

Review

Using Pragmatic Research Methods to Address a Global Pandemic: Lessons Learned from NACMI

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Abstract

The COVID-19 pandemic presented a unique opportunity for researchers to use pragmatic methods to obtain information about the virus and promptly disseminate the findings for healthcare providers to utilize them. One such approach to studying patients who presented with COVID-19 and ST-Elevation Myocardial Infarction (STEMI) was the development of the North American COVID-19 STEMI (NACMI) registry. By leveraging social media and communication platforms such as WhatsApp, cardiologists across North America initiated the development of the NACMI registry within 14 days—an accomplishment which was unfathomable pre-pandemic. This was followed by ethics approval through a centralized Institutional Review Board, which led to patient consent being waived, and the use of a single coordinating center (Minneapolis Heart Institute Foundation) responsible for sites, database, and analysis. The NACMI findings were published rapidly across various media, including high-profile cardiovascular journals. Early results demonstrated an elevated mortality rate, disproportionality based on race, and angiographic differences showing unique mechanistic differences in the etiology of STEMI due to COVID-19. Additionally, NACMI provided early evidence that vaccination for COVID-19 reduced the risk of mortality in those with COVID-19 and STEMI. NACMI provided a framework for informing cardiologists early on regarding the optimal treatment of STEMI in patients with COVID-19. The lessons learned may be valuable for developing policy in future pandemics to treat patients using real-world application and routinely collected variables.

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1. Introduction

The coronavirus 2019 (COVID-19) pandemic exposed gaps in healthcare services for cardiovascular patients, including those with ST-segment elevation myocardial infarction (STEMI). Elective cardiovascular procedures were canceled or postponed; cardiac catheterizations, including primary percutaneous coronary intervention (PCI) for STEMI, decreased substantially; and time to treatment times were increased as compared to before the pandemic [1,2]. COVID-19 predisposes patients to a prothrombotic state, with excess inflammation (including occasionally a “cytokine storm”), endothelial dysfunction, and platelet activation, alongside the downregulation of anticoagulants, leading to poor prognosis [3]. An angiographic study of patients with COVID-19 and STEMI found that high thrombus burden was pervasive in these patients, leading to higher rates of unsuccessful PCI and higher mortality rates [4].

As COVID-19 spread at unprecedented rates, there was a worldwide requirement for collaboration to find solutions and treatments for these patients. To address this need, the Society for Cardiovascular Angiography and Interventions (SCAI) and The Canadian Association of Interventional Cardiology (CAIC) in conjunction with the American College of Cardiology Interventional Council collaborated to create a multicenter observational registry, termed the North American COVID-19 STEMI (NACMI) registry, to enroll patients with STEMI from multiple sites in North America [5]. In this review, we highlight the findings from NACMI to identify the research success, challenges, and adjustments needed in the face of a potential future pandemic.

2. Collaboration

The high transmission and worldwide mortality rates for patients with COVID-19 and STEMI dictated a collaborative effort to understand the overall risk to patients and healthcare workers and to implement diagnostic and treatment strategies in the midst of a pandemic. Immediate pragmatic measures included waivers of patient consent and uniform ethics applications and forms through a centralized Institutional Review Board, thus providing a framework for expedited enrollment at multiple sites in North America. A single center (Minneapolis Heart Institute Foundation) was responsible for coordinating sites, database, and analysis [5]. The use of a clinical registry provided the flexibility to address urgent needs in a cost-effective manner, even when utilizing an international, multicentered approach [6]. The use of registries reduces cost by allowing for remote data acquisition and entry, increasing feasibility and reducing resource requirements, ultimately allowing for the timely dissemination of data [6].

