIHTA report<sup>17</sup> included 2 relevant uncontrolled observational studies, both of which were conducted in New Zealand, and one<sup>28</sup> is a pilot study of the other.<sup>24</sup> These 2 studies had similar eligibility criteria: the pilot study<sup>28</sup> included adult patients presenting to 1 of 12 rural family practices (n = 180 participants) for whom symptoms of suspected ACS began within 72 hours of presentation and transfer to hospital for serial cTn measurement was intended. The subsequent study<sup>24</sup> recruited from up to 29 sites (n = 1,205 participants) and, while it recruited from rural hospitals and general and urgent care practices, it was included in this review as eligibility was limited to patients who would have required transfer for an urgent hospital-based assessment if they had presented to a general or urgent care practice. In both studies, practices do not include specialist care or central laboratory services and could be hours from the nearest metropolitan hospital. Participant baseline characteristics were similar between these 2 studies for most risk factors, although Norman et al. (2022)<sup>28</sup> may have included a higher proportion of smokers and those with a family history of cardiovascular disease. Importantly, the study populations had different medians of time from pain onset to initial assessment: approximately 15 hours in Norman et al. (2022)<sup>28</sup> and approximately 4.5 hours in Miller et al. (2022).<sup>24</sup>

### ***Interventions and Comparators***

Eligibility for inclusion in the 2 HTAs was limited to quantitative cTn POCT devices available in Europe. The AIHTA report<sup>17</sup> intended to prioritize evidence from high-sensitivity cTn POCTs over non-high-sensitivity cTn POCTs but found no studies using the former. Both reviews considered all comparators of current diagnostic practice. Nearly all studies identified by the HTAs and this rapid review exclusively report using the i-STAT cTnI test and 3 studies specifically report using this as 1 component of a clinical decision pathway or ADP.<sup>20,24,28</sup> All publications described study or program-specific training and quality control measures.

Two studies<sup>24,28</sup> from the AIHTA report<sup>17</sup> examined the use of cTnI POCT as part of the Rural Accelerated Chest Pain Protocol (RACPP), which was modified from a validated metropolitan ED chest pain ADP.<sup>24,28</sup> This ADP includes, among other assessments, ECG and cTn POCT measurements at presentation and at 2 hours. Both studies used the i-STAT cTnI test and one<sup>24</sup> also used the AQT90 FLEX cTnT test. To increase sensitivity, both used a lower test cut-off for i-STAT than the manufacturer's upper recommended limit based on the 99th percentile. For a patient to be classified as low risk, the following was required: no red flags (e.g.,

crescendo angina, hemodynamic instability, or ongoing chest pain), absence of potentially significant ECG changes at 0 and 2 hours, an Emergency Department Assessment of Chest Pain Score<sup>30</sup> of less than 16, and serial cTn concentrations below the lower rule-out threshold at 0 and 2 hours (i-STAT: 0.04 mcg/L; AQT90: 18 ng/L). If all criteria were met, the patients were discharged home with follow-up as appropriate based on the clinician's assessment. If these criteria were not met or a change of 0.02 mcg/L or more in cTn levels was observed on the i-STAT test, patients were transferred to a referral centre or admitted to hospital.

Spaeth et al. (2017)<sup>20</sup> examined the use of cTnI as part of a modified standard care protocol similar to, but less specific than, that used in other studies (they state they used serial cTn measures at 0 and < 8 hours from presentation and did not state a cTnI concentration used to rule out MI).

## Outcomes

The 2 HTAs<sup>17,18</sup> included outcomes as eligibility criteria. They did not prespecify outcome definitions or methods of measurement other than for major adverse cardiovascular events (MACE). The outcomes assessed in the HTAs (with primary studies reporting these outcomes also referenced) include:

- MACE,<sup>17,18</sup> a composite outcome, was defined in the AIHTA report as ACS, percutaneous coronary intervention, coronary artery bypass grafting, coronary angiography revealing procedurally correctable stenosis managed conservatively, and all-cause mortality
- other safety outcomes (adverse events,<sup>17,18</sup> serious adverse events<sup>17</sup>)
- measures of diagnostic accuracy (specifically: sensitivity, specificity, positive and negative predictive value)<sup>17</sup>
- hospital or ED referrals or visits<sup>17,18,20</sup>
- hospital admissions<sup>17,18</sup>
- patient quality of life (QoL) or health-related quality of life<sup>17,18</sup>
- patient satisfaction<sup>17</sup>
- staff satisfaction<sup>17</sup>
- treatment initiation<sup>18</sup>
- door-to-needle time<sup>18,20</sup>
- turnaround time<sup>18,20</sup>
- time to discharge<sup>18</sup>
- length of stay<sup>18</sup>
- further diagnostic testing<sup>18</sup>
- time to clinical decision or diagnosis.<sup>18,20</sup>

Additional relevant outcomes planned in the included primary studies were:

- clinician adherence to pathway<sup>28</sup>
- number of tests outside a defined critical action limit (i.e., a positive test) and clinical conditions of relevant patients.<sup>19</sup>

### Research Question 3: Evidence-Based Guideline Recommendations on Use of cTnI Point-of-Care Testing in Community Health Care in Rural and Remote Settings

No evidence-based guidelines were identified that recommended best practices specific to cTnI POCTs in community health care and primary care settings in rural and remote locations.

## Summary of Findings

[Appendix 3](#) presents the main study findings.

### Research Question 1: Current Use of cTnI Point-of-Care Testing in Community Health Centres in Rural and Remote Settings

Our search identified no information on the current use of cTnI POCT in rural or remote community health care settings in Canada. [Appendix 3](#) ([Table 5](#)) includes details of 2 point-of-care testing programs in rural or remote settings that include cTnI POCTs; 1 in Australia and 1 in New Zealand.<sup>19,20,23</sup> While not exhaustively searched and identified, these examples serve to provide approaches to structured governance and oversight, training and quality control, challenges experienced in these settings, and may inform the use of these devices in Canada. We also identified 2 surveys on GPs' current and desired use of cTnI POCTs, in South Africa and Germany which, given health system and population dispersion differences, have limited applicability to the setting in Canada.

#### *Current Use of cTn POC Devices*

Data on the current use of cTn POCTs comes from 2 surveys and 1 program evaluation ([Appendix 3](#), [Table 6](#)). Both surveys assessed the current and desired use of POCTs more generally, including specific questions regarding cTn POCTs. Matthes et al. (2023),<sup>21</sup> mailed invitations to more than 2,000 GPs in urban and rural community practices in 3 German federal states in 2022; the total response rate was 14.5%. Thirty-nine percent of GPs from rural community practices reported regular use of cTn POCTs, 35.4% reported infrequent use, and 25.6% reported no use. The authors reported no statistically significant difference between rural and urban GPs' use of cTn POCTs. Mashamba-Thompson et al. (2018)<sup>22</sup> surveyed staff at 100 randomly selected rural primary health care clinics in KwaZulu-Natal, South Africa. Although the survey explicitly asked about current and desired use of cTn POCTs, the authors did not present responses about this test in the publication. The presentation of results was limited to the following: most frequently used tests, top 20 desired POCTs, and top 10 desirable POCTs by disease class, of which cTn POCTs were not rated. Based on the limited information, we can only conclude that cTn POCTs were not one of the most frequently used or desired tests, with less than 10% of respondents from this study indicating desired future need for cTn POCTs.

The 2020 report evaluating Australia's Northern Territory POCT Program, implemented in 2008, showed a steady increase in cTnI POCT use over the first 4 years of the program.<sup>19</sup>

#### *Context: Distance to Tertiary Care*

In Australia's Northern Territory POCT Program, 97.5% of remote health clinics are considered very remote. The region includes 2 tertiary care hospitals with an average distance of 275 km (range, 100 to 700 km) from



practices to hospitals.<sup>19</sup> Distances between centres of the various POCT programs in New Zealand were not described by Herd et al. (2021).<sup>23</sup>

The distance or time from study sites to specialist care and laboratory services was also described in the following included studies:

- Miller et al. (2022):<sup>24</sup> from 45 minutes to 4 hours and 20 minutes
- Norman et al. (2022):<sup>28</sup> 0.01 km to 62.7 km (1 to 79 minutes) to a rural hospital and 32.0 to 178.4 km (30 to 152 minutes) to a base hospital
- Mashamba-Thompson et al. (2018):<sup>22</sup> the mean distance was 41.4 (standard deviation = 42.8) km, with 40% of practices within 10 km of the hospital.

### ***Context: Method of Patient Transportation to Tertiary Care***

We identified little information on transport methods from rural to tertiary care centres. Reports on Australia's Northern Territory POCT Program state that patients can be transferred to 1 of 2 hospitals, typically by airplane or helicopter.<sup>19,20,25,29</sup> Additionally, a report<sup>24</sup> from a study included in 1 HTA<sup>17</sup> noted that 1 study site may require transportation by helicopter or boat, but the mode of transportation was not specified for other sites.

## **Research Question 2: Clinical Use of cTnI Point-of-Care Testing in Community Health Centres in Rural and Remote Settings**

We identified 2 HTAs<sup>17,18</sup> and 2 primary observational studies<sup>19,20</sup> examining the clinical utility of cTnI POCTs in community health or primary care centres in rural and remote settings. Three studies (2<sup>24,28</sup> included in 1 HTA<sup>17</sup> and 1 primary study<sup>20</sup>) described cTnI POCT use as part of an ADP (i.e., a clinical decision algorithm) and the results suggest that a suspected ACS-ADP using cTnI POCTs may be beneficial to identify low-risk patients and safely avoid unnecessary referrals or patient transfers. However, the evidence of clinical utility in these settings comes from a few uncontrolled observational studies focused primarily on 1 cTnI POCT (i-STAT test) used within specific ADPs. As such, the results cannot be translated to other cTnI POCT devices nor those used within other ADPs. It is unclear if the results are valid in other rural and remote settings. Limited information was provided on patients' acceptability and satisfaction with care.

### ***Major Adverse Cardiovascular Events***

One HTA<sup>17</sup> identified 2 uncontrolled studies<sup>24,28</sup> assessing MACE at 30 days. The HTA authors assessed these studies to be at serious and critical risk of bias. The 2 studies used similar ADPs, using the RACPP to stratify patient risk and guide patient transfer and hospital admission decisions. Both studies reported no MACE in patients designated as low risk and at least 1 MACE was experienced by 13%<sup>28</sup> and 23%<sup>24</sup> of participants designated as non-low risk.

### ***Measures of Diagnostic Accuracy of RACPP***

One HTA<sup>17</sup> identified 2 uncontrolled studies<sup>24,28</sup> assessing the diagnostic accuracy of the RACPP to predict 30-day MACE. The HTA authors assessed these studies to be at serious and critical risk of bias. The results for Miller et al. (2022)<sup>24</sup> and Norman et al. (2022),<sup>28</sup> respectively, are as follows:

- sensitivity: 100% (95% confidence interval [CI], 97.3% to 100%) and 100.0% (95% CI, 70.1% to 100.0%)
- negative predictive value: 100% (95% CI, 99.2% to 100%) and 100.0% (95% CI, 96.7% to 100.0%)
- specificity: 50.7% (95% CI, 47.5% to 53.9%) and 63.8% (95% CI, 56.4% to 70.6%)
- positive predictive value: 23.0% (95% CI, 19.8% to 26.6%) and 12.5% (95% CI, 6.7% to 22.1%).

### ***Hospital Referrals, Admissions, Patient Evacuations***

One HTA,<sup>17</sup> including 2 uncontrolled studies,<sup>24,28</sup> and 1 other primary study<sup>20</sup> assessed hospital referrals, admissions, or patient evacuations ([Appendix 3, Table 9](#)). Miller et al. (2022)<sup>24</sup> and Norman et al. (2022)<sup>28</sup> reported that 91.8% (95% CI, 88.8% to 93.9%) and 100% of patients designated as low risk for MI, respectively, were never transferred or admitted to hospital (i.e., were discharged home). Spaeth et al. (2017)<sup>20</sup> included 2 outcomes in this domain. The first outcome was defined as the number of patients designated as cTnI negative within the context of a POCT pathway (i.e., low risk) compared to those who were cTnI positive who were evacuated (10% versus 100%, respectively). The second outcome was based on a retrospective chart analysis by a senior rural medical practitioner who predicted whether patients would have been evacuated at the time of their assessment had cTnI POCTs not been available. The authors reported that cTnI POCTs might have helped avoid 38% of evacuations due to an inability, in their absence, to rule out cardiac involvement; all patients who were cTnI negative who were evacuated would still have been evacuated without cTnI POCTs due to their condition; and of those who were cTnI-positive (n = 7), approximately one-half would not have been evacuated without cTnI POCT testing and would likely have experienced a poorer outcome.

### ***Time to Diagnosis, Time to Treatment, and Door-to-Needle Time***

One retrospective primary study<sup>20</sup> reported both the time from cTnI POCT administration to diagnosis and to treatment. The authors presented summary measures based on whether patients received a single POCT or serial cTnI POCTs, had positive or negative results, and were evacuated or not. As the numbers are small within most groups and interquartile ranges are wide, conclusions cannot be drawn. [Table 10](#) and [Table 11](#) contain the summary measures by group.

