



# Leidraad Prehospitale triage van patiënten met verdenking op een acuut coronair syndroom

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# 1. Preface

Safe and efficient prehospital risk assessment is crucial to ensure that our limited healthcare resources are adequately allocated to those that need our care most. The first multidisciplinary National Working Group for prehospital triage was established to address the growing urgency and importance of harmonising prehospital cardiac risk assessment in order to improve patient care and control increasing health care demand. The working group has conducted a critical review of current literature and organizational practices related to the prehospital risk assessment of chest pain patients with suspected acute coronary syndrome (ACS), with particular focus on (validated) risk stratification decision rules.

This document provides clinical guidance based on currently available literature and expert opinions for current and future prehospital triage of patients with suspected ACS across the Netherlands.

## 1.1. Introduction

The organization of prehospital care in the Netherlands has unique features that contribute to equal access of both prehospital and hospital care for all citizens. Depending on urgency of symptoms, patients may receive ambulance assessment, general practitioner (GP) or self-care advice. For those evaluated in person, further triage occurs at patient's bedside. Dutch ambulance personnel are able to perform and interpret an ECG, while GPs primarily rely on history taking and clinical judgement. Both professions follow established protocols and guidelines [1, 2]. Patients with typical symptoms and a high a-priori risk are referred directly to (cardiac) emergency departments (ED). However, the majority present with less defined symptoms, increasing the risk of missing a serious (cardiac) diagnosis. To mitigate this risk, healthcare professionals often triage defensively, which contributes to overcrowding of EDs. ED overcrowding is a growing public health concern world-wide and negatively impacts access to urgent or emergent care [3, 4].

### 1.1.1. Rationale and Background of prehospital risk assessment of acute chest pain

#### *Scope of the problem*

In the Netherlands, approximately 1.5 million high-urgency ambulance transfers were carried out in 2023, of which nearly 240.000 were related to acute cardiac presentations [5]. In Dutch primary care, chest pain accounts for 1.3%, translating to approximately 850.000 consultations annually [6, 7]. ED visits typically result in extensive diagnostic work-up and prolonged in-hospital stays. Ultimately, only about 10% of acute chest pain presentations are diagnosed with ACS, while the vast majority are classified as non-cardiac chest pain (NCCP).

#### *Health care challenge: balancing efficiency and safety*

Validation of risk assessment instruments that enable prehospital healthcare professionals to make adequate triage decisions – while maintain a balance between efficiency and safety - remains challenging. Current GP assessments are estimated to misclassify 10-20 % of ACS cases as NCCP [7-10]. A national survey among Dutch GPs reported an acceptable miss rate below 2% [11]. Based on these data, we advise a minimum sensitivity of 98% for prehospital risk assessment tools in patients with suspected ACS. This aligns with international consensus regarding acceptable miss rates for major adverse cardiac events (MACE), usually defined as all-cause death, ACS or unplanned revascularization within 30 days [12]. Beyond safety, there is need to improve efficiency and consequently an adequate specificity of prehospital risk assessment. Simply, referring all patients with chest pain to EDs is unaffordable, both in terms of finances and personnel.

#### *Economic Potential of Prehospital Risk Stratification*

According to the ARTICA trial, the added value of its pre-hospital rule-out strategy could amount to an estimated €50 million per year in the Netherlands [13, 14]. The POB HELP-study hypothesized that if a decision rule is implemented in 50% of general practices, and assuming a 10% reduction in referrals, this could potentially lead to an annual cost reduction of €31 million [15].

Therefore, it is important to effectively and safely identify chest pain patients who are at low-risk for ACS in prehospital setting and prevent or at least diminish referral of NCCP to EDs, while maintaining a high level of safety.

## 2. Decision rules

Clinical decision rules, such as HEART (History, ECG, Age, Risk Factors, Troponin) [16], EDACS [17], and T-MACS [18] are commonly used at EDs to risk stratify patients with chest pain. Evolution of point-of-care (POC) troponin tests has driven adaptation of these clinical decision rules from ED to prehospital scenery. These clinical decision rules also face specific challenges in the prehospital environment [13, 14, 19-24]. As such, new clinical decision tools have been developed specifically for prehospital use, in which EMS setting (ambulance) and primary care (GPs) are discussed separately in upcoming paragraphs.

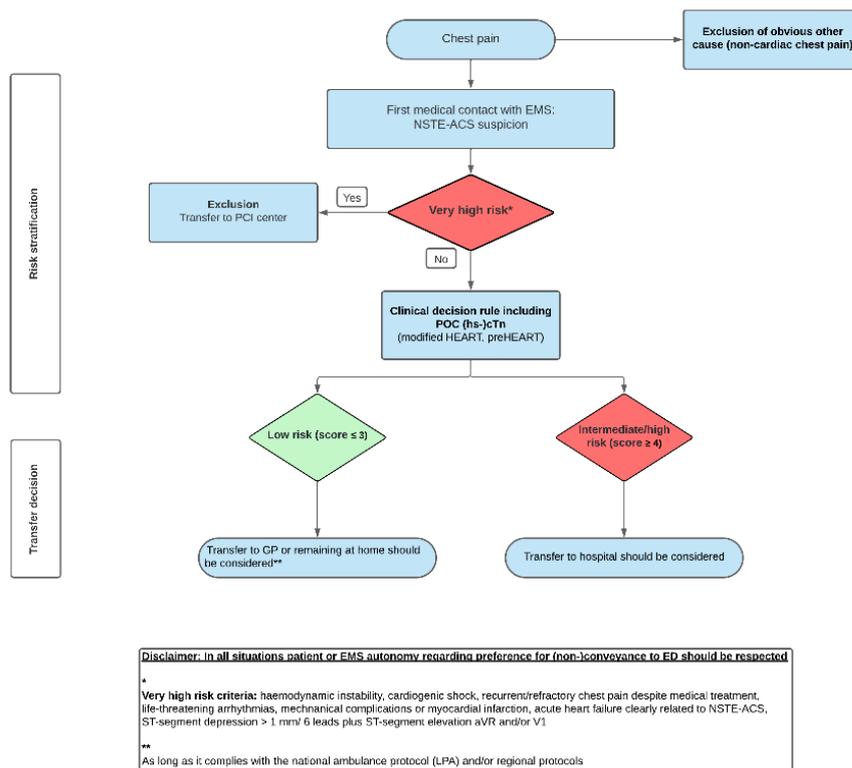
### 2.1. Current consensus regarding prehospital risk assessment