In March of 2020, social media reports highlighted several unique aspects of COVID-19-related STEMI. In contrast to an expected increase in STEMI volume, there appeared to be an apparent decline in STEMI activations, so-called “missing STEMIs”. In addition, when patients were taken to the cardiac catheterization lab, there appeared to be an increased frequency of patients with no clear culprit artery, a phenomenon known as Myocardial Infarction with Non-Obstructive Coronary Arteries (MINOCA). A report of STEMI activations for nine high-volume cardiac catheterization laboratories in the United States from 1 January 2019 to 31 March 2020 confirmed that there was a 38% reduction in US cardiac catheterization laboratory visits during the early phase of the pandemic [7]. Although the exact cause was unclear, it appeared to be related to the reluctance of patients to seek medical care and caution by both patients and healthcare workers about contacting COVID-19, thus stimulating discussion about appropriate reperfusion strategies during the early pandemic [1,8]. This led to an urgent expert manuscript in collaboration with the Society for Cardiovascular Angiography and Interventions (SCAI), the American College of Cardiology (ACC), and the American College of Emergency Physicians (ACEP) on the

management of acute myocardial infarction during the COVID-19 pandemic [9]. This position statement provided guidance pertaining to the varied clinical presentations of patients with STEMI during the pandemic, the appropriate personal protection equipment for healthcare workers, the role of the cardiac catheterization laboratory and Emergency Departments during the pandemic, and the regional STEMI systems of care, with the clear recommendation that primary PCI remain the standard of care for STEMI [9].

In April 2020, these findings stimulated discussions among SCAI leadership, as well as 93 members in a CAIC cardiologist WhatsApp group from Canada and 49 members in a SCAI Emerging Leader Mentorship current and former Fellow group representing most of the United States [5]. The development of steering and subcommittees, support from CAIC and the ACC interventional council, and the sharing of knowledge via Twitter (#CardioTwitter) from eligible centers were all completed within 14 days [5]. This highlights that pragmatic registries, such as NACMI, can be swiftly developed, and their dynamic nature can provide ongoing data to clinicians in the face of a pandemic (Figure 1). The initial findings from NACMI, which were presented in October 2020 at Transcatheter Cardiovascular Therapeutics (TCT) within 6 months of initiating the registry, illustrate how quickly data can be disseminated when utilizing a registry [10]. In 6 months, 56 sites across North America were able to actively enroll 230 patients with COVID-19 and STEMI. These patients with COVID-19 and STEMI had unique presentations and exhibited a 7-fold higher mortality rate compared to matched pre-COVID-19 patients [11]. Additionally, longer time to treatment times, differences in clinical presentation, and the reduced likelihood of receiving invasive angiography in comparison to controls were key early findings from NACMI that were applied to clinical practice [11].