### ***Patient Satisfaction***

One HTA<sup>17</sup> identified 1 observational study<sup>28</sup> assessing patient satisfaction with their care when care was guided by the RACPP that included cTnI POCT ([Appendix 3, Table 12](#)). Patient response rate was 75% (of 148 participants included in this analysis) and most patients reported “Good” or “Excellent” overall satisfaction with the service they received (94.0% of 67 low-risk patients and 95.5% of 44 non-low-risk patients, including 37 of the latter who were transferred to hospital).



### ***Staff Satisfaction***

The 2 HTAs<sup>17,18</sup> identified 2 studies reported in 3 publications that assessed staff satisfaction ([Appendix 3, Table 13](#)).<sup>25,28,29</sup> Norman et al. (2022)<sup>28</sup> did not define this outcome and reported that “The pathway was considered feasible and acceptable by the general practices to the extent that it has been maintained as the standard of care in the participating centres.” Shephard et al. (2012, 2014)<sup>25,29</sup> defined this outcome as “staff satisfaction with pathology services” and collected data using online questionnaires approximately 1 year after introducing the i-STAT POCT program. The results were based on recalled satisfaction for both before implementation and after implementation outcomes. The response rate was 31% (of 127 potential respondents) and results suggested perceived improvements between overall satisfaction of cTn testing in general and timeliness of acute test results before implementation (with laboratory-based assays) versus after implementation (with POCT-based assays). Each question had missing data and results should be interpreted with caution.

### ***Adherence to Pathway***

One HTA<sup>17</sup> identified 1 uncontrolled observational pilot study<sup>28</sup> assessing physicians’ and patients’ adherence to the RACPP ([Appendix 3, Table 14](#)). They reported adherence to the protocol for 95.5% of the 111 patients designated as low risk by the ADP and 81.2% of the 69 patients designated as non–low risk. In the low-risk group, 4 participants did not undergo the 2-hour assessment due to a diagnosis of non-cardiac chest pain and 1 refused to remain at the practice. In the non–low-risk group, 13 participants were not transferred for hospital assessment, against pathway guidance; none of these patients had elevated cTnI or experienced MACE within 30 days.

### ***Proportion of cTnI Tests Outside the Defined Critical Action Limits and Corresponding Patient Clinical Condition***

One study<sup>19</sup> evaluating Australia’s Northern Territory POCT Program examined the number of tests outside the critical action limits (i.e., positive tests) and the diagnosis of corresponding patients ([Appendix 3, Table 15](#)). Three percent of 1,398 cTnI POCTs administered between September and December 2019 were outside the defined clinical limits ( $> 0.09$  ng/m). Corresponding patient clinical conditions included MI ( $n = 34$ ; 2.4%), chronic kidney disease related, ( $n = 4$ ; 0.3%), atrial fibrillation ( $n = 3$ ; 0.2%), respiratory related ( $n = 2$ ; 0.1%), and hypokalemia ( $n = 2$ ; 0.1%).

### ***Outcomes Predefined in HTAs, Not Reported in Included Studies***

The 2 HTAs sought evidence regarding the following outcomes and no relevant evidence was identified: treatment initiation, health or patient-related QoL, adverse events, and serious adverse events, turnaround time, time to discharge, length of stay, and further diagnostic testing.

### **Research Question 3: Evidence-Based Guideline Recommendations on Use of cTnI Point-of-Care Testing in Community Health Care in Rural and Remote Settings**

Our electronic database and grey literature search did not identify evidence-based guideline recommendations specific to the use of cTnI POCTs in community health or primary care centres in rural or remote settings.

## Limitations

Our search identified no information regarding the current use of cTnI POCTs in rural and remote settings in Canada. Surveys that were identified on current and desired use of cTnI POCTs, conducted in Germany and South Africa, are not directly applicable to the context in Canada due to population dispersion and health systems differences. We identified 2 POCT programs, 1 in Australia and 1 in New Zealand, that specifically reference cTnI POCT use in community and primary care centres in rural or remote jurisdictions. The applicability of these programs to the context in Canada, while promising, will need to be considered. Other POCT programs and implementation guidelines identified during this assessment (within or outside the context in Canada) either did not specifically mention or assess cTnI POCTs, did not describe the context as community health or primary care centres in rural and remote settings (e.g., mixed settings, rural hospitals), or did not meet other review eligibility criteria.

We also identified limited evidence to inform the clinical utility of cTnI POCTs in community health centres in remote and rural settings in Canada. The included HTAs appear to be well conducted yet few primary research studies were identified, they lacked a control group, and were assessed as having high risk of bias (by the authors of the HTA). The included studies primarily focused on 1 device, i-STAT, which is available in Canada. While the results of included studies are promising, the evidence is not applicable to other devices due to variations in diagnostic accuracy and recommended diagnostic cut-off values between devices. The included clinical utility studies also considered cTnI POCTs in the context of 2 ADPs and, given cTnI POCT clinical utility is dependent on the ADP guiding patient management, the results of the studies included in this review should not be considered applicable outside of the ADP within which they were tested. Importantly, no study assessed high-sensitivity cTnI POCT devices.

While some existing guidelines provide specific recommendations with respect to components of the review questions (e.g., recommendations on the use of cTn POCTs without a specific setting or not specific to rural and remote settings), we did not identify an evidence-based clinical guideline providing recommendations specific to community health care in rural and remote settings for this rapid review.

## Conclusions and Implications for Decision-Making or Policy-Making

This rapid review evaluated the evidence on the current use, clinical utility, and guideline recommendations regarding cTnI POCTs in rural and remote community health settings. Seven publications were included in the review: 2 HTAs (from which 3 primary studies in 4 reports were applicable), 4 primary observational studies, and 1 report describing experiences with POCT programs in New Zealand. The overall evidence-base to inform the use of cTnI POCT in these settings is limited and no studies were conducted in Canada. The results suggest that cTnI POCTs, when used within the context of an ACS-ADP, have the potential to identify patients who were low-risk (high sensitivity and negative predictive value), reduce unnecessary referrals or transfers, and increase patient and staff satisfaction when there is limited or no efficient access to laboratory-based results. However, the studies we identified did not include control groups and have risks

to their validity (as assessed by the authors of the HTA). As such, while promising, the results should be considered in this context.

Our search identified 2 current POCT programs that include cTnI testing — 1 implemented in Australia's Northern Territory and 1 in New Zealand. These programs may be informative to the context in Canada given the similarities between health care systems and population dispersion. The experiences and challenges described in relation to these programs<sup>19,31</sup> highlight the importance of strong governance and oversight structures; continuing resource needs for training, accreditation, and quality control; advantages of centralized data collection and monitoring; and the challenges with high staff turnover in rural and remote regions, the latter also noted in Canada.<sup>11,27</sup>

The limited evidence on the clinical utility of cTnI POCTs identified in this review comes from studies conducted in New Zealand and Australia and it is not clear whether the results may be applicable to rural and remote community health care in Canada. Research on cTnI POCTs is more established in other settings (EDs, prehospital care, or emergency medical services) and some studies conducted within rural hospitals (e.g., Dee et al.<sup>32</sup>) may also be informative; however, potential differences in the patient population, such as underlying patient risk<sup>4</sup> and access to subsequent care, make it challenging to translate these results to rural and remote community care settings. We also acknowledge there are different levels of rurality and remoteness and that decisions and preferences concerning availability of POCTs may need to vary depending on the setting.

Importantly, cTnI testing is not assessed as an isolated intervention. Rather, it is assessed within the context of suspected ACS-ADPs, in alignment with current guideline recommendations.<sup>7-9</sup> These typically incorporate ECG results, clinical risk scores (e.g., based on symptoms, age, sex, history), and time points and cut-off values for cTnI testing (often laboratory-based) to guide patient management. Guidelines recommend validating suspected ACS-ADPs within the intended context<sup>9</sup> as numerous factors can affect their utility, including time from symptom onset to presentation and local prevalence of other risk factors, patient transport protocols, staff training, patient preferences, and staff and patient fidelity with the protocols. Both the authors of the most recent HTA<sup>17</sup> and those of largest prospective patient-focused study<sup>24</sup> conclude that further assessment is needed (e.g., larger studies, RCTs, longer follow-up, validation of ADPs in the settings of interest). Additionally, limited evidence was available on patient-focused outcomes such as QoL and satisfaction with care and these would be valuable additions to future research. The included evidence was almost all conducted using i-STAT cTnI, the results of which are not generalizable to other cTnI POCT devices, and no studies assessed a high-sensitivity cTnI POCT device; this evolving technology may affect POCT recommendations.<sup>7</sup>

Our initial search for evidence-based guidelines did not identify any specific recommendations regarding the use of cTnI POCTs in rural and remote community care centres. Some reports included evidence-based recommendations on cTn testing but not specific to the settings of interest,<sup>33</sup> while others provided recommendations but did not describe both a systematic search for evidence and a defined consensus process.<sup>27,34</sup> The 2023 European Society of Cardiology Guidelines acknowledged this is a rapidly evolving

field and that an update of current recommendations may be required with the introduction of high-sensitivity cTn POCT devices in clinical settings.

Since completion of this rapid review, the anticipated 2025 update<sup>35</sup> to the 2016 ACS guidelines<sup>9</sup> by the National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand has been released. While no recommendation specifically guides the use of cTnI POCTs in community health or primary care centres in rural and remote settings, this guideline describes factors associated with all these variables separately and includes considerations for care of priority populations including those living in remote areas. Specifically, authors recommend use of high-sensitivity cTn assays, wherever possible, versus contemporary (non-high sensitivity) cTn assays and, as with previous guidance, they recommend the use of an evidence-based clinical decision pathway. The authors discuss considerations for testing and interpreting results based on other factors, including age, race, and the effect of sex hormones for transgender individuals. Authors note that cTn POCTs may lead to more timely management with comparable safety to laboratory-based assays and that emerging evidence supports rapid assessment using high-sensitivity cTn assays. They also acknowledge that the evidence-base is rapidly evolving and that the use of POCTs with ADPs, including in primary care, may become more common. No specific recommendation is provided regarding use of cTn POCTs in rural and remote settings. The authors recommend, more broadly, the establishment of centralized support systems for regional and remote health services to facilitate prompt assistance with ECG interpretation and access to cTn results when onsite access is not available.

Overall, while the results of this rapid review suggest that, when used within the context of an ACS-ADP, cTnI POCTs have the potential to identify patients who were considered at low-risk and reduce unnecessary referrals or transfers for people presenting with symptoms of ACS in community health care in rural and remote settings (with limited access to laboratory-based results), there are concerns about the validity and applicability of the evidence. We found no evidence from studies conducted in Canada, the evidence was limited primarily to 1 device, and it was assessed within uncontrolled observational studies. As such, when considering implementation of these devices, it would be advantageous to first assess them within the context of a suspected ACS-ADP in the settings of interest. This is important to account for variables such as the underlying community cardiac risk factors, patient experience, available resources, and availability of trained, qualified personnel. The advent of high-sensitivity cTn POCTs holds promise to help overcome some of the concerns with currently available non-high-sensitivity cTnI POCTs and future research will be important to better understand their utility. Health care decision-makers will ultimately need to balance the limited existing and emerging evidence with the challenges of their current standard of care.

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## Appendix 1: Detailed Methods and Selection of Included Studies

Please note that this appendix has not been copy-edited.

### Literature Search Methods

An information specialist conducted a literature search on key resources including MEDLINE, the Cochrane Database of Systematic Reviews, the International HTA Database, the websites of HTA agencies in Canada and major international HTA agencies, as well as a focused internet search. The search approach was customized to retrieve a limited set of results, balancing comprehensiveness with relevance. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (medical subject headings), and keywords. Search concepts were developed based on the elements of the research questions and selection criteria. The main search concepts were cTnI POCT and the rural or remote setting. To address question 3, search filters were applied to limit retrieval to HTAs, SRs, meta-analyses, or indirect treatment comparisons and guidelines; no filters were applied to limit the retrieval by study type for questions 1 and 2. The search was completed on November 28, 2024, and limited to English-language documents published since January 1, 2009. Internet links were provided, where available. We provide the search strategy for MEDLINE in Table 2.