The modified HEART and preHEART (prehospital HEART) score, both derived from the original HEART score, are most frequently studied decision rules in EMS setting [13, 14, 19-23]. Differences between these scores are summarized in Table 1. Using the HEART score or modified HEART score, patients with 0-3 points are classified as low risk for MACE, 4-6 points as intermediate, and 7-10 points as high risk. Currently, limited evidence is available regarding direct comparison between different prehospital decision rules in EMS, however both preHEART and HEART scores have better overall diagnostic performance compared to T-MACS and sole POC-troponin measurement [20].

A recent meta-analysis of 15 studies highlighted the efficacy and added value of prehospital clinical decision rules with POC troponin testing, compared to relying solely on conventional POC-troponin measurement [22]. Even in patients with short duration of symptoms ("early presenters" with onset of chest pain within 2 hours before EMS contact), decision rules incorporating troponin have shown good diagnostic performance in EMS setting [13, 14, 21]. No safety concerns have been reported to date, although larger trials are currently underway [26]. Ongoing EMS studies will further evaluate prehospital risk stratification using newer, high sensitivity (hs)-POC troponin assays (Table 2).

Figure 1 illustrates the current consensus regarding prehospital risk assessment in patients presenting with chest pain. The first step in risk stratification is to exclude patients with NCCP and promptly identify those with very high-risk features of ACS, such as cardiogenic shock or ST segment elevation [27]. For these patients, immediate hospital transfer is indicated. In all other cases, clinical decision rules incorporating (hs)-POC troponin- such as modified HEART or preHEART- are advised to stratify patients into low-risk or intermediate/high-risk categories. In well-trained EMS systems, where prompt and accurate follow-up of low-risk patients is possible, HEART-derived clinical risk scores effectively identify patients with a very low risk of 30-day mortality and MACE [25]

Figure 1



A more detailed guidance document for implementation and monitoring by Ambulancezorg Nederland, is currently available [28]. At present, both intermediate and high risk patients in the EMS setting should continue to be considered for hospital transfer to enable further diagnostic evaluation and potential treatment. This decision should consider the overall clinical assessment, regional protocols, and (where applicable) shared decision-making in consultation with an emergency or cardiology physician.

Patients who present to their GP with chest pain differ from those seen by EMS in terms of symptom characteristics and overall risk for ACS. Therefore, risk stratification tools must be validated specifically for use in primary care setting. Several risk scores have been evaluated in this context [29], most notably the Marburg heart Score. Although this score demonstrate high negative predictive values, it does not meet the required safety standards in terms of accepted miss rate or false negative rate of <2% [30]. The HEART score has been assessed in a large cohort of patients presenting to urgent primary care. However, it did not outperform a standalone hs-troponin assay combined with clinical judgment in patients presenting  $\geq 3$  hours after symptom onset [31, 32]. In Dutch primary care, only one study has evaluated a simplified version of the HEART score in which the troponin component was either omitted or replaced by GP's clinical intuition ("gut feeling"). These modified versions showed promise but require further validation [33]. With the introduction of POC troponin, two ongoing studies are currently evaluating strategies including a single hs-POC troponin measurement in daytime general practices (POB-HELP) and out-of-hours primary care settings (HEART-GP) [15, 33].

### 3. Cardiac troponin – which POC to use?

Within aforementioned clinical decision rules, cardiac Troponin (cTn) plays a central role.

CTn is a serum biomarker with high diagnostic accuracy for myocardial necrosis and hs-cTn is the cornerstone of the universal definition of myocardial infarction (MI) [34].

Two important analytical performance characteristics are:

- The limit of detection (LOD) for quantitative results.
- The 99th percentile in a normal reference population.

Hs-cTn tests detect values above the LOD in  $\geq 50\%$  of healthy individuals and measure the 99th percentile with coefficient of variation of  $\leq 10\%$  [35]. These tests are routinely used in hospitals (Table 3). Recently, POC (hs)-cTn tests (Table 4) have emerged, which do not require central laboratory infrastructure and significantly reduce time-to-diagnosis, enabling their use in (pre)hospital settings. Cullen et al. recently provided a comprehensive overview of potential applications of POC hs-cTn assays, including prehospital environment [24]. Table 5 summarizes available POC (hs)-cTn assays suitable in EMS setting. The introduction of POC hs-cTn testing in prehospital settings can improve safety (quickly ruling in MI) and efficiency (avoiding unnecessary referrals). Clinicians have faced a conflict between POC speed and central lab accuracy [36]. Combining them both in a POC hs-cTn assay is the next step to enhance prehospital risk assessment quality and safety.

There is growing evidence that conventional (non-hs) POC cTn T (Cobas h232) and I (iSTAT by Abbot) tests – when incorporated in a clinical risk tools – may help rule out MI in low-risk patients [37-41]. Current efforts evaluate various POC hs-cTn I devices (Siemens' Atellica VTLi, Quidel's TriageMeter Pro, LSI Medience's Pathfast, Abbott i-STAT), addressing logistical challenges in standardizing assays across single rule out strategies in prehospital care. Siemens' Atellica VTLi hs-cTnI using a whole blood cut-off value near the LOD of 4 ng/L, has already demonstrated safety and reliability for ruling out myocardial ischemia in ED settings [14, 42, 43]. However, recent developments indicate that Siemens will discontinue its healthcare division, and the Atellica system will no longer be available on the Dutch market as of 2026.