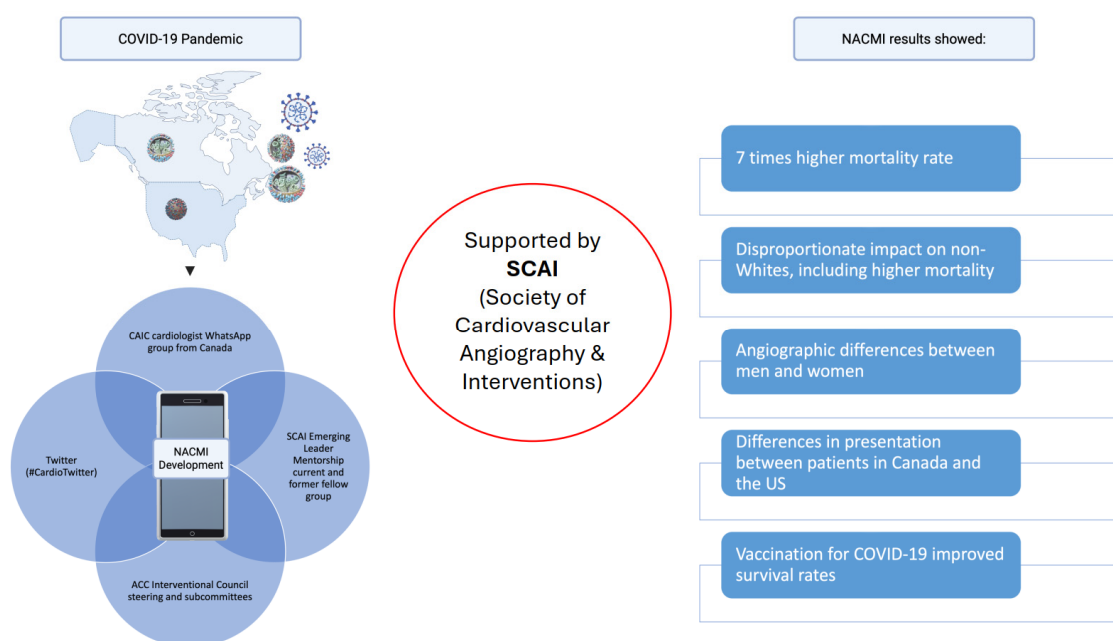


Figure 1. Overview of NACMI Development and Findings.

While WhatsApp and CardioTwitter enabled the real-time global sharing of NACMI findings, this speed often bypasses peer review, risking an “infodemic” of preliminary or decontextualized information [12]. Future registries may benefit from structured rapid communication channels that preserve this speed while improving verification and coordination. NACMI’s 14-day launch enabled real-time pandemic data capture, and it also produced operational challenges instructive for future registries. Sites joined on a staggered, voluntary basis with variable capacity to submit core laboratory materials, potentially bi-

asing sub-cohorts toward the earliest, most severely affected patients. Harmonization was also imperfect: given inconsistent COVID-19 test turnaround early on, “person under investigation” status was left to local hospital discretion, which potentially introduced cross-site classification heterogeneity. In addition, several key variables such as vaccination status, antithrombotic therapy, and ischemic/transfer times were not captured from inception and required later amendments, leaving the opportunity for missing variables. These experiences point to practical lessons for future pandemic registries: it is necessary to define a mandatory harmonized core dataset from the outset, centrally adjudicate key case definitions, and build pre-planned mechanisms to capture emerging exposures as they arise.

3. Equity in Healthcare

COVID-19 disproportionately affected non-Whites, in particular Blacks and Hispanics, with higher morbidity and mortality [11,13–15]. Only 54% of patients enrolled in NACMI were White [15]. Racial and ethnic differences were notable when comparing access to treatment, with a much higher prevalence of Black and Hispanic patients than typical for a STEMI population and with higher mortality [16]. Comparably, of the patients in NACMI, it was found that minority groups were more likely to have infiltrates on chest X-ray and cardiomegaly, pointing to a potential difference in illness; thus minority groups were less likely to have coronary angiography performed, as compared to Whites [11,13,15]. Among patients that underwent angiography, Whites and Hispanic/Latinx patients were more likely to be treated with primary PCI. The higher mortality in minority groups was an important early insight from NACMI [11,15]. Over time, as the pandemic evolved, Caucasians became the predominant ethnic group in NACMI, similarly to pre-pandemic North American STEMI registries [13].

Whilst the disparities may reflect a combination of inequitable healthcare access, higher comorbidity burden, and structural/socioeconomic determinants of health, NACMI is currently limited in the ability to distinguish these factors from differences in underlying pathophysiology or comorbidity burden [17,18]. NACMI’s lower rate of angiography and PCI among Black and Hispanic patients, despite comparable illness severity, suggests differential access to care as a contributing factor. However, NACMI did not collect granular socioeconomic or structural data, and the relative contribution of these pathways could not be directly adjudicated within the registry.

Sex differences are also notable from NACMI. Men more frequently presented with chest pain and women with dyspnea [19]. Additionally, women presenting with a STEMI were more likely to have MINOCA, and therefore PCI was performed less frequently in women, and medical therapy was utilized more often [19]. These findings were later confirmed using core-lab-identified angiograms, demonstrating that men were more likely to have multiple culprits and women were more likely to have no clear culprit [4]. This provided insights into the underlying pathophysiology of COVID-19, and STEMI in women differs in comparison to men.