**Table 2: Search Strategy for Ovid MEDLINE (1946 to November 27, 2024)**

Terms	Results
1. exp "Point-of-Care Systems"/	21,753
2. (portable or hand-held or mobile or point of care or near patient or bedside or bed side or hand-held or POC or POCT or ambulatory or rapid test or rapid tests or rapid testing or rapid screen or rapid screening or remote test or remote tests or remote testing or rapid diagnostic test or rapid diagnostic tests or rapid diagnosis or rapid diagnoses or transportable or test kit or test kits).ti,ab,kf.	409,330
3. (point adj4 care adj4 (test or testing or assay or assays)).ti,ab,kf.	12,478
4. (portable adj4 (test or testing or assay or assays)).ti,ab,kf.	1,332
5. ((rapid or bedside or bed side) adj4 (test or testing or assay or assays)).ti,ab,kf.	43,049
6. 1 or 2 or 3 or 4 or 5	439,716
7. exp Troponin/	21,493
8. (troponin* or cTn* or TnI* or TnT*).ti,ab,kf.	50,400
9. cardiac biomarker*.ti,ab,kf.	4,083
10. 7 or 8 or 9	55,040
11. 6 and 10	1,704
12. (i?STAT or iSTAT or iSTATr or triage cardiac or cardio2 or cardio3 or Alfa Scientific or Instant View or (Vidas adj5 ultra) or miniVidas or LifeSign or Meritas or PathFast or Cardiac STATus or AQT90 or AQT90flex or (Response and RAMP) or Cobas h232 or "Cobas h 232" or Cardiac Reader or Stratus CS or (ZAP and troponin) or GEM Immuno or ReLIA TZ* or Radiometer AQ* or ATQ90* or Atellica?VTLi or Triage?True).ti,ab,kf.	3,636
13. (triage and Alere).ti,ab,kf.	36



Terms	Results
14. (bioMerieux and Vidas).ti,ab,kf.	226
15. (Roche and (" Trop T" or "Troponin T" or TropT) and cardiac).ti,ab,kf.	199
16. 12 or 13 or 14 or 15	4,067
17. 11 or 16	5,693
18. Rural Population/ or Rural Health/ or exp Rural Health Services/ or Hospitals, Rural/ or Regional Medical Programs/ or Medically Underserved Area/ or Health Services, Indigenous/ or exp Community Health Services/ or exp ambulatory care facilities/	499,627
19. (underserved or under-served or rural* or countryside* or country-side* or non-urban or nonurban or non-metropolitan or nonmetropolitan or remote* or mountain* or wilderness or outpost* or village* or resource-poor or resource limited or resource constrained or fly-in or Arctic or isolated communit* or community health centre* or community health centre* or primary care or general practition* or pre?hospital or (urgent adj3 care adj3 clinic*)).ti,ab,kf.	639,911
20. 18 or 19	1,018,854
21. 17 and 20	219
22.limit 21 to (english language and yr = "2009 -Current")	174
23. (systematic review or meta-analysis).pt.	369,111
24. meta-analysis/ or systematic review/ or systematic reviews as topic/ or meta-analysis as topic/ or "meta-analysis (topic)"/ or "systematic review (topic)"/ or exp technology assessment, biomedical/ or network meta-analysis/	412,452
25. ((systematic* adj3 (review* or overview*)) or (methodologic* adj3 (review* or overview*))).ti,ab,kf.	390,927
26. ((quantitative adj3 (review* or overview* or syntheses*) or (research adj3 (integrati* or overview*))).ti,ab,kf.	18,632
27. ((integrative adj3 (review* or overview*)) or (collaborative adj3 (review* or overview*)) or (pool* adj3 analy*)).ti,ab,kf.	44,666
28. (data syntheses* or data extraction* or data abstraction*).ti,ab,kf.	48,317
29. (handsearch* or hand search*).ti,ab,kf.	11,834
30. (mantel haenszel or peto or der simonian or dersimonian or fixed effect* or latin square*).ti,ab,kf.	40,009
31. (met analy* or metanaly* or technology assessment* or HTA or HTAs or technology overview* or technology appraisal*).ti,ab,kf.	13,631
32. (meta regression* or metaregression*).ti,ab,kf.	17,501
33. (meta-analy* or metaanaly* or systematic review* or biomedical technology assessment* or bio-medical technology assessment*).mp,hw.	550,703
34. (medline or cochrane or pubmed or medlars or embase or cinahl).ti,ab,hw.	406,400
35. (cochrane or (health adj2 technology assessment) or evidence report).jw.	22,224
36. (comparative adj3 (efficacy or effectiveness)).ti,ab,kf.	20,069
37. (outcomes research or relative effectiveness).ti,ab,kf.	12,081
38. ((indirect or indirect treatment or mixed-treatment or bayesian) adj3 comparison*).ti,ab,kf.	4,828
39. [(meta-analysis or systematic review).md.]	0
40. (multi* adj3 treatment adj3 comparison*).ti,ab,kf.	321
41. (mixed adj3 treatment adj3 (meta-analy* or metaanaly*)).ti,ab,kf.	184

Terms	Results
42. umbrella review*.ti,ab,kf.	2,383
43. (multi* adj2 paramet* adj2 evidence adj2 synthesis).ti,ab,kf.	15
44. (multiparamet* adj2 evidence adj2 synthesis).ti,ab,kf.	19
45. (multi-paramet* adj2 evidence adj2 synthesis).ti,ab,kf.	13
46. or/23 to 45	796,491
47. 17 and 46	76
48. limit 47 to (english language and yr = "2009 -Current")	63
49. (guideline or practice guideline or consensus development conference or consensus development conference, NIH).pt.	49,816
50. (guideline* or standards or consensus* or recommendat*).ti.	208,203
51. (practice parameter* or position statement* or policy statement* or CPG or CPGs or best practice*).ti.	20,162
52. (care adj2 (path or paths or pathway or pathways or map or maps or plan or plans or standard)).ti.	9,787
53. ((critical or clinical or practice) adj2 (path or paths or pathway or pathways or protocol)).ti.	5,192
54. (algorithm* and (pharmacotherap* or chemotherap* or chemotreatment* or therap* or treatment* or intervention*).ti.	4,184
55. (algorithm* and (screening or examination or test or tested or testing or assessment* or diagnosis or diagnoses or diagnosed or diagnosing)).ti.	5,055
56. (guideline* or standards or consensus* or recommendat*).au.	11
57. [(guideline* or standards or consensus* or recommendat*).co.]	0
58. (guideline* or standards or consensus* or recommendat*).ca.	2,535
59. systematic review.ti,pt,kf,sh. and (practice guideline* or treatment guideline* or clinical guideline* or guideline recommendation*).ti,ab,kf.	5,126
60. or/49 to 59	273,028
61. 17 and 60	40
62. limit 61 to (english language and yr = "2009 -Current")	32
63. 48 or 62	93
64. 21 or 63	296

## Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in [Table 1](#).

## Exclusion Criteria

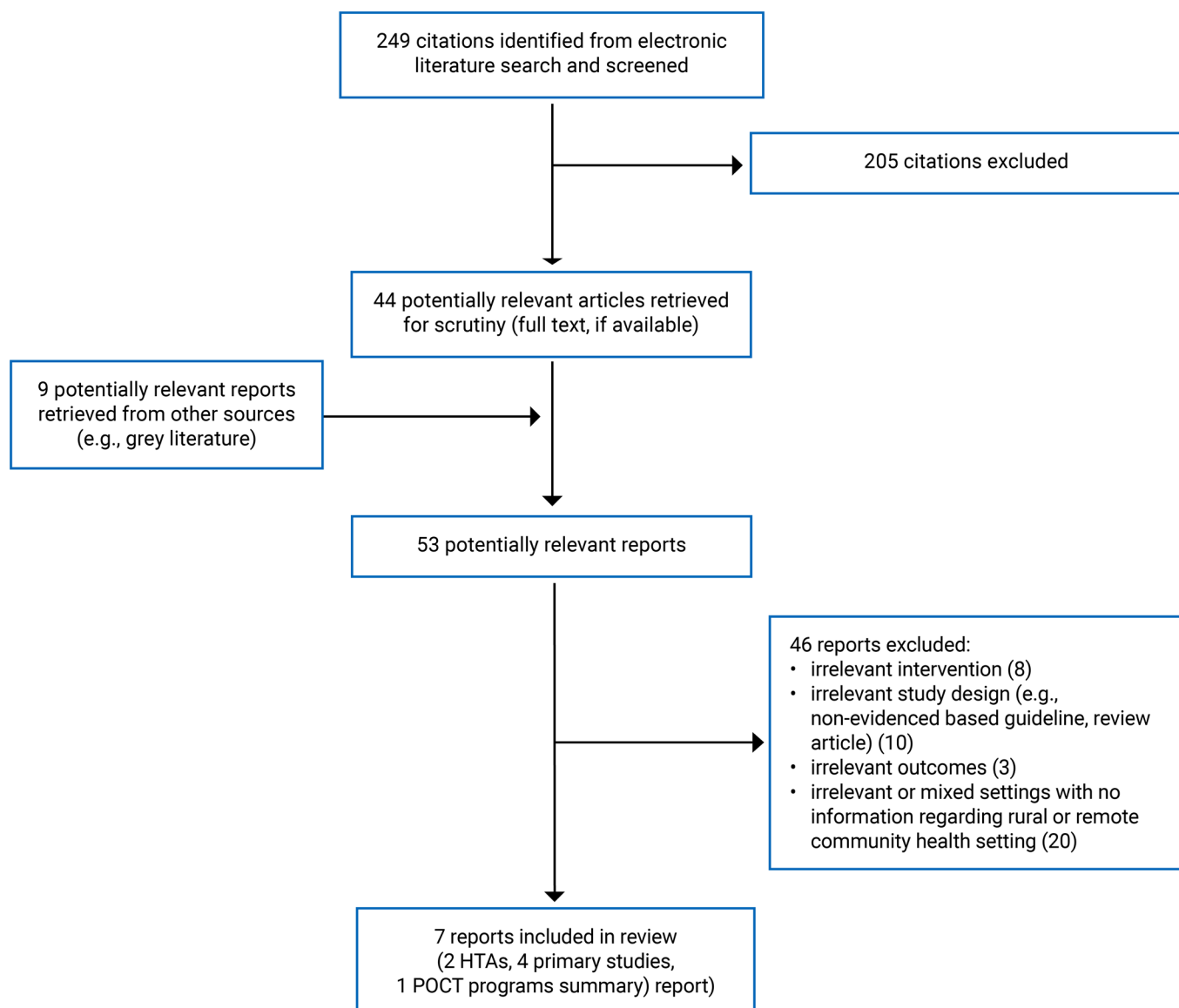
Articles were excluded if they did not meet the selection criteria outlined in [Table 1](#), they were duplicate publications or were published before 2009. SRs in which all relevant studies were captured in other more recent or more comprehensive SRs were excluded. Primary studies retrieved by the search were excluded

if they were captured in 1 or more included SRs. Guidelines with unclear methodology were also excluded. Studies conducted in urban settings, hospitals or EDs or mixed settings, unless results were reported separately for rural and remote settings, were not eligible.

### Critical Appraisal of Individual Studies

We did not conduct a formal critical appraisal of individual studies for this review. The limitations of the included studies are discussed.

**Figure 1: Selection of Included Studies**



HTA = health technology assessment; POCT = point-of-care test; SR = systematic review.

## Appendix 2: Characteristics of Included Publications

**Table 3: Characteristics of Included Health Technology Assessments**

Study citation, country, funding source	Search, study designs, numbers of primary studies included	Population characteristics, settings	Intervention and comparator(s)	Clinical outcomes, length of follow-up
<p>Huic et al. (2024)<sup>17</sup> Austria <b>Funding source:</b> Not directly stated – created by AIHTA</p>	<p>This review updated (with a narrower focus) the EUnetHTA (2019) HTA.<sup>18</sup> This review aims to assess the clinical utility of troponin (in patients with suspected MI) and D-Dimer (in patients with suspected deep vein thrombosis or pulmonary embolism) POCT. The present summary is limited to the methods and results of troponin POCT.</p> <p><b>Search dates and limits:</b> June 1, 2019, to March 1, 2024; German and English studies only</p> <p><b>Eligible study designs:</b></p> <ul style="list-style-type: none"> <li>• Stepwise - SR/MA/HTAs; when none identified, they stated they may include controlled primary studies with ≥ 10 participants</li> <li>• Clinical or diagnostic practice guidelines</li> </ul> <p><b>Included studies:</b></p> <ul style="list-style-type: none"> <li>• No relevant SRs or clinical or diagnostic guidelines identified</li> <li>• Included 3 primary studies in 4 publications (1 RCT, 2 observational studies)</li> <li>• 2 observational studies, are relevant for present review: one, Norman et al. (2022)<sup>28</sup> (186 eligible participants) is a pilot study of the other, Miller et al. (2022)<sup>24</sup> (1,205 enrolled)</li> </ul>	<p><b>Participants:</b> Adult patients (≥ 18 years) with suspected NSTEMI-ASC (including signs/symptoms such as chest pain or breathlessness potentially indicative of acute MI)</p> <p><b>Exclusions:</b> Specific high-risk groups (STEMI)</p> <p><b>Settings:</b> Primary and community care (general practice, internal medicine or pulmonology in private practice)</p>	<p><b>Intervention:</b> Quantitative D-dimer or troponin POCT with the intention to rule-out acute disease. For troponin, they favoured high-sensitivity (hs) tests but would consider non-hs POCT if the latter was not available.</p> <p><b>Comparator:</b> Current diagnostic practice; all comparators eligible</p> <p><b>Intervention in 2 relevant included studies:</b> Rural accelerated diagnostic chest pain pathway (RACPP) which included Abbott i-STAT troponin POCT to “rule out” MI</p>	<p><b>Outcomes:</b></p> <ul style="list-style-type: none"> <li>• MACE<sup>a</sup></li> <li>• AEs, SAEs</li> <li>• Hospital or ED referrals and visits</li> <li>• Hospital admissions</li> <li>• Health related QoL</li> <li>• Patient satisfaction</li> <li>• Staff satisfaction</li> <li>• Diagnostic accuracy</li> </ul> <p><b>Follow-up:</b> None stated; 2 relevant studies included outcomes up to 30 days follow-up</p>