Before implementing POC hs-cTn in prehospital settings, several requirements must be met. At first, the optimal cut off value per POC hs-cTn device for rule out of low risk ACS patients in a prehospital setting has to be defined. Using a cut off value near the LOD (high diagnostic sensitivity) enhances safety, whereas efficiency is served by a slightly higher cut off value – that includes intermediate measurement uncertainty – in order to rule out myocardial ischemia in a substantial number of patients. Besides cut-off values, other factors affecting diagnostic performance are the a priori risk, the time interval between symptom onset and testing, and patient factors (age, sex). Table 5 presents the 99th-percentile cutoff values for men and women for the various high-sensitivity point-of-care troponin assays.

In addition, it is advised that the entire process of POC hs-cTn should be supported by an ISO15189 accredited laboratory as quality standards and analytical performance requirements for hs cTnT/I tests are high. They should align to the International Federation of Clinical Chemistry (IFCC) guidelines. POC devices should preferably be firm and handheld. It's imperative to ascertain the robust diagnostic reliability of POC tests, taking into account the variability in measurement accuracy across devices and the necessity for stringent quality controls as per laboratory standards.

Furthermore, operators of POC devices must be competent in correctly operating the devices, collecting patient material and ensuring the quality of the entire procedure. Recording of test results should preferably be automatic (electronic patient file) and traceable to the (certified) operator.

## 4. Prehospital clinical context combined with other patient data

Beyond clinical decision rules and POC troponin testing, prehospital risk assessment should centrally incorporate the patient's clinical context, symptom presentation and individual preferences. Shared decision-making plays a crucial role in this process, especially when hospital referral is not straightforward.

The HART-c study evaluated a prehospital triage strategy approach that combined patient data with remote cardiologist consultation. Compared to a historical control group, this approach showed a significantly increased proportion of patients who remained at home (11.8% vs. 5.9%) with a low MACE rate of <1% [44].

Although this strategy may be beneficial for patient prehospital risk assessment, particularly in cases where hospital referral is not straight forward, such comprehensive risk assessment method requires several preconditions before it can be implemented. Most notably, the integration of shared data platforms and remote hospital consultation is still a future perspective and requires regional endorsement. Establishing a regional triage network among health care providers is essential to facilitate collaboration and ensure continuity of care. In addition, questions regarding professional responsibility and liability must be addressed- particularly in cases where patients are not referred to the hospital. In principle, all healthcare professionals involved in the risk assessment share responsibility for patient outcomes, with primary responsibility resting with the provider physically present at prehospital scene. Finally, structural reimbursement for remote hospital consultation must be formalized. The Dutch healthcare authority (NZa) recently introduced a nationwide reimbursement method ("Facultatieve prestatie") for remote consultations in prehospital (ambulance) settings [45].

## 4.1. Organization of prehospital risk assessment of NSTEMI-ACS in regional networks

The aforementioned triage networks can only be established through close collaboration between EMS, GPs, ED's, clinical chemists, patient representatives, and cardiologists of both PCI and non-PCI centers. In the Netherlands, such collaborations already exist for ST elevation acute coronary syndrome (STEMI-ACS) patients [46]. Expanding these existing networks should include patients presenting with chest pain and suspected NSTEMI-ACS with a prehospital assessment incorporating a clinical decision rule and hs POC troponin

In detail, the proposed extension of regional NSTEMI-ACS networks should include:

- Advice already supported by current guidelines:
  - Clearly defined geographic areas of responsibility.
  - Shared written protocols for prehospital risk assessment.
  - Remote technologies enabling prehospital ECG interpretation by dedicated physicians.
- New advice based on recent EMS studies [13,14,19,20,42,44,47]:
  - Regional consensus and alignment of implementation of prehospital risk assessment, including:
    - Exclusion of patients with very high-risk ACS criteria or unstable vital signs (according to national ambulance and ESC protocols)
    - Inclusion of self-referrals or GP referrals (depending on regional arrangements).
    - Inclusion of "early presenters" (onset of chest pain / complaints within 2 hours) when using hs-cTn embedded in a clinical decision rule and followed by appropriate monitoring.
  - Same day and "closed-loop" communication between EMS and GP in cases where care is transferred to GP (e.g. very low-risk chest pain).
  - Monitoring the quality of prehospital risk assessment implementation, including:
    - EMS documentation of the algorithm used and corresponding results (troponin levels and risk score)
    - Quality control of patient outcome. Ambulance services take responsibility for structuring and maintaining their quality systems, as defined in their implementation plan [28]. In their implementation plan, monitoring of patients not

referred to the ED will be mandatory and will be carried out by the ambulance services

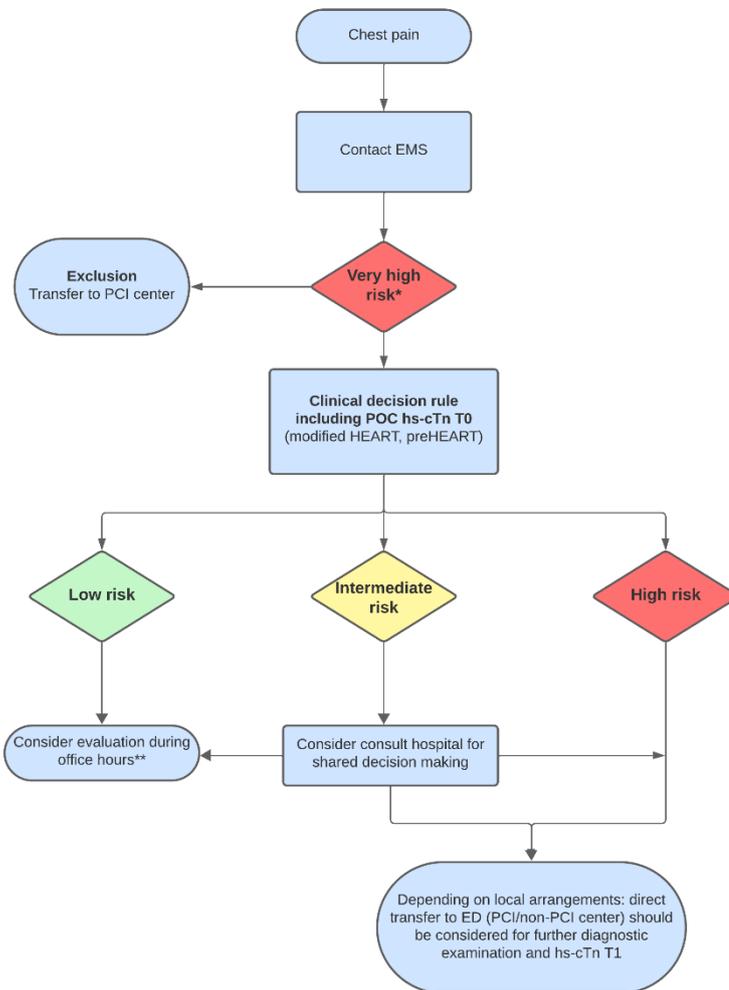
Regional coordination bodies, such as the Acute Care Regions (AZOs) and the Regional Consultation on Acute Care (ROAZ), serve as key strategic platforms for guiding and supporting the implementation of prehospital triage protocols incorporating point-of-care troponin testing within ambulance service networks.