The ability to evaluate variations in patient care was possible due to the international, multicenter nature of NACMI. Canadian patients more often presented with chest pain and carried a lower comorbidity burden, while US patients showed more advanced baseline illness [20]. Despite this, primary PCI remained dominant in both countries with similar door-to-balloon times and no difference in adjusted mortality, though US patients were less likely to receive fibrinolysis and more often managed medically after angiography, potentially reflecting differences in triage thresholds or the two countries’ distinct health system structures [11,13,16,20]. This comparable mortality across structurally different systems suggests that both countries’ pre-pandemic STEMI networks were resilient enough

to buffer against an additional pandemic-specific gap [20,21], though the small Canadian sample (13% of the cohort) limits this comparison's precision.

4. Assessments of Treatment Approaches

As the pandemic developed and mortality figures increased worldwide, multiple mortality risk scores were developed for patients with severe COVID-19. The data collected from NACMI provided the foundation for developing a risk score specifically for patients with COVID-19 and STEMI [22]. The NACMI risk score used routinely collected variables, allowing for immediate use and application for patients with COVID-19 and STEMI, with no resource utilization. The key variables included cardiogenic shock, elevated respiratory rate, poor oxygen saturation, older age, infiltrates on chest X-ray, and comorbidities [22]. The treatment of cardiogenic shock in patients with MI often includes the use of mechanical circulatory support (MCS). In patients with STEMI and COVID-19, the need for MCS was associated with higher in-hospital mortality in comparison to those with MCS without COVID-19 [21]. STEMI patients with COVID-19 more frequently presented with respiratory complications and therefore more frequently required extracorporeal membrane oxygenation (ECMO) in comparison to those using MCS without COVID-19 from NACMI [21]. COVID-19 patients without STEMI or cardiogenic shock had a significant increase in the need for ECMO due to respiratory failure, creating severe resource utilization challenges [21].

To treat an ever-growing problem like the COVID-19 pandemic, collaborative efforts across all sectors, including academia, industry and healthcare, at unparalleled rates were required [23]. One such approach was the development of COVID-19 vaccines. From the NACMI registry, we quickly observed a decrease in mortality following vaccine utilization [13]. In fact, we found zero in-hospital mortality in patients who had been vaccinated for COVID-19 [13]. Additionally, the worldwide impact of vaccines was noted in both the US and Canada, in that vaccination was strongly associated with a lower risk of in-hospital mortality [20]. These important NACMI findings were collected rapidly, allowing for quick dissemination through peer-reviewed journals much faster than pre-pandemic registries [6].

5. Advancement of Science Through Mechanistic Insights

The NACMI registry provided a unique opportunity to gain understanding into novel physiological mechanisms regarding both the increased rate of STEMI, the high mortality rate with COVID-19 and the higher prevalence of MINOCA. Based on external pathological and mechanistic studies, it has been hypothesized that COVID-19 leads to a hyper-inflammatory state and prothrombotic milieu that contributed to the higher mortality [3,24]; NACMI itself was not designed to test this mechanism directly, but its angiographic findings were consistent with it. The first angiographic core-lab (Cardiovascular Imaging Research Core Laboratory (CIRCL), Vancouver, Canada)-controlled study of patients with COVID-19 and STEMI came from NACMI, which confirmed that the angiographic features of these patients were unique with respect to historical control patients with STEMI [4]. Specifically, excess thrombus and multiple culprits on presentation led to poor TIMI flow and perfusion, even following PCI [4]. In fact, using classic definitions, one-third of patients with COVID-19 and STEMI had an unsuccessful PCI [4]. Another important finding was the higher incidence of MINOCA. These NACMI angiographic observations are consistent with, though were not designed to directly confirm, findings from concurrent external pathological studies showing that COVID-19 patients have microvascular thrombi, a unique pathophysiological mechanism with COVID-19 [24]. Typically, no reflow in STEMI patients is due to distal embolization, but in the case of patients with

STEMI and COVID-19, it becomes clear that the problem began with microvascular thrombi leading to delayed outflow and ultimately leading to microvascular dysfunction. This is a hallmark of Long COVID [24]. While our results were consistent with this hypothesis, NACMI did not include intracoronary imaging or long-term post-discharge mechanistic follow-up to confirm it.

