National
Cardiogenic Shock Initiative

Version 3.0
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Henry Ford Health System

National Cardiogenic Shock Initiative (NCSI, National CSI)

STUDY SPONSOR:

Henry Ford Health System
2799 W. Grand Blvd.
Center for Structural Heart Disease - CFP # 439
Detroit, Michigan 48202
(313) 916-8708
NationalCSI@hfhs.org

PRINCIPLE INVESTIGATOR:

William W. O'Neill, MD, FACC, FSCAI
Henry Ford Health System
2799 W. Grand Blvd.
Center for Structural Heart Disease - CFP # 439
Detroit, Michigan 48202
(313) 916-8708

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Introduction

Acute myocardial infarction complicated by cardiogenic shock (AMICS) is a deadly condition with a historical in-hospital survival of only 50%[1-3]. To date, the only therapy proven to benefit patients in AMICS using data from randomized control trials has been early mechanical reperfusion[3]. Accordingly, current American and European guidelines confer a class IB indication for reperfusion therapy in the setting of AMICS[4]. Unfortunately, little progress has been made on improving survival with subsequent therapies, including intra-aortic balloon pump counter-pulsation (IABP) [5]. This lack of progress is worrisome since the incidence of AMICS appears to be increasing[6-7].

With the FDA approval of Impella (Abiomed, Danvers, MA) in AMICS, a powerful new tool has become available for hemodynamic support. Impella is a transcatheter axial flow pump, delivered percutaneous, with the ability to provide 2.5 to 4.0 liters/minute of forward flow. The device should provide sufficient forward cardiac flow to support vital organs in the majority of patients who present with AMICS. Since Impella is the only percutaneous temporary ventricular support device approved as safe and effective for use in AMICS, the use of the device has steadily grown[8]. Unfortunately, there is little data available to providers as to the best practice patterns associated with the delivery and use of Impella in AMICS. In fact, a retrospective analysis of 15,259 patients treated with an Impella between 2009 and 2017 revealed a wide variety of outcomes associated with the use of Impella in AMICS, with approximately one third of hospitals having a survival rate of 25%, another third of hospitals having a survival rate of 50%, and yet another third of hospitals having a survival rate of 75%.

In the summer of 2016, cardiologists from four highly competitive healthcare systems in southeast Michigan came together in an attempt to increase survival in patients who present with

AMICS. Leaders from each healthcare system debated and discussed key elements in the improvement of care for patients who present with AMICS. Using the most up-to-date research, a treatment algorithm for AMICS was developed and subsequently implemented as a quality improvement initiative throughout southeast Michigan. Patient information was gathered by each of the sites and collected in a retrospective registry. Outcomes and results were shared during quarterly meetings and concluded with a 41-patient pilot feasibility study. This initial pilot study revealed a 76% survival to discharge, a significant improvement compared to prior historical controls[9].

Given the promising outcomes, leaders from around the world have implemented the treatment algorithm in their local clinical practices with similar results. We have therefore launched the National Cardiogenic Shock Initiative (NCSI). The aim of the NCSI is to bring together experienced centers across the nation who are experts in mechanical reperfusion therapies and have a large experience with the use of mechanical circulatory support devices to systematize care in AMICS. Our goal is to dramatically decrease the duration patients remain in cardiogenic shock and attempt to decrease total usage and duration of vasopressors and ionotropic agents. We aim to further demonstrate that rapid delivery of mechanical circulatory support will improve hemodynamics, reverse the spiraling neuro-hormonal cascade associated with cardiogenic shock, allowing clinicians to decrease use of vasopressors and inotropic agents and ultimately improve survival.

Healthcare systems that have agreed to adopt the NCSI treatment algorithm are being asked to participate in this prospective registry so that patient outcomes can be analyzed (see Appendix 2). Participating investigators will be asked to voluntarily provide data from patients completing the treatment algorithm to be included in the NCSI Registry.