## 5. Future perspectives

Prehospital triage is a dynamic process, and developments are advancing rapidly. It is therefore important to remain informed about future developments.

Figure 2 presents a proposed future risk assessment pathway for chest pain patients in EMS setting using a clinical decision rule in which hs-POC troponin testing is embedded. I

Figure 2



**Disclaimer: In all situations patient or EMS autonomy regarding preference for (non-)conveyance to ED should be respected**

\*  
**Very high risk criteria:** haemodynamic instability, cardiogenic shock, recurrent/refractory chest pain despite medical treatment, life-threatening arrhythmias, mechanical complications or myocardial infarction, acute heart failure clearly related to NSTEMI-ACS, ST-segment depression > 1mm/ 6 leads plus ST-segment elevation aVR and/or V1.

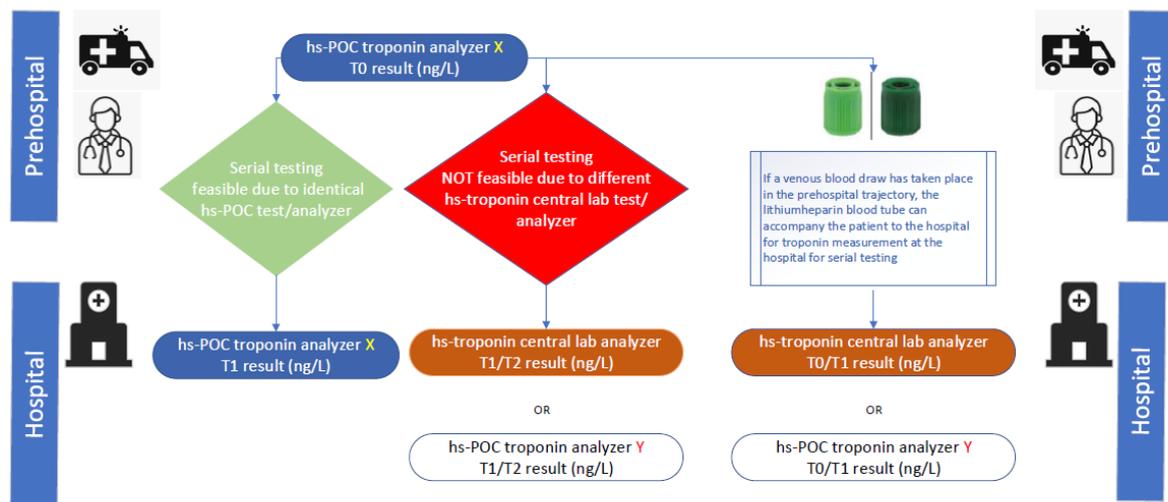
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 According to LPA.

The majority of this proposed pathway resembles current practice, except a separate identification of intermediate risk patients, in which remote consultation with a hospital physician (HART-c study) [44], may be considered. This approach could significantly improve outcomes in this group, where MACE percentages range from 13% to 20%.

For high risk patients, the TRIAGE ACS study has evaluated the feasibility and cost-effectiveness of prehospital risk assessment and direct transfer to a PCI center in patients at high risk for NSTEMI-ACS [47]. Ongoing research aims to further establish the evidence supporting the added value of this strategy.

For referred patients, the GP or ambulance personnel can collect the initial blood sample (T0) (figure 3), allowing only one additional hs-cTn test at the ED (T1), thereby reducing ED length of stay [48]. However, this strategy requires either the use of the same hs-cTn POC device in both EMS and hospital setting or analysis hs-cTn measurement of the T0-sample on the hospital's central lab analyzer.

Figure 3



## 6. Reimbursement of prehospital risk assessment

Multiple studies have demonstrated that prehospital risk assessment systems—designed to reduce unnecessary hospital transfers by ruling out ACS—can lead to substantial healthcare savings [13, 14, 21, 47]. These systems result in fewer patients being transported to hospitals, thereby reducing the need for diagnostics procedures and treatment efforts [48].

For hospitals, the Dutch healthcare authority (NZa) recently introduced a nationwide reimbursement method (“Facultatieve prestatie”) for remote consultations in prehospital (ambulance) settings [45]

From 2026 onwards, prehospital risk assessments conducted by ambulance professionals will be structurally reimbursed.

## 7. Implementation

Effective implementation of prehospital risk stratification using POC devices requires structured training of EMS and primary care personnel (28). This training should cover the use of clinical decision rules, patient assessment and interdisciplinary collaboration. Ongoing education and structured quality assurance- supported by registry-based monitoring- are essential to maintain diagnostic sensitivity and ensure consistent application of the pathway. It is the responsibility of each regional ambulance service to maintain regular training and education.

It is advised to evaluate this proposed pathway on an annual basis per region. As part of the implementation strategy, both daytime GP visits and out-of-hours GP consultations should be monitored to assess impact and identify areas for improvement. The AZO and ROAZ may serve a facilitating or coordinating role in this context.

## 8. Knowledge Gaps / future research

Prehospital risk assessment of patients with suspected ACS still faces several knowledge gaps and future studies should address the following questions:

- A direct comparison between existing clinical decision rules has not yet been conducted, and future studies are needed to determine which score is most suitable in prehospital setting.