A NACMI substudy collected ECG at presentation to better understand the impact of the degree of ST-elevation as a predictor of hospital survival [25]. These ECGs were sent to a core laboratory (Canadian VIGOUR Centre, Edmonton, Canada) with the goal of obtaining additional mechanistic insights into the culprit vessels in these patients. The extent of ST-segment elevation (deviation) was shown to be associated with in-hospital mortality, and it was in fact a stronger predictor of in-hospital mortality than coronary angiography [25]. The methods from NACMI have been expanded to non-STEMI patients with COVID-19. These NSTEMI patients also exhibited high thrombus burden and LV dysfunction, with fewer culprit lesions identified on angiogram. Their outcomes also mirrored the NACMI population, with higher mortality and more frequent unsuccessful revascularization [26]. By providing a strong mechanistic understanding of patients with COVID-19 and STEMI, NACMI allowed for improved prognosis, better treatment modalities, and immediate triaging for future pandemics.

6. Summary of Lessons Learned and Recommendations for Future Preparedness

The COVID-19 pandemic has provided an opportunity for healthcare systems to re-evaluate their preparedness to deal with potential future excess resources strains. Of the key findings, immediate collaboration using feasible and practical methods, such as clinical registries, and unified ethics boards can provide a vehicle for accelerated knowledge sharing, with insights into treatment via a new and unique collaboration [1,4,9,11,13]. In addition, racial minorities were disproportionately affected, in terms of both mortality and the type of treatment they receive, despite the absence of additional high-risk features [15]. Finally, the excess mortality in COVID-19 patients with STEMI extended beyond the index hospitalization. Patients with COVID-19 and STEMI have an elevated 1-year mortality rate compared to those without COVID-19, even when considering only those who survived the index hospitalization [27]. As such, NACMI provides a framework for informing policy in the face of future pandemics in regard to racial/ethnic discrepancies in management and outcomes in those affected.

Women and men in NACMI presented differently and had different angiographic patterns [19]. Therefore, NACMI identified gaps in care based on racial and ethnic differences, sex differences, and the compounding of thrombus from the presence of COVID-19 [5]. These findings can be used to develop tailored treatment options and emergency response plans for vulnerable populations. Finally, when considering the continuity of care and treatment modalities, outcomes are similar across both Canada and the US; however, there are differences in clinical presentation [20]. By understanding the unique demographics and symptoms of patients with COVID-19 and STEMI, NACMI informed the development of clinical guidelines and best-practice management using data from centers across North America [9].

Despite the strength of the design of the NACMI registry, there were challenges and limitations that are worthy of discussion (Table 1). First, NACMI did not have any independent event adjudication. Whilst the ECG and angiographic core labs were both adjudicated, NACMI relied on site-reported outcomes and diagnoses, which creates the potential for site-to-site variability in how outcomes such as cardiogenic shock and reinfarction were defined. Second, the core lab ECG and angiographic sub-cohorts are not

representative of the full registry as they are skewed toward 2020, leading to a population with lower vaccination rates, and excluded those unstable for imaging. Third, the lack of pre-hospital data regarding total ischemic and transfer times for patients presenting to a non-PPCI hospital limits the ability to separate a healthcare system delay from disease severity as a cause of poor outcomes, as delayed symptom–hospital presentation may act as a contributor to worse outcomes [11,13]. Fourth, the estimates of D2B time may be inaccurate due to atypical presentations (such as dyspnea instead of chest pain) that could not be timed to STEMI onset, which can underestimate true total ischemic time. Fifth, as viruses continue to evolve throughout the course of a pandemic, future studies should ensure this information is captured to understand how their evolution impacts clinical characteristics [13]. Finally, the general limitations of research associated with multi-site, observational, non-randomized registry designs, such as non-causal inferences, selection bias, and decentralized data entry without independent source data verification via auditing or data quality checks, all contribute to NACMI limitations.