Study citation, country, funding source	Search, study designs, numbers of primary studies included	Population characteristics, settings	Intervention and comparator(s)	Clinical outcomes, length of follow-up
<p>EUnetHTA OTCA22 Assessment Team. (2019)<sup>18</sup> The Netherlands</p> <p><b>Funding source:</b> European Union's Health Programme</p>	<p>This review aims to assess the clinical utility of troponin and D-Dimer POCT. The present summary is limited to the methods and results for assessing troponin POCT.</p> <p><b>Search dates and limits:</b> 2009 to 2019 for SRs and HTAs; up to 2019 for guidelines; 2016 to 2019 for primary studies; German and English studies only</p> <p><b>Eligible study designs:</b></p> <ul style="list-style-type: none"> <li>• Stepwise – most recent and high-quality SR/MA/HTA with search update for primary studies</li> <li>• Clinical practice guidelines</li> </ul> <p><b>Included studies:</b></p> <ul style="list-style-type: none"> <li>• 2 SRs: <ul style="list-style-type: none"> <li>◦ one CADTH review<sup>14</sup> (rated with high certainty) which included 41 primary studies, and 2 guidelines - 2 primary studies<sup>25,29</sup> would be relevant for the present review</li> <li>◦ one SR (rated with moderate certainty) with a broader scope and no studies relevant to this review</li> <li>◦ 8 clinical practice guidelines</li> </ul> </li> </ul>	<p><b>Participants:</b> Adult patients (≥ 18 years old) with signs or symptoms suggested of ACS, such as chest pain or breathlessness presenting in ambulatory or emergency settings in whom MI is suspected and has not been ruled out</p> <p><b>Settings:</b> Ambulatory (primary or community) or emergency care</p>	<p><b>Interventions:</b></p> <ul style="list-style-type: none"> <li>• i-STAT cTnI (Abbott Point of Care),</li> <li>• Roche CARDIAC Troponin T, Cobas h232 (Roche),</li> <li>• Stratus CS Analyzer (Siemens),</li> <li>• Minicare I-20 Troponin-I assay (Philips),</li> <li>• LABGEO TnI analyzer (Samsumg),</li> <li>• ADEXUSDx Troponin I Test (NowDiagnostics),</li> <li>• RAMP Cardiac Troponin I test (Response Biomedical),</li> <li>• Troponin I Test (Eurolyser), mLabs Troponin I (Micropoint),</li> <li>• PATHFAST (LSI Medience Corporation; former Mitsubishi),</li> <li>• Triage Troponin I Test (Quidel),</li> <li>• AQT90 FLEX cTnI and AQT90FLEX cTnT (Radiometer),</li> <li>• troponin I test (PBM),</li> <li>• i-CHROMA Diagnostics (Syncomed)</li> </ul> <p><b>Comparator:</b> Usual care – any (including central laboratory methods)</p> <p><b>Intervention in 2 relevant</b></p>	<p><b>Outcomes:</b></p> <ul style="list-style-type: none"> <li>• Patient management including: <ul style="list-style-type: none"> <li>◦ Number of hospital admissions</li> <li>◦ Treatment initiation</li> <li>◦ Referral rates</li> <li>◦ Door-to-needle time</li> <li>◦ Turnaround time</li> <li>◦ Time to discharge</li> <li>◦ Length of stay</li> <li>◦ Further diagnostic testing</li> <li>◦ Time to clinical decision</li> </ul> </li> <li>• Mortality/morbidity</li> <li>• Patient QoL</li> <li>• Safety – side effects/disadvantages</li> </ul> <p><b>Follow-up:</b> None prespecified</p>

Study citation, country, funding source	Search, study designs, numbers of primary studies included	Population characteristics, settings	Intervention and comparator(s)	Clinical outcomes, length of follow-up
			<b>included studies:</b> Abbott i-STAT	

ACS = acute coronary syndrome; AE = adverse event; AIHTA = Austrian Institute for Health Technology Assessment; cTnI = cardiac troponin I; cTnT = cardiac troponin T; ED = emergency department; EUnetHTA = European Network for Health Technology Assessment; HTA = health technology assessment; hs = high sensitivity; MA = meta-analysis; MACE = major adverse cardiovascular events; MI = myocardial infarction; NSTEMI = non-ST-segment elevation acute coronary syndrome; POCT = point-of-care test; QoL = quality of life; RACPP = Rural Accelerated Chest Pain Pathway; RCT = randomized controlled trial; SAE = serious adverse event; SR = systematic review; STEMI = ST-elevation acute myocardial infarction.

Note: This table has not been copy-edited.

\*MACE is defined as a combined end point of ACS, percutaneous coronary intervention, coronary artery bypass grafting, coronary angiography revealing procedurally correctable stenosis managed conservatively and all-cause mortality.

**Table 4: Characteristics of Included Primary Clinical Studies**

Study citation, country, funding source	Study design, Study setting, Study duration, Number of participants	Population characteristics, Inclusion criteria, Exclusion criteria	Intervention and comparator(s), POCT device/manufacture, Troponin test, Test protocol	Health care professional(s) performing test, Training/Quality control	Outcomes, Length of follow-up
<b>Matthes et al. (2023)<sup>21</sup></b> Germany <b>Funding/support:</b> Open Access funding by Projekt DEAL. The study is embedded in the project POCT-ambulant which is funded by the Bundesministerium für Bildung und Forschung (Ministry of Education and Research). "The funding source had no role in the design, conduct or reporting of this study; or in the decision to submit the manuscript for publication."	Cross-sectional study; survey <b>Settings/Sites:</b> Outpatient general practices in Germany from 3 federal states; results for cTn POCT reported separately for rural and other settings <b>Duration:</b> NA <b>Number of participants:</b> <ul style="list-style-type: none"> <li>2,052 GPs surveyed and reached</li> <li>292 responded (14.5%)</li> <li>84 from rural community practice locations</li> </ul>	<b>Inclusion:</b> General practitioners from 3 German federal states <b>Exclusion:</b> None <b>Characteristics:</b> Characteristics such as age, sex, work experience, practice type reported but this data not separated for practitioners in rural practice locations (n = 84 / 2014) Authors noted overrepresentation of GPs in rural settings ('slightly over-represented') and females (60% vs. 49%) compared to survey population characteristics	<b>Intervention:</b> Mailed survey; 12 questions on POCT utilization and limitations, and perspectives toward POCT use in general practice. Included specific question on current use of cTnI/cTnT POCTs. <b>Device/manufacture:</b> Any; not stated	<b>Training/Quality Control:</b> NA	<b>Outcomes:</b> <ul style="list-style-type: none"> <li>Use of cTnI/cTnT POCTs.</li> <li>Other results reported specifically for rural practice GPs were not specific to cTn POCT (rather, to POCT in general) and were not extracted</li> </ul>

Study citation, country, funding source	Study design, Study setting, Study duration, Number of participants	Population characteristics, Inclusion criteria, Exclusion criteria	Intervention and comparator(s), POCT device/manufacture, Troponin test, Test protocol	Health care professional(s) performing test, Training/Quality control	Outcomes, Length of follow-up
<p><b>From AIHTA (2024)</b><sup>17</sup> (relevant study 1 of 2) <b>Miller et al. (2022)</b><sup>24</sup> New Zealand <b>Funding:</b> Heart Foundation of New Zealand; Abbott Diagnostics Point of Care investigator grant</p>	<p>Prospective observational study <b>Settings/Sites:</b> 27 to 29 (depending on reporting in paper) sites: 75.9% of patients presented to rural hospitals, 20.2% to general practices 3.8% to urgent care clinics. Sites were at least 45 minutes (up to 4 hours 20 minutes) drive from nearest metropolitan hospital with specialist care and central laboratory services. Means of transportation are not all described but include helicopter, boat and road. <b>Duration:</b> 30 days after presentation <b>Number of participants;</b> 1,205 enrolled; 132 (11%) excluded mostly due to protocol breaches. 1,073 included in primary analysis. Low risk: 474 (44%) Not low risk: 599 (56%)</p>	<p><b>Inclusion:</b> Adults with symptoms suggestive of cardiac ischemia or AMI that began or worsened within the last 72 hour and ordinarily requiring transfer for an urgent hospital-based assessment if presenting to a primary care setting (GP or urgent care) <b>Exclusion:</b> Those who presented with STEMI; proven or suspected non-coronary artery cause; required transfer regardless of RACPP result; anticipated follow-up concern. <b>Median time from pain onset to initial assessment:</b> <i>Low risk group:</i> 4 hours and 36 minutes (IQR: 2 hours to 14 hours and 30 minutes) <i>Not low-risk group:</i> 4 hours and 20 minutes (IQR: 2 hours and 8 minutes to 10 hours and 9 minutes) <b>Age (Mean (SD)):</b> 63 (15) <b>Sex:</b> 48% Female; 52% Male <b>Hypertension:</b> 47%</p>	<p><b>Intervention:</b> RACPP including EDACS, ECG and 2 cTn POCTs – 1 at presentation and 1 at 2 hours <b>Device/manufacture:</b>  <ul style="list-style-type: none"> <li>i-STAT cTnI/Abbott Point of Care Diagnostics: <ul style="list-style-type: none"> <li>URL based on 99th percentile 0.08 mcg/L</li> <li>Limit of blank = 0.02 mcg/L</li> <li>Coefficient of variation at the 99th percentile was 16.5%</li> </ul> </li> <li>AQT-90 FLEX cTnT/Radiometer: <ul style="list-style-type: none"> <li>URL based on 99th percentile 0.17 mcg/L</li> <li>Limit of detection = 0.008 mcg/L</li> <li>Coefficient of variation at the 99th percentile was 5.2%</li> </ul> </li> </ul> <b>RACPP:</b> <ul style="list-style-type: none"> <li>Low risk (all of the following): <ul style="list-style-type: none"> <li>No 'red flags' (crescendo angina, hemodynamic instability or ongoing chest pain)</li> <li>Absence of potentially significant ECG changes suggestive of ischemia at 0 and 2 hours</li> <li>EDACS score &lt; 16</li> <li>Serial cTn POCT</li> </ul> </li> </ul> </p>	<p>Predominantly nurses <b>Training/Quality Control:</b> Manufacturers installed the necessary hardware, trained, and certified device users. Ongoing quality control included daily electronic and liquid quality control sampling. Study authors provided sites with education, training and support to implement the pathway.</p>	<p><b>Outcomes:</b></p> <ul style="list-style-type: none"> <li>30-day MACE</li> <li>Percentage of low-risk patients immediately able to be discharged from care after assessment</li> <li>Diagnostic measures for the RACPP (sensitivity, specificity, PPV, NPV, LR)</li> </ul>



Study citation, country, funding source	Study design, Study setting, Study duration, Number of participants	Population characteristics, Inclusion criteria, Exclusion criteria	Intervention and comparator(s), POCT device/manufacture, Troponin test, Test protocol	Health care professional(s) performing test, Training/Quality control	Outcomes, Length of follow-up
		<b>Dyslipidemia:</b> 30% <b>Diabetes:</b> 15% <b>Current smoker:</b> 15% <b>Family history of premature CAD:</b> 14% <b>Obesity:</b> 11%	concentrations below the lower rule-out threshold at 0 and 2 hours. (i-STAT: 0.04 mcg/L; AQT90: 18 ng/L) <ul style="list-style-type: none"> <li>◦ If all criteria met, discharge home with follow-up as appropriate</li> </ul> <ul style="list-style-type: none"> <li>• Not low risk:               <ul style="list-style-type: none"> <li>◦ Those patients not meeting low-risk criteria</li> <li>◦ Those in this category are transferred to referral centre or admitted to hospital.</li> </ul> </li> </ul> <b>High risk:</b> i-STAT - any cTn concentration above URL or between thresholds but changes between tests of $\geq 0.02$ mcg/L		
<b>From AIHTA (2024)</b> <sup>17</sup> (relevant study 2 of 2) <b>Norman et al. (2022)</b> <sup>28</sup> New Zealand <b>Funding/support:</b> Heart Foundation of New Zealand; Waikato Medical Research Foundation; Devices and training provided by Abbott Point of Care	Prospective observational study <b>Settings/Sites:</b> 12 rural general practices. Patients can be transferred to 1 metropolitan ED or 1 of 4 rural hospitals. Distance (time) from practice to rural hospital ranged from 0.01 km to 62.7 km (1 to 79 minutes) and distance from practice to base hospital ranged from 32.0 to 178.4 km (30 to 152 minutes)	<b>Inclusion:</b> Patients $\geq 18$ years old, presenting to rural general practice with suspected ischemic chest pain for whom the doctor intended transfer to hospital for serial troponin measurement <b>Exclusion:</b> Those who presented with STEMI; proven or suspected non-coronary artery cause; required transfer regardless of RACPP result; chest pain $> 72$ hours; re-presentation	<b>Intervention:</b> RACPP adapted for management of suspected cardiac chest pain in rural practices including EDACS, ECG and 2 troponin POCTs – 1 at presentation and 1 at 2 hours. <b>Device/manufacture:</b> <ul style="list-style-type: none"> <li>• i-STAT cTnI/Abbott Point of Care Diagnostics:               <ul style="list-style-type: none"> <li>◦ URL based on 99th percentile 80 ng/L</li> <li>◦ Limit of quantitation = 40 ng/L</li> <li>◦ Limit of blank = 20 ng/L</li> </ul> </li> </ul> <b>Reference laboratory diagnostic tests (duplicate samples at both</b>	<b>Training/Quality Control:</b> Onsite training and performance were provided by an Abbott Point of Care representative to identify 'primary users' at each site who could train others and run quality control. Sites were given face-to-face education regarding the pathway.	<b>Outcomes:</b> <ul style="list-style-type: none"> <li>• Proportion of low-risk patients immediately able to be discharged from care after assessment with no transfer to hospital and no 30-day MACE</li> <li>• 30-day MACE</li> <li>• ACS (AMI or unstable angina) within 30 days of presentation</li> </ul>