- The definition of low risk (modified HEART or preHEART  $\leq 3$ ) requires further clarification. Increasing the threshold to a score of 4, when combined with an embedded hs-POC troponin measurement, may allow more patients to be managed outside the hospital.
- To enhance the safety of ruling out ACS, one could consider implementing serial (second) troponin on site by EMS personnel [21]. However, diagnostic value of serial hs-POC troponin measurements in prehospital setting remains uncertain [49].
- The value of clinical decision rule and/or hs POC troponin testing in primary care as compared to GP clinical judgment alone is not yet known. Additionally, integration of machine learning and artificial intelligence (AI) tools (telemedicine, AI recognition of ECG's at risk for NSTEMI ACS) may further improve the positive predictive value of prehospital risk assessment in patients with chest pain [50].

## 9. Summary and advice

1. In EMS settings, the use of HEART-score derived clinical risk scores (*modified HEART or preHEART score*) with *high sensitivity POC troponin* is advised for risk assessment and triage of chest pain patients with suspected ACS
2. Withholding hospital referrals of patients at low risk (modified HEART or preHEART score  $\leq 3$ ) appears to be cost effective. Safety of this strategy has not yet proven in adequately powered clinical trials. A nationwide implementation strategy with monitoring of patients left at home is being initiated.
3. Patients at intermediate or high risk for ACS might be transferred to a (cardiac) ED - either PCI or non-PCI center- depending on local arrangements.
4. Studies are ongoing to determine whether the use of clinical decision rule and/or hs POC troponin testing in primary care adds value compared to GP clinical judgment alone.
5. Dedicated regional risk assessment networks remain the cornerstone of safe and effective prehospital triage. Shared data and collaborative decision-making between prehospital and hospital professionals may further enhance the quality and safety of prehospital risk assessment.

## 10. Establishment of the document

This practice document was written by the Chest Pain/ACS Prehospital Triage Project Group of the Netherlands Society of Cardiology (NVVC), and endorsed by the NVVC.

### **Authors project group:**

*Chairs:*

C. Camaro, MD<sup>1,2</sup>

M.J. Boogers, MD, PhD<sup>2,10</sup>

*Members:*

R.T. Tolsma, PhD<sup>3</sup>

M. Fokkert, PhD<sup>4</sup>

R.E. Harskamp, MD, PhD<sup>5</sup>

J.G. Meeder, MD, PhD<sup>6,7</sup>

D. van Dongen, MD, PhD<sup>8</sup>

J. Demandt, MD<sup>9</sup>

P. Vlaar, MD, PhD<sup>9</sup>

E. De Koning, MD<sup>10</sup>

Prof P. van der Harst, MD, PhD<sup>11</sup>

G.W.A. Aarts, MD, PhD<sup>1</sup>

N. van Royen, MD, PhD<sup>1</sup>

J. Azzahafi, MD<sup>12</sup>

Prof J. Ten Berg, MD, PhD<sup>12</sup>

S. van den Bulk, MD<sup>13</sup>

T.N. Bonten, MD, PhD<sup>13</sup>

R.T.A. Willemsen, MD, PhD<sup>14</sup>

R.J. Slingerland, PhD<sup>4</sup>

B. Backus, MD, PhD<sup>15, 16</sup>

D.C. Sagel, MSc<sup>17</sup>

I. Melessen, MD<sup>5</sup>

M. Rutten, MD, PhD<sup>18</sup>

Prof C.M. Cobbaert, MD, PhD<sup>19</sup>

F. Arslan, MD, PhD<sup>10,20</sup>

B. Rahel, MD, PhD<sup>6</sup>

Prof A. van 't Hof, MD, PhD<sup>21</sup>

### **Affiliations:**

<sup>1</sup>Radboudumc Center for Cardiovascular Care, Nijmegen, the Netherlands,

<sup>2</sup>Netherlands Heart Institute, Utrecht, the Netherlands;

<sup>3</sup>Emergency Medical Service, Ambulance IJsselland, Zwolle, The Netherlands,

- <sup>4</sup>Department of Clinical Chemistry, Isala Hospital, Zwolle, the Netherlands
- <sup>5</sup>Department of General Practice, Amsterdam University Medical Center, the Netherlands,
- <sup>6</sup>Department of Cardiology, VieCuri Medical Centre, Venlo, the Netherlands,
- <sup>7</sup>Netherlands society of Cardiology, the Netherlands;
- <sup>8</sup>Department of Cardiology, Isala Hospital, Zwolle, The Netherlands,
- <sup>9</sup>Department of Cardiology, Catharina Hospital, Eindhoven, the Netherlands,
- <sup>10</sup>Department of Cardiology, Leiden University Medical Centre, Leiden, The Netherlands,
- <sup>11</sup>Department of Cardiology, University Medical Centre Utrecht, Utrecht, the Netherlands,
- <sup>12</sup>Department of Cardiology, St Antonius Hospital, Nieuwegein, The Netherlands,
- <sup>13</sup>Department of Public Health and Primary Care, Leiden University, Leiden, The Netherlands,
- <sup>14</sup>Maastricht University Medical Centre, Maastricht, the Netherlands,
- <sup>15</sup>Ambulancezorg Rijnmond, Rotterdam and Stroom Huisartsen Zorg, Dordrecht, the Netherlands,
- <sup>16</sup> Emergency Department, Amsterdam Medical Center, Amsterdam, The Netherlands
- <sup>17</sup>University of Groningen, Groningen, The Netherlands,
- <sup>18</sup> General Practitioner center Praktijk v Noord, Venlo, The Netherlands,
- <sup>19</sup> Department of Clinical Chemistry, Leiden University Medical Centre, Leiden, the Netherlands,
- <sup>20</sup> Working group Acute Coronary Syndrome, Netherlands society of Cardiology, the Netherlands,
- <sup>21</sup> Department of Cardiology, Maastricht University Medical Centre, Maastricht, The Netherlands,