Table 1. NACMI registry lessons learned, strategies, and recommendations.

Domain	Key Takeaways from NACMI	Strategy Implemented During COVID-19	Recommendation for Future Registries
Rapid activation and governance	Multinational registry was developed within 14 days, demonstrating that pandemic-scale research is operationally feasible	Investigator-initiated collaboration across 3 societies (SCAI, CAIC, ACC) with expedited local IRB approval at each of 64 sites	Provide multi-institutional ethics and data-sharing agreements before the next emergency, so activation time is expedited
Data harmonization	Cross-site heterogeneity in case definitions (“person under investigation” status left to local discretion) limited comparability	Standardized REDCap data collection forms modeled on ACC NCDR definitions	Define a mandatory, harmonized core dataset from inception (vaccination, transfer/ischemic times, pathogen variant); centrally adjudicate key case definitions
Racial/ethnic and sex-based disparities	Minorities experienced disproportionate mortality and differential treatment despite similar risk profiles; men and women showed distinct angiographic patterns	Descriptive reporting of race, ethnicity, and sex within registry analyses	Systematically capture race/ethnicity/sex variables from the outset alongside structural/socioeconomic context to support equitable risk stratification and resource planning
Mechanistic insight	Core laboratory analyses revealed a COVID-specific thrombotic/microvascular phenotype distinct from typical STEMI	Independent, blinded ECG (Canadian VIGOUR Centre) and angiographic (CIRCL) core laboratories	Build core laboratory adjudication into the registry design to maximize enrollment rather than a select subset of patients
Accelerated knowledge dissemination	Findings reached a global clinical audience within days via WhatsApp, CardioTwitter, and other informal networks	Organic, unstructured dissemination through clinician social media use	Formally integrate social media into the research network’s design (e.g., designated communications liaison, structured internal verification paired with swift posting, co-dissemination via official society channels) to preserve speed while reducing infodemic risk

Table 1. *Cont.*

Domain	Key Takeaways from NACMI	Strategy Implemented During COVID-19	Recommendation for Future Registries
International/system-level comparison	Similar mortality was observed across two structurally distinct health systems despite differing baseline risk and reperfusion patterns	Multinational enrollment across 64 US and Canadian sites	Expand international enrollment to capture organizational/system-level variation and support cross-system policy comparison
Long-term outcomes	Excess mortality persisted to 1-year post-discharge, beyond what in-hospital data alone captured	In-hospital-outcome-focused data collection	Prospectively build post-discharge follow-up into the registry protocol at inception

Taken together, evidence from NACMI suggests several practical principles for future pandemic-era collaborative registries: (1) provide multi-institutional ethics and data-sharing agreements for quick and timely activation; (2) define a mandatory, harmonized core dataset from inception, including pre-hospital times, vaccination status, and pathogen variant; (3) systematically capture race, ethnicity, and sex-specific variables to enable equitable risk stratification; (4) centrally adjudicate key case definitions rather than deferring to local discretion; (5) formally integrate social media and informal communication channels into the research network's design by designating a communications liaison role within the consortium and pairing rapid dissemination with structured internal verification before public release; and (6) prospectively capture post-discharge outcomes, since in-hospital data alone may underestimate true disease burden.

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Abbreviations

The following abbreviations are used in this manuscript:

PCI	percutaneous coronary intervention
STEMI	ST-segment elevation myocardial infarction

SCAI	Society for Cardiovascular Angiography and Interventions
CAIC	Canadian Association of Interventional Cardiology
NACMI	North American COVID-19 STEMI
MINOCA	Myocardial infarction with non-obstructive coronary arteries
ACC	American College of Cardiology
ACEP	American College of Emergency Physicians
TCT	Transcatheter Cardiovascular Therapeutics
MCS	Mechanical circulatory support
ECMO	Extracorporeal membrane oxygenation

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