Study citation, country, funding source	Study design, Study setting, Study duration, Number of participants	Population characteristics, Inclusion criteria, Exclusion criteria	Intervention and comparator(s), POCT device/manufacture, Troponin test, Test protocol	Health care professional(s) performing test, Training/Quality control	Outcomes, Length of follow-up
	<p><b>Duration:</b> 30 days after presentation</p> <p><b>Number of participants:</b></p> <ul style="list-style-type: none"> <li>• 186 identified; 6 excluded</li> <li>• 180 included in analyses</li> <li>• Low risk: 111 (61.7%)</li> <li>• Not low risk: 69 (38.3%)</li> </ul>	<p>with chest pain during the evaluation period; anticipated follow-up concern</p> <p><b>Median time from pain onset to initial assessment:</b></p> <ul style="list-style-type: none"> <li>• Low risk group: 14 hours (IQR: 3.9 hours to 39.5 hours)</li> <li>• Non-low-risk group: 15 hours (IQR: 1.4 hours to 40.5 hours)</li> </ul> <p><b>Age (Mean years (SD)):</b></p> <ul style="list-style-type: none"> <li>• Low risk: 52 (11.8)</li> <li>• Non-low risk: 69 (10.9)</li> </ul> <p><b>Sex (% Women):</b></p> <ul style="list-style-type: none"> <li>• Low risk: 67 (60.4)</li> <li>• Non-low risk: 21 (30.4)</li> </ul> <p><b>Hypertension (%):</b></p> <ul style="list-style-type: none"> <li>• Low risk: 33 (29.7)</li> <li>• Non-low risk: 42 (60.9)</li> </ul> <p><b>Dyslipidemia:</b></p> <ul style="list-style-type: none"> <li>• Low risk: 20 (18.0)</li> <li>• Non-low risk: 29 (42.0)</li> </ul> <p><b>Diabetes mellitus:</b></p> <ul style="list-style-type: none"> <li>• Low risk: 8 (7.2)</li> <li>• Non-low risk: 5 (7.2)</li> </ul> <p><b>Current smoker:</b></p> <ul style="list-style-type: none"> <li>• Low risk: 39 (35.1)</li> </ul>	<p><b>time points):</b></p> <ul style="list-style-type: none"> <li>• Elecsys high-sensitivity cardiac troponin/Roche Diagnostics: <ul style="list-style-type: none"> <li>◦ Limit of detection = 5 ng/L</li> <li>◦ 99th percentile = 14 ng/L</li> <li>◦ Threshold for males and females: <math>\leq 14</math> ng/L</li> </ul> </li> <li>• Access cardiac troponin I/ Beckman Coulter: <ul style="list-style-type: none"> <li>◦ Limit of detection = 2.5 ng/L</li> <li>◦ 99th percentile = 17.5 ng/L</li> <li>◦ Threshold for males: <math>&lt; 20</math> ng/L</li> <li>◦ Threshold for females: <math>&lt; 10</math> ng/L</li> </ul> </li> </ul> <p><b>RACPP:</b></p> <ul style="list-style-type: none"> <li>• Low risk (all of the following): <ul style="list-style-type: none"> <li>◦ No 'red flags' (crescendo angina, hemodynamic instability or ongoing chest pain)</li> <li>◦ Absence of potentially new significant ECG changes suggestive of ischemia at 0 and 2 hours.</li> <li>◦ EDACS score <math>&lt; 16</math></li> <li>◦ Serial cTn POCT concentrations below the lower rule-out threshold at 0 and 2 hours. (i-STAT: 40 ng/L)</li> <li>◦ If all criteria met, eligible for discharge home with follow-up</li> </ul> </li> </ul>		<ul style="list-style-type: none"> <li>• Non-emergency coronary revascularization within 30 days of presentation</li> <li>• Agreement between POCT and laboratory measured troponin concentrations</li> <li>• Adherence to pathway</li> <li>• Patient acceptability and satisfaction with care</li> <li>• Participating sites' acceptability</li> </ul>

Study citation, country, funding source	Study design, Study setting, Study duration, Number of participants	Population characteristics, Inclusion criteria, Exclusion criteria	Intervention and comparator(s), POCT device/manufacture, Troponin test, Test protocol	Health care professional(s) performing test, Training/Quality control	Outcomes, Length of follow-up
		<ul style="list-style-type: none"> <li>• Non-low risk: 13 (18.8)</li> </ul> <b>Family history of premature CAD:</b> <ul style="list-style-type: none"> <li>• Low risk: 36 (32.4)</li> <li>• Non-low risk: 16 (23.2)</li> </ul> <b>Known ischemic heart disease:</b> <ul style="list-style-type: none"> <li>• Low risk: 10 (9.0)</li> <li>• Non-low risk: 32 (46.4)</li> </ul>	<p>as appropriate</p> <ul style="list-style-type: none"> <li>• Non-low risk: <ul style="list-style-type: none"> <li>◦ Those patients who did not meet low-risk criteria</li> <li>◦ Those in this category were referred to hospital for assessment and serial cTn testing</li> </ul> </li> </ul>		
<b>Matthews et al. (2020)<sup>19</sup></b> Australia <b>Funding:</b> Northern Territory Department of Health' Northern Territory Department of Health and no financial COI	<b>Program evaluation – descriptive</b> <b>Settings/Sites:</b> Up to 80 remote health centres Northern Territory POCT program. 97.5% are in 'very remote locations' and the remainder in 'outer regional' as described by Australia's Remoteness Structure. Patients can be transferred to 1 of 2 hospitals typically by airplane or helicopter. Average distance from practice to hospital is 275 km (range: 100 to 700 km) <b>Number of participants:</b> Not stated. Total cTnI cartridges used for this study: 1,398	<b>Inclusion:</b> clinical audit results from September 1 to December 31, 2019 <b>Exclusion:</b> NR	<b>Intervention:</b> i-STAT Point-of-Care Testing Program using 4 testing cartridges, 1 being cTnI <b>Device/manufacture:</b> i-STAT 300 analyzer/Abbott Point of Care and the following cartridges: Chem8+, CG4+, PT/INR, cTnI	<b>Training/Quality Control:</b> <ul style="list-style-type: none"> <li>• Detailed training and accreditation are required for relevant staff. Recertification is required every 2 years.</li> <li>• Quality control policies, activities and oversight are imbedded in program management and communications.</li> </ul>	<b>Outcomes:</b> <ul style="list-style-type: none"> <li>• Number (%) of tests outside defined critical action limits and clinical conditions of relevant patients</li> <li>• Quality control measures (not extracted)</li> </ul>

Study citation, country, funding source	Study design, Study setting, Study duration, Number of participants	Population characteristics, Inclusion criteria, Exclusion criteria	Intervention and comparator(s), POCT device/manufacture, Troponin test, Test protocol	Health care professional(s) performing test, Training/Quality control	Outcomes, Length of follow-up
<p><b>From EUnetHTA (2019)<sup>18</sup></b>  <b>HTA (2 relevant studies)</b>  <b>Shephard et al. (2014)<sup>25</sup></b>  <b>and Shephard et al. (2012)<sup>29</sup></b>  Program also assessed in <b>Matthews et al. (2020)<sup>19</sup></b> (program evaluation, included separately in this table), <b>Spaeth et al. (2018)<sup>36</sup></b> (economic evaluation, excluded) and <b>Spaeth et al. (2017)<sup>20</sup></b> (included separately in this table)  Australia  <b>Funding/support: Study 1:</b><sup>25</sup> The authors declare no funding was received for this work and no COI  <b>Study 2:</b><sup>29</sup> ‘Sources of support that require acknowledgement: Northern Territory Department of Health’</p>	<p>Program description and evaluations with survey  <b>Settings/Sites:</b> 33 remote health centres from the Northern Territory Department of Health and 3 Aboriginal Community Controlled Health Services of the Aboriginal Medical Services Alliance of the Northern Territory. Patients can be transferred to 1 of 2 hospitals typically by airplane or helicopter. Average distance from practice to hospital is 275 km (range: 100 to 700 km)  <b>Number of participants:</b>  The 2012 survey results seem to be repeated (in part) in 2014 publication: 39 respondents (31%) of 127 operators sent the questionnaire; other data captured electronically. Conducted 1 year after program inception.</p>	<p><b>Inclusion:</b> Staff at all remote health centres participating in the POCT program  <b>Exclusion:</b> NR</p>	<p><b>Intervention:</b> i-STAT Point-of-Care Testing Program using 4 testing cartridges, 1 being cTnI  <b>Device/manufacture:</b> i-STAT 300 analyzer/Abbott Point of Care and the following cartridges: Chem8+, CG4+, PT/INR, cTnI</p>	<p><b>Training/Quality Control:</b></p> <ul style="list-style-type: none"> <li>• Detailed training and accreditation are required for relevant staff. Recertification is required every 2 years.</li> <li>• Quality control policies, activities and oversight are imbedded in program management and communications.</li> </ul>	<p><b>Outcomes:</b> Staff satisfaction</p>

Study citation, country, funding source	Study design, Study setting, Study duration, Number of participants	Population characteristics, Inclusion criteria, Exclusion criteria	Intervention and comparator(s), POCT device/manufacture, Troponin test, Test protocol	Health care professional(s) performing test, Training/Quality control	Outcomes, Length of follow-up
<b>Mashamba-Thompson et al. (2018)</b> <sup>22</sup> South Africa <b>Funding/support:</b> African Population and Health Research Center; University of KwaZulu-Natal College of Health Sciences; South African Centre of Excellence for Epidemiology and Modelling Analysis; and the National Institute of Allergy and Infectious Disease of the National Institutes of Health (K23 AI108293). Authors stated that funders played no role in study conduct.	Cross-sectional study; survey <b>Settings/Sites:</b> 100 randomly selected rural primary health care clinics of KwaZulu-Natal; selection method aimed to ensure uniform sampling across districts. The mean distance from each practice to the nearest emergency tertiary hospital was 41.4 km (SD = 42.8 km), with most (40%) being within 10 km. <b>Duration:</b> NA <b>Number of participants:</b> 100 sites contacted, 100 responded (100% response rate)	<b>Inclusion:</b> Staff (1 per clinic; including operations managers, primary health care specialist nurses, and staff nurses). <b>Exclusion:</b> None <b>Characteristics:</b> Respondent (year of qualification) and clinic (e.g., number of different staff, number of patients, clinic processes) characteristics were reported.	<b>Intervention:</b> Mailed survey. Pilot tested in 5 rural clinics Closed ended questions on demographics and current accessibility, availability, usage, and future needs for POCT tests in their practice. Included 2 questions on current use and potential use of troponin POCTs. <b>Device/manufacture:</b> Any; not stated	<b>Training/Quality Control:</b> NA	<b>Outcomes:</b> <ul style="list-style-type: none"> <li>• Clinic and respondents' use of or desire to use troponin POCTs</li> <li>• Respondents' views of potential frequency of future use of troponin POCT</li> </ul>
<b>Spaeth et al.(2017)</b> <sup>20</sup> Australia <b>Funding:</b> supported by a grant provided by the Emergency Medicine Foundation (Emergency Medicine Foundation Ltd.)	Retrospective observational study Audit of clinical outcomes at selected centres "to determine the effectiveness of POCT as a decision support tool for triaging acutely ill patients"; 1 of 3 POCT tools, cTnI POCT was assessed to support	<b>Inclusion:</b> Patients who initially presented to 1 of 6 remote health centres over a 6-month period with a primary presentation of acute chest pain, normal ECG and clinical symptoms of non-ST elevation myocardial infarction (NSTEMI) with a completed troponin POCT	<b>Intervention:</b> <b>Device/manufacture:</b> <ul style="list-style-type: none"> <li>• i-STAT cTnI/Abbott Point of Care Diagnostics               <ul style="list-style-type: none"> <li>◦ Uses 17 mcg venous whole blood</li> <li>◦ Results within 10 minutes</li> <li>◦ URL based on 99th percentile 0.08 mcg/L</li> </ul> </li> </ul> <b>Clinical 'POCT pathway'; for</b>	No information about staff conducting the test <b>Training/Quality Control:</b> Onsite training and competency assessment of i-STAT POCT. Centres conducted monthly quality control testing.	<b>Outcomes:</b> <ul style="list-style-type: none"> <li>• Patient evacuated or not</li> <li>• Hospital diagnosis/ outcome if evacuated – information is not available for all patients so has not been</li> </ul>