## 11. Tables

**Table 1. Clinical Decision Rules**

| <b>Table 1. Variables of the different clinical risk scores and points awarded</b>   |   |  |   |
|--|---|--|---|
|  | <b>HEART</b>  | <b>Modified HEART</b>                    | <b>preHEART</b>   |
| <b>History</b>   | Clinical suspicion<br>(mildly suspicious = 0, moderately suspicious = 1, highly suspicious = 2)                               |  |   |
| <b>ECG</b>   | ST-deviation <sup>a</sup> = 2<br>Non-specific repolarization abnormalities <sup>b</sup> = 1<br>Normal = 0                     |  |   |
| <b>Age</b>   | ≥ 65 years = 2<br>> 45 years and < 65 years = 1<br>≤ 45 years = 0   |  | ≥ 70 years = 2<br>≥ 40 years and < 70 years = 1<br>< 40 years = 0 |
| <b>Risk factors</b>  | ≥ 3 risk factors <sup>c</sup> or medical history of atherosclerotic disease = 2<br>1-2 risk factors = 1<br>0 risk factors = 0 |  | Male gender = 2<br>Female gender = 0                              |
| <b>Central laboratory Troponin</b>   | ≤ Normal limit = 0<br>1– 3 <x normal limit = 1<br>≥ 3 x normal limit = 2  | Depending on analyzer and study protocol |   |
| <b>POC-troponin</b>  | Depending on analyzer and study protocol  |  |   |
| Abbreviations: ECG; electrocardiogram, POC; point-of-care<br><sup>a</sup> ST-deviation: ST depression or T-wave inversion in 2 consecutive leads<br><sup>b</sup> Non-specific repolarization disturbances: left or right bundle branch block, pericarditis<br><sup>c</sup> Risk Factors: diabetes mellitus, tobacco smoker, hypertension, hypercholesterolemia, obesity, family history of coronary artery disease |   |  |   |

Risk categories (modified) HEART/preHEART: Low risk for MACE occurrence = ≤ 3, Intermediate risk for MACE = (modified) HEART score 4-6 point, preHEART score 4-7, High risk for MACE = (modified) HEART score 7-10, preHEART score 8-10

**HEART score** as adapted from Backus et al. A prospective validation of the HEART score for chest pain patients at the emergency department. *Int J Cardiol.* 2013 Oct 3;168:2153-8.

**preHEART score** as adapted from Sagel et al. (Prehospital risk stratification in patients with chest pain. *Emerg Med J.* 2021;38:814-9)

**Table 2. Studies on prehospital decision rules for chest-pain**

| Study         | Study design  | Setting | No. of patients | Decision Tool              | Troponin assessment     | Primary endpoint  | Follow up          |
|---------------|---|---------|-----------------|----------------------------|-------------------------|---|--------------------|
| Famous II     | Famous II Prospective observational cohort                  | EMS     | 700             | HEART                      | POC troponin Cobas h232 | MACE: death, ACS, revascularization                                     | 45 days            |
| Famous III    | Famous III Prospective implementation al cohort             | EMS     | 536             | HEART                      | POC troponin Cobas h232 | MACE: death, ACS, revascularization                                     | 45 days            |
| ARTICA        | ARTICA Randomized clinical multicenter trial                | EMS     | 866             | HEART                      | POC troponin Cobas h232 | Costs   | 30 days and 1 year |
| preHEART 1-2  | preHEART 1-2 prospective cohort, development and validation | EMS     | 1208 & 435      | HEART Pre-HEART            | Abbott i-Stat           | MACE and Mortality at 3 dys   | 30 days            |
| TRIAGE-ACS    | TRIAGE-ACS Prospective, implementation al cohort            | EMS     | 1069            | preHEART, HEART, T-MACS    | Abbott i-Stat           | ACS and MACE 30 days  | 30 days and 1 year |
| preHEART 3    | preHEART3 RCT (PROBE)                                       | EMS     | 5170            | preHEART                   | Abbott i-Stat           | Combined: Mortality at 3/30dys, and ACS with CABG/PCI to non-pci centre | 1 year             |
| ACCESS study  | ACCESS study Prospective cohort                             | EMS     | 1054            | HEART                      | Samsung LABGEO POC Tnl  | MACE  | 30 days            |
| URGENT 2.0    | URGENT 2.0 RCT  | EMS     | 852             | HEART with hs-POC troponin | Atellica® VTLi          | MACE  | 30 days            |
| POPular HEART | POPular HEART Prospective observational cohort              | EMS     | 650             | HEART                      | Abbott i-Stat           | MACE  | 30 days            |

|  |  |              |             |                                 |                |   |                    |
|--|--|--------------|-------------|---------------------------------|----------------|---|--------------------|
| IPD meta-analyse prehospital risk stratification | IPS meta-analyse prehospital risk stratification<br>IPD meta-analyse | EMS          | > 10.000    | HEART<br>preHEART               |                | ACS or MACE   | 30 days            |
| IMPRESS study                                    | IMPRESS study<br>Cross-sectional study                               | Primary care | 2192        | Symptom based prediction model  | -              | ACS   | 30 days            |
| HEART GP   | HEART GP<br>Diagnostic accuracy study                                | Primary care | 900         | H(E)ART, MHS, INTERCHES T       | Atellica® VTLi | ACS   | 6 weeks            |
| POB-HELP   | POB HELP<br>RCT  | Primary care | 1500        | MHS + hs-troponin I             | Atellica® VTLi | ACS and MACE  | 6 months           |
| Safety First & TRACE                             | Safety First & TRACE<br>Diagnostic accuracy                          | Primary care | 2000 + 1473 | NTS, MHS, INTERCHES T           |                |   | 6 weeks            |
| HARTc 2.0 study                                  | HARTc 2.0 study<br>RCT   | EMS          | 1368        | Modified HEART with hs-troponin | Atellica® VTLi | MACE (Death, ACS, unplanned revascularization), costs | 30 days and 1 year |