Study citation, country, funding source	Study design, Study setting, Study duration, Number of participants	Population characteristics, Inclusion criteria, Exclusion criteria	Intervention and comparator(s), POCT device/manufacture, Troponin test, Test protocol	Health care professional(s) performing test, Training/Quality control	Outcomes, Length of follow-up
	<p>triage of patients with acute chest pain. Our focus is limited to this research goal.</p> <p><b>Settings/Sites:</b> 6 remote health centres in the Northern Territory with routinely available POCT. Within this region, a POCT network operates in 72 remotely located primary health care centres. Site selection was by study size and location to “eliminate any potential sources of bias”</p> <p><b>Duration:</b> NA</p> <p><b>Number of participants:</b> N = 147</p>	<p>identified by the i-STAT Central Data Station, a centrally administered repository of all de-identified results for each i-STAT device.</p> <p><b>Exclusion:</b> Those with ST elevation on ECG (STEMI)</p> <p><b>Median time from pain onset to initial assessment:</b> NR</p> <p><b>Age (Median):</b></p> <ul style="list-style-type: none"> <li>• cTnI negative, not evacuated: 45 years; cTnI negative, evacuated: 47 years</li> <li>• cTnI positive, evacuated: 56 years</li> </ul> <p><b>Male Sex (n, (% in outcome group)):</b></p> <ul style="list-style-type: none"> <li>• cTnI negative, not evacuated: 68 (54%); cTnI negative, evacuated: 7 (50%)</li> <li>• cTnI positive, evacuated: 4 (57%)</li> </ul>	<p><b>patients with acute chest pain (without ST elevation on ECG).</b></p> <p>Based on defined ‘standard care’ protocols but adapted by the study team</p> <p><b>Low risk:</b></p> <ul style="list-style-type: none"> <li>• Absence of significant ECG changes suggestive of ischemia</li> <li>• Serial cTn POCT concentrations below threshold at 0 and &lt; 8 hours after presentation (rule-out concentration not stated in report)</li> <li>• If clinical pathway followed, no evacuation is expected for low-risk patients</li> </ul> <p><b>Not low risk:</b></p> <ul style="list-style-type: none"> <li>• Those patients who did not meet low-risk criteria</li> <li>• The clinical pathway states those who are cTnI positive should be evacuated</li> </ul>		<p>extracted</p> <ul style="list-style-type: none"> <li>• Clinical judgment of likely outcome (evacuation or not) in hypothetical absence of POCT troponin i-STAT</li> <li>• Time to diagnosis</li> <li>• Time to treatment</li> </ul> <p>Other data collected but not presented in this review: time to prepare for and perform test, time to initiate treatment, treatments given.</p> <p><b>Follow-up:</b> NR</p>

ACS = acute coronary syndrome; AIHTA = Austrian Institute for Health Technology Assessment; AMI = acute myocardial infarction; CAD = cardiovascular disease; COI = conflict of interest; cTn = cardiac troponin; cTnI = cardiac troponin I; cTnT = cardiac troponin T; GP = general practitioner; ECG = electrocardiogram; ED = emergency department; EDACS = Emergency Department Assessment of Chest Pain Score; EUnetHTA = European Network for Health Technology Assessment; IQR = interquartile range; LR = likelihood ratio; MACE = major adverse cardiovascular events; NA = not applicable; NPV = negative predictive value; NR = not reported; NSTEMI = non-ST-elevation myocardial infarction; POCT = point-of-care test; PPV = positive predictive value; RACPP = Rural Accelerated Chest Pain Pathway; SD = standard deviation; STEMI = ST-elevation acute myocardial infarction; URL = upper reference limit.

Note: This table has not been copy-edited.

<sup>a</sup>Terminology from the original source.

## Appendix 3: Main Study Findings

Please note that this appendix has not been copy-edited.

**Table 5: Point of Care Testing Programs Identified in this Review<sup>a</sup>**

Country, Region, Example of POCT program	Select notes from included publications
Australia Northern Territory Northern Territory Department of Health and Community Point of Care Services Unit (Flinders University International Centre for Point-of-Care Testing) <sup>19,20,25,29,36</sup>	<p><b>Timeline:</b> Initiated in 2008</p> <p><b>Scope:</b> For both acute and chronic conditions</p> <p><b>Settings/sites:</b> As of 2020 the program had included at least 80 remotely located primary care centres which deliver general health services</p> <p><b>Staff:</b></p> <ul style="list-style-type: none"> <li>• Sites are typically staffed by 3 to 4 full-time, remote area nurses and 1 to 2 'aboriginal'<sup>b</sup> health workers</li> <li>• They do not typically include a resident medical practitioner and very few have regular specialty services</li> <li>• Average number of visits of physicians to each site per year = 35</li> <li>• On call emergency services medical officers take approximately 1,800 calls per month</li> </ul> <p><b>Volume / population:</b> Each centre services an average population of 523</p> <p><b>Distance from hospitals:</b> 2 Territorial hospitals - located on average 275 km (range:100 to 700km) from centres.</p> <p><b>Method of transport:</b> Patients generally transported by airplane or helicopter to the nearest hospital emergency department</p> <p><b>Access to laboratory services:</b> A 2007 internal Northern Territory government report noted most have regular access to pathology services twice a week or less (part of rationale for this program)</p> <p><b>Device(s) (Manufacturer) and Tests:</b> i-STAT (Abbott Point of Care). Tests include Chem 8+ (Electrolytes, total CO<sub>2</sub>, urea, creatinine, glucose, ionized calcium, hemoglobin), CG4+ (Blood gas and lactate), PT/INR (prothrombin time / international normalized ratio), and cTnI (troponin I)</p> <p><b>Other:</b> The program also includes an advanced web-based data manager (InfoHQ, Abbott), replacing the former Central Data Station (Abbott), electronically capturing deidentified patient and quality data from remote devices.</p> <p><b>Governance/Structure:</b></p> <ul style="list-style-type: none"> <li>• Management committee</li> <li>• Central unit responsible for producing training resources, conducting primary training workshops, maintaining competency register of trained operators and a device asset register of all POCT devices in field use, managing the central data station, preparing monthly summary reports for the management committee and implementing an audit management framework to monitor analytical performance of the devices</li> <li>• A specific group (NT Remote Health Branch team) responsible for ordering and dispatching i-STAT reagents and consumables to each health centre and coordinating the delivery of mobile field training and competency assessment</li> </ul> <p><b>Training / Quality control:</b></p> <ul style="list-style-type: none"> <li>• The training program was updated in 2019. Training in 2014 included a comprehensive 38-page training manual, a set of A3 laminated posters providing simple visual step-by-step guides on how to conduct patient and quality testing, and electronic resources such as a power-point presentation, DVD, and web-streamed video presentations, taking the</li> </ul>

Country, Region, Example of POCT program	Select notes from included publications
	<p>trainee through the theory and practice of POCT on the i-STAT.<sup>25</sup> Up to 2017, this included face-to-face training at a central location and onsite workshops, self-directed study and access to web-based training and video conferences.</p> <ul style="list-style-type: none"> <li>• Face-to-face i-STAT training ceased during 2017, moving to virtual training and an online training module was available as of 2019.</li> <li>• In 2019 the program was updated to include information on common drug interferences (poster, education, and so forth) to address updated knowledge of the problem and following an audit of the program.</li> <li>• Competency assessment and certification includes a training checklist, a competency test and a practical test. When certified, operators are issued an operator identification number which is valid for 2 years, after which competency must be renewed.</li> <li>• Quality control: automated data collection and a monthly feedback report to each health centre manager including data on use, errors and summary of quality testing.</li> <li>• Other: quarterly newsletter.</li> </ul> <p><b>Assessments:</b> Most tests have met professional-based analytical goals and laboratory performance.</p> <p><b>Financial:</b> “when used to aid medical decision-making in acutely ill patients, the NT POCT Program was estimated to save the Northern Territory health care system approximately A\$21.75 million per annum by the prevention of unnecessary emergency medical retrievals for 3 common acute presentations.”<sup>19</sup></p> <p><b>Other notes:</b> Staff turnover has been a significant issue (&gt; 36% staff leaving program centres within 1 year)</p>
<p>New Zealand has many POCT programs, some discussed in Herd and Musaad (2021)<sup>23</sup> and are governed by practice guidelines.<sup>31</sup></p> <p>One example identified includes cTnI POCT:</p> <p>The Waitemata District Health Board (DHB) Rural Point of Care Testing Service<sup>37</sup></p>	<p><b>Scope:</b> The Rural Alliance group of general practices identified the 4 most clinically valuable POCT tests for the management of people presenting acutely unwell in a rural setting. The rationale: to enable rapid decision-making and to reduce unnecessary ED presentations.</p> <p><b>Settings/sites:</b> All rural general practices across both Auckland DHB and Waitemata DHB areas.</p> <p><b>Device(s) (Manufacturer) and Tests:</b> Troponin I and INR on the Abbott i-STAT analyzer, D-dimer on the Roche h232 analyzer (Roche Diagnostics, F. Hoffmann-La Roche Ltd.), and a full blood count on the QBC STAR Hematology Centrifugal Analyzer (Drucker Diagnostics, Philipsburg, Pennsylvania).</p> <p><b>Governance/Structure:</b></p> <ul style="list-style-type: none"> <li>• The 4 pillars for safe POCT services in New Zealand: the regulation of POCT devices, the New Zealand Health and Disability Consumers Code of Rights 1996, accreditation, and the New Zealand Best Practice Guidelines for Point-of-Care Testing.<sup>31</sup></li> <li>• The Waitemata DHB Laboratories POCT team oversees and manages the R-POCT service on behalf of both Auckland and Waitemata DHBs.</li> </ul> <p><b>Training / Quality control:</b></p> <ul style="list-style-type: none"> <li>• Herd et al. (2021) stated that, while some facilities are accredited for POCT services by International Accreditation New Zealand, POCT services in rural clinics and in most remote hospitals are not (at the time of publication).</li> <li>• The Waitemata DHB Laboratories POCT team ensures consistency in quality assurance and control measures across all primary care practices within the Rural Alliance.</li> </ul>

cTnI = cardiac troponin I; DHB = District Health Board; ED = emergency department; NT = Northern Territory; POCT = point-of-care test.

<sup>a</sup>Is not intended to be interpreted as a complete list of POCT programs.

<sup>b</sup>Terminology from the original source.



**Table 6: Summary of Findings by Outcome — Rural GP Use or Desired Use of Troponin POCTs**

Study citation, Design, Number of participants	POCT device/manufacture, Troponin test, Test protocol	Outcome definition, Measurement, Time point	Outcome, n (%)
<b>Matthes et al. (2023)<sup>21</sup></b> Survey 2,052 GPs surveyed and reached from 3 German federal states 292 responded (14.5%) 84 from rural community practice locations	<b>Device/manufacture:</b> Any; not stated <b>Test protocol:</b> NR	<b>Definition:</b> Use of cTnI/cTnT POCTs <b>Measurement:</b> Mailed survey; responses to the question: “How often do you use POCTs for the following laboratory analyses in your routine work as a GP? Troponin I, Troponin T...” Response options included: <ul style="list-style-type: none"> <li>• Regularly as POCT (<math>\geq 1x</math> in 14 days);</li> <li>• Infrequently as POCT (<math>&lt; 1x</math> in 14 days);</li> <li>• No use as POCT.</li> </ul> <b>Time point:</b> Survey conducted between April 2022 and June 2022	<b>GPs from practices in rural communities</b> – responses from 81 / 84 respondents <ul style="list-style-type: none"> <li>• Regular use: 32 (39.0%)</li> <li>• Infrequent use: 29 (35.4%)</li> <li>• No use: 21 (25.6%)</li> </ul> The authors used Pearson’s Chi-square test to compare these responses to those from GPs from practices in towns (n = 130) and GPs from practices in urban centres (n = 66) and reported no significant difference ( $X^2 = 9.222$ , df = 4, P = 0.056)
<b>Mashamba-Thompson et al. (2018)<sup>22</sup></b> Survey Staff (1 per clinic) at 100 rural primary health care clinics of KwaZulu-Natal, South Africa; 100 clinics responded (100% response rate)	<b>Device/manufacture:</b> Any; not stated <b>Test protocol:</b> NR	<b>Definition:</b> Current and potential desired use of specific POCTs, troponin being 1 of 50 included in specific questions. <b>Measurement:</b> Responses to the question: “Please select the answer that best matches your views about current or potential use of POCTs...Troponin” <b>Time point:</b> Survey conducted between April 2015 and August 2015	<ul style="list-style-type: none"> <li>• The results are not presented for this outcome. The authors limited the presentation of the results to:               <ul style="list-style-type: none"> <li>◦ the top 8 most frequently available tests; troponin POCT was not one</li> <li>◦ the “Top 20 requested point of care tests in the clinics”: troponin was not 1 (lowest reported was calcium, requested by <math>&lt; 15\%</math> respondents), and</li> <li>◦ the top 10 list of desirable point of care tests by test class and disease type for each of “Communicable diseases,” “non-communicable disease,” and “Communicable and non-communicable”; Troponin was not listed. Sodium was 10th</li> </ul> </li> </ul>



Study citation, Design, Number of participants	POCT device/manufacturer, Troponin test, Test protocol	Outcome definition, Measurement, Time point	Outcome, n (%)
			for non-communicable diseases, listed as of interest to 10% of respondents

cTnI = cardiac troponin I; cTnT = cardiac troponin T; GPs = general practitioners; NR = not reported; POCT = point-of-care test.

**Table 7: Summary of Findings by Outcome — Major Adverse Cardiovascular Events Within 30 days of Index Presentation and Diagnostic Accuracy of Accelerated Diagnostic Pathway**

Study citation, design, number of patients	POCT device/manufacturer, troponin test, Test protocol	Outcome definition, measurement, time point	Outcomes per group		Pathway diagnostic accuracy for 30-day MACE (95% CI)					
			Low risk	Not-low risk	Sens	NPV	LR <sup>-</sup>	Spec	PPV	LR <sup>+</sup>
<b>From AIHTA (2024)<sup>17</sup></b> (relevant study 1 of 2) <b>Miller et al. (2022)<sup>24</sup></b> Prospective observational study; n = 1,205 enrolled; 1,073 included in primary analysis	<b>Device/manufacturer:</b> <ul style="list-style-type: none"> <li>i-STAT cTnI/Abbott Point of Care Diagnostics)</li> <li>AQT-90 FLEX cTnT/Radiometer</li> </ul> <b>Intervention:</b> <ul style="list-style-type: none"> <li>RACPP including EDACS, ECG and up to 2 cTn POCTs – 1 at presentation and 1 at 2 hours</li> <li>Risk stratification to low risk and not-low risk</li> </ul>	<b>Definition:</b> Death, cardiac arrest, emergency revascularization procedure, cardiogenic shock, ventricular arrhythmia, ventricular fibrillation, high-degree atrio-ventricular block needing intervention, or acute myocardial infarction <b>Measurement:</b> From National Minimal Dataset of public hospital admissions, NZ MOH and National Mortality	0 of 474 (0%) 95% CI, 0 to 0.3%	138 of 599 (23%) 124 / 236 (52.5%) of those identified as high risk had a 30-day MACE; 14 / 363 (3.9%) of those identified as intermediate risk had a 30-day MACE Included: 3 deaths, 125 patients with MI and 41 receiving emergency revascularization procedure	100% (97.3% to 100%)	100% (99.2% to 100%)	0 (CI not estimable)	50.7% (47.5% to 53.9%)	23.0% (19.8% to 26.6%)	2.0 (1.9 to 2.2)

Study citation, design, number of patients	POCT device/ manufacturer, troponin test, Test protocol	Outcome definition, measurement, time point	Outcomes per group		Pathway diagnostic accuracy for 30-day MACE (95% CI)					
			Low risk	Not-low risk	Sens	NPV	LR <sup>-</sup>	Spec	PPV	LR <sup>+</sup>
		Collection (MOH) <b>Time point:</b> up to 30 days after presentation								
<b>From AIHTA (2024)<sup>17</sup></b> (relevant study 2 of 2) <b>Norman et al. (2022)<sup>28</sup></b> Prospective observational study; n = 186 identified, 180 included in analyses	<b>Device/manufacturer:</b> i-STAT cTnl/Abbott Point of Care Diagnostics) <b>RACPP</b> including EDACS, ECG and 2 troponin POCTs – 1 at presentation and 1 at 2 hours. Risk stratification to low risk and non-low risk	<b>Definition:</b> Death that was not known to be from non-cardiac causes, emergency coronary revascularization procedure, cardiac arrest, ventricular arrhythmia, cardiogenic shock, and high-degree atrioventricular block needing intervention <b>Measurement:</b> Electronic template in the practice management system. From National Health Index identifier event searches and nurse telephone follow-up at 30	0 of 111 (0.0%)	9 of 69 (13.0%) 8 at index presentation; 2 during readmission (1 patient with 2 events)	100.0% (70.1% to 100.0%)	100.0% (96.7% to 100.0%)	NR	63.8% (56.4% to 70.6%)	12.5% (6.7% to 22.1%)	NR

Study citation, design, number of patients	POCT device/ manufacturer, troponin test, Test protocol	Outcome definition, measurement, time point	Outcomes per group		Pathway diagnostic accuracy for 30-day MACE (95% CI)					
			Low risk	Not-low risk	Sens	NPV	LR <sup>-</sup>	Spec	PPV	LR <sup>+</sup>
		days. <b>Time point:</b> up to 30 days after presentation								

AIHTA = Austrian Institute for Health Technology Assessment; CI = confidence interval; cTnI = cardiac troponin I; ECG = electrocardiogram; EDACS = Emergency Department Assessment of Chest Pain Score; LR<sup>-</sup> = negative likelihood ratio; LR<sup>+</sup> = positive likelihood ratio; MACE = major adverse cardiovascular events; MI = myocardial infarction; NPV = negative predictive value; NR = not reported; NZ MOH = New Zealand Ministry of Health; POCT = point-of-care test; PPV = positive predictive value; RACPP = Rural Accelerated Chest Pain Pathway; Sens = sensitivity; Spec = Specificity.

**Table 8: Summary of Findings by Outcome — Agreement Between POCT and Laboratory Measured Cardiac Troponin Concentrations**

Study citation, design, number of patients	POCT device/manufacture, troponin test, test protocol	Outcome definition, measurement, time point	Outcomes per group
<b>From AIHTA (2024)<sup>17</sup></b> (relevant study 2 of 2) <b>Norman et al. (2022)<sup>28</sup></b> Prospective observational study; n = 186 identified; 180 included in analyses	<b>Device/manufacture:</b> i-STAT cTnI/Abbott Point of Care Diagnostics) <b>Reference laboratory diagnostic tests (duplicate samples at both time points):</b> <ul style="list-style-type: none"> <li>• Elecsys high-sensitivity cardiac troponin/Roche Diagnostics</li> <li>• Access cardiac troponin I/ Beckman</li> </ul>	<b>Definition:</b> Qualitative agreement between test results (positive or negative) <b>Measurement:</b> Pre-established cut points to define positive and negative tests (Refer to <a href="#">Table 7</a> ) <b>Time point:</b> 0 and 2 hours from presentation (samples stored for laboratory analysis)	<ul style="list-style-type: none"> <li>• POCT troponin Positive; Laboratory hs-troponin Positive: 1 (0.7%)</li> <li>• POCT troponin Positive; Laboratory hs-troponin Negative: 7 (3.6%)</li> <li>• POCT troponin Negative; Laboratory hs-troponin Positive: 4 (2.4%)</li> <li>• POCT troponin Negative; Laboratory hs-troponin Negative: 153 (92.7%)</li> </ul> <p>The authors noted that all discordant samples had measured concentration “very near the relevant cut-off and no patient with discordant troponin experienced a MACE within 30 days.”</p>

AIHTA = Austrian Institute for Health Technology Assessment; cTnI = cardiac troponin I; hs-troponin = high-sensitivity troponin; MACE = major adverse cardiovascular events; POCT = point-of-care test.

**Table 9: Summary of Findings by Outcome — Hospital Referrals, Admissions, Evacuations<sup>a</sup>**

Study citation, design, number of patients	POCT device/manufacture, troponin test, test protocol	Outcome definition, measurement, time point	Outcome
<b>Percentage of patients managed as low risk who were never transferred or admitted to hospital</b>			
<b>From AIHTA (2024)<sup>17</sup></b> (relevant study 1 of 2) <b>Miller et al. (2022):<sup>24</sup></b> Prospective observational study; n = 1,205 enrolled; 1,073 included in primary analysis	<b>Device/manufacture:</b> <ul style="list-style-type: none"> <li>• i-STAT cTnI/Abbott Point of Care Diagnostics)</li> <li>• AQT-90 FLEX cTnT/Radiometer</li> </ul> <b>Intervention:</b> <ul style="list-style-type: none"> <li>• RACPP including EDACS, ECG and up to 2 troponin POCTs – 1 at presentation and 1 at 2 hours</li> <li>• Risk stratification to low risk and not-low risk</li> </ul>	<b>Definition:</b> Percentage of patients managed as low risk who were never transferred or admitted to hospital <b>Measurement:</b> From National Minimal Dataset of public Hospital admissions, NZ MOH and National Mortality Collection (MOH) <b>Time point:</b> NR	<ul style="list-style-type: none"> <li>• 435 of 474 (91.8%) (95% CI, 88.8% to 93.9%)</li> <li>• 293 of 330 (88.8%) (95% CI, 84.8% to 91.9%) of those presenting to rural hospitals</li> <li>• 101 of 102 (99.0%) (95% CI, 94.7% to 99.8%) of those presenting to general practice</li> <li>• 41 of 42 (97.6%) (95% CI, 87.7 to 99.9%) of those presenting to urgent care clinics</li> </ul>

Study citation, design, number of patients	POCT device/manufacture, troponin test, test protocol	Outcome definition, measurement, time point	Outcome
<b>From AIHTA (2024)<sup>17</sup></b> (relevant study 2 of 2) <b>Norman et al. (2022)<sup>28</sup></b> Prospective observational study; n = 186 identified; 180 included in analyses	<b>Device/manufacture:</b> i-STAT cTnI/Abbott Point of Care Diagnostics) <b>RACPP</b> including EDACS, ECG and 2 troponin POCTs – 1 at presentation and 1 at 2 hours. Risk stratification to low risk and non-low risk	<b>Definition:</b> The proportion of patients identified as low-risk by the pathway, and managed in the community, without transfer to hospital, with no 30-day MACE. <b>Measurement:</b> Electronic template in the practice management system. From National Health Index identifier event searches and nurse telephone follow-up at 30 days. <b>Time point:</b> up to 30 days after presentation	111 of 111 (100%)
<b>Patients requiring evacuation</b>			
<b>Spaeth et al. (2017)<sup>20</sup></b> Retrospective observational study; n = 147 relevant to the current analysis	<b>Intervention:</b> “POCT Pathway” including ECG, clinical assessment and up to 2 troponin POCTs – 1 at presentation and 1 at > 8 hours after presentation <b>Device/manufacture:</b> <ul style="list-style-type: none"> <li>i-STAT cTnI/Abbott Point of Care Diagnostics)</li> <li>Data collected retrospectively from i-STAT CDS</li> </ul>	<b>Definition:</b> n (%) patients requiring evacuation <b>Measurement:</b> The Northern Territory’s Department of Health Primary Care Information System <b>Time point:</b> NR	<b>cTnI negative:</b> 14 of 140 (10%) patients evacuated <b>cTnI positive:</b> 7/7 (100%) patients evacuated
<b>Clinical judgment (retrospective) on patient evacuation status if troponin POCT had not been used</b>			
<b>Spaeth et al. (2017)<sup>20</sup></b> Retrospective observational study; n = 147 relevant to the current analysis	<b>Intervention:</b> “POCT Pathway” including ECG, clinical assessment and up to 2 troponin POCTs – 1 at presentation and 1 at > 8 hours after presentation <b>Device/manufacture:</b> <ul style="list-style-type: none"> <li>i-STAT cTnI/Abbott Point of Care Diagnostics)</li> <li>Data collected retrospectively from i-STAT CDS</li> </ul>	<b>Definition:</b> Clinical judgment of likely outcome (evacuation or not) in hypothetical absence of POCT troponin i-STAT <b>Measurement:</b> Assessment by a clinical data by a Senior Rural Medical Practitioner with extensive experience in the decision-making of patient evacuations. <b>Time point:</b> NR	<b>cTnI negative, not evacuated (n = 126):</b> Clinical advisor stated that 48 (38%) of these patients would have been evacuated without i-STAT device availability (cardiac involvement could not be ruled out) <b>cTnI negative, evacuated (n = 14):</b> Clinical advisor stated that all 14 (100%) of these patients would have been evacuated without i-STAT device availability <b>cTnI positive, evacuated (n = 7):</b> Clinical advisor stated that 4 (57%) of these patients would have been evacuated without i-STAT device available and that

Study citation, design, number of patients	POCT device/manufacture, troponin test, test protocol	Outcome definition, measurement, time point	Outcome
			those not evacuated would likely have had a poorer outcome.

AIHTA = Austrian Institute for Health Technology Assessment; CDS = Central Data Station; CI = confidence interval; cTnI = cardiac troponin I; cTnT = cardiac troponin T; ECG = electrocardiogram; EDACS = Emergency Department Assessment of Chest Pain Score; MACE = major adverse cardiovascular events; NZ MOH = New Zealand Ministry of Health; NR = not reported; POCT = point-of-care test; RACPP = Rural Accelerated Chest Pain Pathway.

<sup>a</sup>Includes both actual evacuation data or equivalent and clinical judgment of hypothetical evacuation status, depending on study.