**Table 3. Central Lab** High Sensitivity cardiac Troponin (hs cTnT/I) tests on the EU market in 2023

| Company/<br>Platform / Assay   | LoB<br>(ng/L)    | LoD<br>(ng/L)    | % CV at<br>99 <sup>th</sup><br>Percentile    | Conc<br>at 20%<br>CV<br>(ng/L) | Conc<br>at 10%<br>CV<br>(ng/L) | Reference<br>Population N,<br>Ages, Sex                                   | 99 <sup>th</sup><br>Percentile<br><br>Overall M/F<br>(ng/L)                   | Specimen Type   | Percent Normals<br>Measures ≥LoD<br>Overall M/F                      |
|--|------------------|------------------|--|--------------------------------|--------------------------------|---|---|---|--|
| Abbot systems/<br>Alinity STAT High<br>Sensitivity<br>Troponin-I;<br>commercial-OUS                              | 1.0              | 1.6              | Overall:<br>4.0%<br><br>F:5.3%<br><br>M:3.5% | 1.3                            | 4.7                            | Overalln=153<br>121-75y<br><br>F:n=76421-<br>75y<br><br>M:n=76621-<br>73y | Overall:<br>26.2<br><br>F:15.6<br><br>M:34.2                                  | Lithiumheparin<br>(with/without<br>separator), K2<br>EDTA, K3<br><br>EDTA, serum<br>(with/without<br>separator),<br>serumwith<br>thrombin-based<br>clot activator | Overall:85%<br><br>F:78%<br><br>M:92%                                |
| Abbott/<br>ARCHITECT<br><br>i systems/<br>ARCHITECT<br><br>STAT High<br>Sensitivity<br>Troponin-I;<br>commercial | 0.7<br><br>to1.3 | 1.1              | Overall:<br>4.0%<br><br>F:5.3%<br><br>M:3.5% | 1.3                            | 4.7                            | Overalln=153<br>121-75y<br><br>F:n=76421-<br>75y<br><br>M:n=76621-<br>73y | Overall:<br>26.2<br><br>F:15.6<br><br>M:34.2                                  | Lithiumheparin<br>(with/without<br>separator), K2<br>EDTA, K3<br><br>EDTA, serum<br>(with/without<br>separator),<br>serumwith<br>thrombin-based<br>clot activator | Overall:85%<br><br>F:78%<br><br>M:92%                                |
| Beckman<br>Coulter/Access 2,<br>Dxl /Access hsTnI;<br>commercial –OUS  | 0.0<br><br>to1.7 | 1.0<br><br>to2.3 | Overall:<br>3.7%<br><br>F:4.2%<br><br>M:3.6% | 1.0to2.<br>3                   | 5.6                            | Overalln=108<br>921-99y<br><br>F:n=595M:n=4<br>94                         | Overall:<br>17.5<br><br>F:11.6<br><br>M:19.8                                  | Heparinplasma   | >50%   |
| bioMérieux VIDAS<br>High Sensitive<br>Troponin I;<br>commercial  | 1.9              | 3.2              | 7.0%   | 4.9                            | NP                             | Overalln=815<br>41-80y<br><br>F:36841-80y<br><br>M:44741-80y              | Overall:19<br><br>F:11<br><br>M:25  | Serum or heparin<br>plasma  | NP   |
| Fujirebio<br>Lumipulse G<br>G1200and<br>G600IhsTnI   | 1.2              | 2.1              | ≤4.6%  | NP                             | 7.3                            | Overall<br>n=1018,18-90<br>years<br><br>F:428<br><br>M:590                | Overall:<br>28.6<br><br>F:22.4<br><br>M:32.9<br><br>Serum<br>Overall:<br>26.9 | Redtopserum,<br>serum<br>separatortube,<br>rapid clotting<br>tubes;Disodium<br>EDTA*,<br><br>Dipotassium<br><br>EDTA*,Lithium<br>heparin,Sodiumhe                 | Overall: 68.3%<br><br>Serum: 68.1%<br><br>LiHeparin<br>Plasma: 65.0% |

**Table 4. Point of Care (POC) non-high sensitivity and high sensitivity cardiac troponin devices on the EU market in 2023**