**Table 10: Summary of Findings by Outcome — Time to Diagnosis**

Study citation, design, number of patients	POCT device/manufacture, troponin test, test protocol	Outcome definition, measurement, time point	Outcome, group (n): median ± IQR
<b>Spaeth et al.(2017):</b> <sup>20</sup> Retrospective observational study; n = 146 relevant to the current analysis	<b>Intervention:</b> “POCT Pathway” including ECG, clinical assessment and up to 2 troponin POCTs – 1 at presentation and 1 at > 8 hours after presentation <b>Device/manufacture:</b> <ul style="list-style-type: none"><li>• i-STAT cTnI/Abbott Point of Care Diagnostics)</li><li>• Data collected retrospectively from i-STAT CDS</li></ul>	<b>Definition:</b> Time from test to diagnosis <b>Measurement:</b> i-STAT CDS and Northern Territory’s Department of Health PCIS <b>Time point:</b> NR	<b>Single Positive test + Evacuated (n = 3):</b> 20 (± 68) minutes <b>Single Negative test + Evacuated (n = 11):</b> 50 (± 130) minutes <b>Single Negative test + Not Evacuated (n = 97):</b> 30 (± 34) minutes <b>Serial Positive test + Evacuated (n = 4):</b> 255 (± 570) minutes <b>Serial Negative tests + Evacuated (n = 3):</b> 100 (± 80) minutes <b>Serial Negative + Not Evacuated (n = 28):</b> 480 (± 630) minutes

CDS = Central Data Station; cTnI = cardiac troponin I; ECG = electrocardiogram; IQR = interquartile range; NR = not reported; POCT = point-of-care test; PCIS = Primary Care Information System.

**Table 11: Summary of Findings by Outcome — Time to Treatment**

Study citation, design, number of patients	POCT device/manufacture, troponin test, test protocol	Outcome definition, measurement, time point	Outcome, group (n): median ± IQR
<b>Spaeth et al.(2017):</b> <sup>20</sup> Retrospective observational study; n = 147 relevant to the current analysis	<b>Intervention:</b> “POCT Pathway” including ECG, clinical assessment and up to 2 troponin POCTs – 1 at presentation and 1 at > 8 hours after presentation <b>Device/manufacture:</b> <ul style="list-style-type: none"><li>• i-STAT cTnI/Abbott Point of Care Diagnostics)</li><li>• Data collected retrospectively from i-STAT CDS</li></ul>	<b>Definition:</b> Time from test to treatment <b>Measurement:</b> i-STAT CDS and Northern Territory’s Department of Health PCIS <b>Time point:</b> NR	<b>Single Positive test + Evacuated (n = 3):</b> 20 (± 5) minutes <b>Single Negative test + Evacuated (n = 6):</b> 38 (± 64) minutes; missing data for 5 <b>Single Negative test + Not Evacuated (n = 26):</b>

Study citation, design, number of patients	POCT device/manufacture, troponin test, test protocol	Outcome definition, measurement, time point	Outcome, group (n): median $\pm$ IQR
			<p>15 (<math>\pm</math> 20) minutes; the remaining patients in this group did not require treatment</p> <p><b>Serial Positive test + Evacuated (n = 4):</b> 40 (<math>\pm</math> 20) minutes</p> <p><b>Serial Negative tests + Evacuated (n = 2):</b> 5 (<math>\pm</math> 0) minutes; missing data for 1 patient</p> <p><b>Serial Negative + Not Evacuated (n = 11):</b> 30 (<math>\pm</math> 45) minutes; the remaining patients in this group did not require treatment</p>

CDS = Central Data Station; cTnI = cardiac troponin I; ECG = electrocardiogram; IQR = interquartile range; NR = not reported; POCT = point-of-care test; PCIS = Primary Care Information System.

**Table 12: Summary of Findings by Outcome — Patient Satisfaction**

Study citation, Design, Number of patients	POCT device/manufacture, Troponin test, Test protocol	Outcome definition, Measurement, Time point	Outcome
<p><b>From AIHTA (2024)</b><sup>17</sup> (relevant study 2 of 2)</p> <p><b>Norman et al. (2022)</b><sup>28</sup></p> <p>Prospective observational study; n = 186 identified; 180 included in analyses</p>	<p><b>Device/manufacture:</b> i-STAT cTnI/Abbott Point of Care Diagnostics)</p> <p><b>RACPP</b> including EDACS, ECG and 2 troponin POCTs – 1 at presentation and 1 at 2 hours.</p> <p>Risk stratification to low risk and not-low risk</p>	<p><b>Definition:</b> Patient responses (options Good-excellent, fair, poor) to questions about their satisfaction with:</p> <ul style="list-style-type: none"> <li>• The urgency of their assessment assessed</li> <li>• The thoroughness of their assessment</li> <li>• Understanding of explanations of tests and procedures</li> <li>• Understanding of explanations of process and time exception</li> <li>• Delivery of service</li> <li>• The service they received overall</li> </ul> <p><b>Measurement:</b> Telephone call from a research nurse</p> <p><b>Time point:</b> 30 days after index presentation</p>	<p>Response rate: 111 of 148 (75%); 67 classified and managed as low risk; 44 classified as non-low risk of whom 37 were referred to the hospital</p> <p>Overall, 94.0% of low-risk and 95.5% of not low-risk respondents felt 'good-excellent' satisfaction with the service they received at the general practice.</p> <p>Refer to the study for more information.</p>

AIHTA = Austrian Institute for Health Technology Assessment; cTnI = cardiac troponin I; ECG = electrocardiogram; EDACS = Emergency Department Assessment of Chest Pain Score; POCT = point-of-care test; RACPP = Rural Accelerated Chest Pain Pathway.



**Table 13: Summary of Findings by Outcome — Staff Satisfaction**

Study citation, design, number of patients	POCT device/manufacture, troponin test, test protocol	Outcome definition, measurement, time point	Outcome
<b>From AIHTA (2024)<sup>17</sup></b> <b>Norman et al. (2022):<sup>28</sup></b> Prospective observational study; n = 186 identified; 180 included in analyses	<b>Device/manufacture:</b> i-STAT cTnI/Abbott Point of Care Diagnostics <b>RACPP</b> including EDACS, ECG and 2 troponin POCTs – 1 at presentation and 1 at 2 hours. Risk stratification to low risk and not-low risk	<b>Definition:</b> NR <b>Measurement:</b> NR <b>Time point:</b> NR	Authors state: "The pathway was considered feasible and acceptable by the general practices to the extent that it has been maintained as the standard of care in the participating centres"
<b>From EUnetHTA (2019)<sup>18</sup></b> <b>Shephard et al. (2014)<sup>25</sup></b> <b>and Shephard et al. (2012):<sup>29</sup></b> <ul style="list-style-type: none"> <li>Program description and evaluation with surveys</li> <li>2012: 39 respondents (31%) of 127 operators who were sent the questionnaire</li> <li>For 2012 survey results seem to be repeated (in part) in 2014 publication</li> </ul>	<b>Intervention:</b> i-STAT Point-of-Care Testing Program using 4 testing cartridges, 1 being cTnI <b>Device/manufacture:</b> i-STAT 300 analyzer/Abbott Point of Care and the following cartridges: Chem8+, CG4+, PT/INR, cTnI	<b>Definition:</b> Staff satisfaction with pathology services after introduction of i-STAT POCT program <b>Measurement:</b> Online questionnaires <b>Time point:</b> 2012 publication- Approximately 1 year after the start of program implementation	39/127 (31%) response rate No information on characteristics of respondents and nonrespondents. cTnI POCT-relevant questions: <ul style="list-style-type: none"> <li>Satisfaction with cTnI by lab before introduction of POCT program: Unsatisfied: 12 (52%); Unsure: 4 (18%); Satisfied: 7 (31%); 16 missing</li> <li>Satisfaction with cTnI by POCT after introduction of POCT program: Unsatisfied: 0 (0%); Unsure: 1 (4%); Satisfied: 22 (96%); 2 missing</li> <li>Satisfaction with timeliness of lab for acute tests before introduction of POCT program: Unsatisfied: 12 (48%); Unsure: 6 (24%); Satisfied: 7 (28%); 14 missing</li> <li>Satisfaction with timeliness of POCT for acute tests after introduction of POCT program: Unsatisfied: 0 (0%); Unsure: 1 (4%); Satisfied: 25 (96%); 14 missing</li> </ul> Note: the following is not specific to cTnI POCTs <ul style="list-style-type: none"> <li>[NT POCT program] is more convenient than laboratory service: Yes: 94.7%; Not applicable: 5.3%</li> <li>[NT POCT program] assisted in stabilizing acutely ill clients on site: Yes: 84.2%; Unsure:</li> </ul>

Study citation, design, number of patients	POCT device/manufacture, troponin test, test protocol	Outcome definition, measurement, time point	Outcome
			<p>10.5%; Not applicable: 5.3%</p> <ul style="list-style-type: none"> <li>• [NT POCT program] assisted in reducing the need for medical retrievals: Yes: 42.1%; No: 21.1%; Unsure: 31.6%; Not applicable: 5.3%</li> <li>• [NT POCT program] helped motivate clients to work to improve their own health: Yes: 47.4%; No: 15.8%; Unsure: 36.8%</li> <li>• [NT POCT program] improved compliance with taking medication: Yes: 21.1%; No: 21.1%; Unsure: 57.9%</li> </ul>

AIHTA = Austrian Institute for Health Technology Assessment; cTnI = cardiac troponin I; ECG = electrocardiogram; EDACS = Emergency Department Assessment of Chest Pain Score; EUnetHTA = European Network for Health Technology Assessment; NR = not reported; NT POCT program: Northern Territory Point-of-Care Testing Program; POCT = point-of-care test; RACPP = Rural Accelerated Chest Pain Pathway.

**Table 14: Summary of Findings by Outcome — Adherence to Pathway**

Study citation, Design, Number of patients	POCT device/manufacture, Troponin test, Test protocol	Outcome definition, Measurement, Time point	Outcome
<p><b>From AIHTA (2024)<sup>17</sup></b> (relevant study 2 of 2)</p> <p><b>Norman et al. (2022)<sup>28</sup></b> Prospective observational study; n = 186 identified; 180 included in analyses</p>	<p><b>Device/manufacture:</b></p> <ul style="list-style-type: none"> <li>• i-STAT cTnI/Abbott Point of Care Diagnostics</li> <li>• RACPP including EDACS, ECG and 2 troponin POCTs – 1 at presentation and 1 at 2 hours</li> <li>• Risk stratification to low risk and non-low risk</li> </ul>	<p><b>Definition:</b> Adherence to the RACPP pathway (staff and patients)</p> <p><b>Measurement:</b></p> <ul style="list-style-type: none"> <li>• Electronic template in the practice management system.</li> <li>• From National Health Index identifier event searches and nurse telephone follow-up at 30 days.</li> </ul> <p><b>Time point:</b> NR</p>	<p><b>Low-risk patients:</b></p> <ul style="list-style-type: none"> <li>• Adherent: 106 of 111 patients (95.5%)</li> <li>• Not-adherent: 5 of 111 patients (4.5%) did not complete a 2-hour assessment due to subsequent diagnosis of non-cardiac chest pain (n = 4) or refusal to remain at practice (n = 1).</li> </ul> <p><b>Non-low-risk patients:</b></p> <ul style="list-style-type: none"> <li>• Adherent: 56 of 69 patients (81.2%)</li> <li>• Non-adherent: 13 of 69 patients (18.8%) were not transferred for hospital assessment against pathway guidance.</li> <li>• None had elevated cTnI and none experienced a MACE within 30 days</li> </ul>

AIHTA = Austrian Institute for Health Technology Assessment; cTnI = cardiac troponin I; ECG = electrocardiogram; EDACS = Emergency Department Assessment of Chest Pain Score; MACE = major adverse cardiovascular events; NR = not reported; POCT = point-of-care test; RACPP = Rural Accelerated Chest Pain Pathway.

**Table 15: Summary of Findings by Outcome — Number (%) of cTnI Test Results Outside “Defined Critical Actions Limits” and Patient Clinical Conditions**

Study citation, design, number of patients	POCT device/manufacture, troponin test, test protocol	Outcome definition, measurement, time point	Outcome
<b>Matthews et al.(2020)<sup>19</sup></b> Clinical audit / program evaluation Number of cTnI tests performed: 1,398	<b>Intervention:</b> i-STAT Point-of-Care Testing Program using 4 testing cartridges, 1 being cTnI <b>Device/manufacture:</b> i-STAT 300 analyzer/Abbott Point of Care and the following cartridges: Chem8+, CG4+, PT/INR, cTnI	<b>Definition:</b> Number (%) of tests conducted between September 1, 2019, and December 31, 2019, with POCT cTnI outside the defined clinical limit (critical range: 0.09 to 48.5 ng/mL; Median critical: 0.35 ng/mL; average critical: 3.08 ng/mL) and clinical condition of the relevant patients. <b>Measurement:</b> i-STAT 300 analyzer/Abbott Point of Care with cTnI cartridge <b>Time point:</b> NR	<ul style="list-style-type: none"> <li>• Number (%) of POCT tests with cTnI outside the defined clinical limit: 45 / 1,398 (3%)</li> <li>• Clinical condition of patients with POCT cTnI result outside the defined critical action limit (n (%)):              Myocardial infarction 34 (2.4); Chronic kidney disease related: 4 (0.3); Atrial fibrillation: 3 (0.2); Respiratory related: 2 (0.1); Hypokalemia 2 (0.1)</li> <li>• The median flagged cTnI concentration was 0.35 ng/mL (range = 0.09 to 48.5 ng/mL).</li> </ul>

cTnI = cardiac troponin I; NR = not reported; POCT = point-of-care test.



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