| Company/<br>Platform /<br>Assay   | LoB<br>(ug/L)   | LoD<br>(ug/L)  | % CV at<br>99 <sup>th</sup><br>Percentil<br>e   | Conc<br>at 20%<br>CV<br>(ug/L)  | Conc at<br>10%<br>CV<br>(ug/L)   | Referenc<br>e<br>Populatio<br>n N,<br>Ages,<br>Sex | Specimen<br>Type  | 99 <sup>th</sup><br>Percentil<br>e (ug/L<br>unless<br>noted)  |
|---|---|--|---|---|--|--|---|---|
| Abbott-<br>(non hs) i-<br>STAT  | 0.02  | NP   | 16.5%   | 0.07  | 0.1  | Overall,<br>N=162                                  | Sodium<br>and<br>Lithium<br>heparinize<br>d whole<br>blood<br>and<br>plasma | Overall:<br>0.08  |
| Abbott- <b>hs-<br/>Tnl</b> i-STAT   | 0.57<br>ng/L<br>(plasm<br>a) 0.78<br>ng/L<br>(whole<br>blood)       | 1.05<br>ng/L<br>(plasm<br>a) 1.61<br>ng/L<br>(whole<br>blood)          | < 4.9%<br>(plasma<br>) ≤ 5.1%<br>whole<br>blood at<br>21 ng/L                                 | 3.70<br>ng/L<br>(plasm<br>a)<br>6.88<br>ng/L<br>(whole<br>blood)        |  | Overall<br>N=895<br>F: 490<br>M: 404               | Li-Hep<br>whole<br>blood<br>and<br>plasma                                   | Overall<br>21 ng/L<br>F: 13<br>ng/L<br>M 28<br>ng/L           |
| Roche<br>Cardiac<br>POC (non<br>hs)<br>Troponin T –<br>Roche<br>Cobas 232 | NP  | 0.04   | NP  | 0.04-2.0  | 9.3%<br>betwee<br>n 0.04-<br>0.2                                       | Overall N<br>= 302                                 | Heparinize<br>d whole<br>blood  | NP  |
| LSI<br>Medience<br>Pathfast<br><b>hs-cTnl</b> /<br>Pathfast<br>cTnl-II    | 1.23<br>ng/L  | 2.33<br>ng/L   | 6.1%  | 4 ng/L  | 15 ng/L  | Overall<br>n=734<br>F:352<br>M:382                 | Heparin-<br>Na,<br>Heparin-Li<br>or EDTA<br>whole<br>blood or<br>plasma     | Overall<br>66.3%<br>F: 52.8%<br>M: 78.8%                      |
| Quidell/Ale<br>re Triage<br>True <b>hs-cTnl</b>                           | 0.4<br>ng/L<br>(plasm<br>a) 0.5-<br>0.8<br>ng/L<br>(whole<br>blood) | 0.7-1.6<br>ng/L<br>(plasm<br>a)<br>1.5-1.9<br>ng/L<br>(whole<br>blood) | 5-5.9%<br>at 21<br>ng/L<br>(plasma<br>)<br>5.9-<br>6.5^%<br>at<br>22 ng/L<br>(whole<br>blood) | 2.1-3.6<br>ng/L<br>(plasm<br>a) 5.8-<br>6.2<br>ng/L<br>(whole<br>blood) | 4.4-8.4<br>ng/L<br>(plasm<br>a)<br>5.8-6.2<br>ng/L<br>(whole<br>blood) | Overall<br>N=789<br>F: 391<br>M: 398               | EDTA<br>whole<br>blood or<br>plasma   | Overall<br>20.5<br>ng/L<br>F: 14.4<br>ng/L<br>M: 25.7<br>ng/L |
| Siemens<br>Atellica<br>VTLi <b>hs-cTnl</b>                                | 0.55<br>ng/L  | 1.2<br>ng/L<br>(plasm<br>a)<br>1.6<br>ng/L<br>(whole<br>blood)         | 6.5%<br>(plasma<br>) 6.1%<br>whole<br>blood at<br>22 ng/L                                     | 2.1<br>ng/L<br>(plasm<br>a) 3.7<br>ng/L<br>(whole<br>blood)             | 6.7 ng/L<br>(plasm<br>a) 8.9<br>ng/L<br>(whole<br>blood)               | Overall<br>N=694<br>F: 331<br>M:363                | Li-Hep<br>whole<br>blood<br>and<br>plasma,<br>capillary<br>blood            | Overall<br>22.9<br>ng/L<br>F: 18.5<br>ng/L<br>M 27.1<br>ng/L  |

**Table 5.** Available high sensitivity cardiac troponin devices for EMS, which are available on the EU market anno 2023. The first three analyzers are hand-held, whereas the Triage True analyze represents a small portable analyzer.

| Company/<br>Platform /<br>Assay                       | LoB<br>(ug/L)   | LoD<br>(ug/L)  | % CV at<br>99 <sup>th</sup><br>Perc   | Conc at<br>20% CV<br>(ug/L)   | Conc at<br>10%<br>CV<br>(ug/L)   | Referenc<br>e<br>Populatio<br>n N,<br>Ages,<br>Sex | Specime<br>n Type  | 99 <sup>th</sup><br>Percentil<br>e<br>Cut offs                 |
|---|---|--|---|---|--|--|--|--|
| Abbott-<br>i-STAT<br><br>hs-cTnl                      | 0.57<br>ng/L<br>(plasma<br>) 0.78<br>ng/L<br>(whole<br>blood)       | 1.05<br>ng/L<br>(plasma<br>) 1.61<br>ng/L<br>(whole<br>blood)          |   | 3.70<br>ng/L<br>(plasma<br>) 6.88<br>ng/L<br>(whole<br>blood)       |  | Overall<br>N=895<br>F: 490<br>M: 404               | Li-Hep<br>whole<br>blood<br>and<br>plasma                        | Overall<br>21 ng/L<br>F: 13<br>ng/L<br>M 28<br>ng/L            |
| Axonlab<br><br>Atellica<br>VTLi<br><br>hs-cTnl *      | 0.55<br>ng/L  | 1.2 ng/L<br>(plasma<br>)<br>1.6 ng/L<br>(whole<br>blood)               | 6.5%<br>(plasma<br>) 6.1%<br>whole<br>blood<br>at 22<br>ng/L                                  | 2.1 ng/L<br>(plasma<br>) 3.7<br>ng/L<br>(whole<br>blood)            | 6.7 ng/L<br>(plasma<br>) 8.9<br>ng/L<br>(whole<br>blood)               | Overall<br>N=694<br>F: 331<br>M:363                | Li-Hep<br>whole<br>blood<br>and<br>plasma,<br>capillary<br>blood | Overall<br>22.9 ng/L<br>F: 18.5<br>ng/L<br>M 27.1<br>ng/L      |
| QuidellOrtho<br><br>Triage<br>MeterPro<br><br>hs-cTnl | 0.4 ng/L<br>(plasma<br>)<br><br>0.5-0.8<br>ng/L<br>(whole<br>blood) | 0.7-1.6<br>ng/L<br>(plasma<br>)<br>1.5-1.9<br>ng/L<br>(whole<br>blood) | 5-5.9%<br>at 21<br>ng/L<br>(plasma<br>)<br>5.9-<br>6.5^%<br>at 22<br>ng/L<br>(whole<br>blood) | 2.1-3.6<br>ng/L<br>(plasma<br>) 5.8-6.2<br>ng/L<br>(whole<br>blood) | 4.4-8.4<br>ng/L<br>(plasma<br>)<br>5.8-6.2<br>ng/L<br>(whole<br>blood) | Overall<br>N=789<br>F: 391<br>M: 398               | EDTA<br>whole<br>blood or<br>plasma                              | Overall<br>20.5 ng/L<br><br>F: 14.4<br>ng/L<br>M: 25.7<br>ng/L |

LoB, limit of blank; LoD, limit of detection; CV, coefficient variation; Perc, percentile; M, male, F, female; Conc, concentration; . All data have been listed as provided by the manufacturer

\* As of Q2 2026, siemens will discontinue its healthcare division, and the Atellica system will no longer be available on the Dutch market

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