Research Procedures

After a patient has been treated according to the NCSI treatment algorithm at the discretion of their physician (see Appendix 1), they will be approached prior to discharge and asked to participate in NCSI registry, including obtaining permission to allowing coordinators to conduct a 1-month and 1-year follow-up. This data collection can occur via follow up phone call, electronic chart review, or any other method that complies with the site's SOPs. If the patient is discharged prior to obtaining consent, consent form and explanation of the study can be mailed to the patient for their signature and return. If more than one (1) year has passed, all data may be obtained retrospectively.

If consent is provided, then the following data will be collected (see case report form - Appendix 3):

Retrospective Data (from their medical records)

- Medical history
- Admission characteristics
- Procedure dates and times
- Procedure characteristics
- Diagnostic values
- Post-procedure information

Prospective Data (from follow-up) (see Appendix 5 and Appendix 6)

- Mortality at 1 month from AMICS
- Mortality at 12 months from AMICS

From this data, the following Quality Metrics will be tracked:

- Discharge survival
- Duration of shock-to-support times

- Use of Impella Support pre-PCI
- Use of right heart catheter for hemodynamic monitoring
- Attainment of TIMI III flow post reperfusion
- Attainment of Cardiac power > 0.6 watts after completion of therapy
- Reduction or elimination of vasopressors and inotropic agents.

Population and Eligibility Criteria

Due to the heterogeneous cohort of patients who present with AMICS, we have defined a specific subset of patients from whom outcomes are to be collected. Approximately 500 adult patients will be approached to participate in the registry at approximately 75 sites in the United States. The duration of hospital participation in this research study is anticipated to be approximately 3 years.

Registry Inclusion Criteria

1. Symptoms of acute myocardial infarction (AMI) with ECG and/or biomarker evidence of S-T elevation myocardial infarction (STEMI) or non-S-T elevation myocardial infarction (NSTEMI)
2. Cardiogenic shock is defined as the presence of at least two of the following:
    a. Hypotension (systolic blood pressure ≤90 mm Hg, or inotropes/vasopressors to maintain systolic blood pressure ≥90 mmHg)
    b. Signs of end organ hypoperfusion (cool extremities, oliguria or anuria, or elevated lactate levels)
    c. Hemodynamic criteria represented by a cardiac index of <2.2 L/min/m^2 or a cardiac power output ≤0.6 watts.

3. Patient is supported with an Impella
4. Patient undergoes PCI

Registry Exclusion Criteria

1. Evidence of Anoxic Brain Injury
2. Unwitnessed out of hospital cardiac arrest or any cardiac arrest in which return of spontaneous circulation (ROSC) is not achieved within 30 minutes
3. IABP placed prior to Impella
4. Septic, anaphylactic, hemorrhagic, and neurologic causes of shock
5. Non-ischemic causes of shock/hypotension (pulmonary embolism, pneumothorax, myocarditis, tamponade, etc.)
6. Active bleeding for which mechanical circulatory support is contraindicated
7. Recent major surgery for which mechanical circulatory support is contraindicated
8. Mechanical complications of AMI (acute ventricular septal defect (VSD) or acute papillary muscle rupture)
9. Known left ventricular thrombus for which mechanical circulatory support is contraindicated
10. Mechanical aortic prosthetic valve
11. Contraindication to intravenous systemic anticoagulation

Risks/Benefits of and Alternatives to Patient Participation

This is not a treatment study. This is a single-arm prospective registry that captures data generated during procedures which are considered standard of care using FDA-approved technology. There are no risks other than breach of confidentiality. To mitigate this risk, patient identifiers are not being captured, and all data will be stored in a secure REDCap database

(please see below). There are no benefits in participation other than the scientific knowledge gained, and the only alternative to participation is not participating.

Data Management

Data collected by the participating sites will be stored and managed in a secure REDCap study database hosted through the Henry Ford Health System Department of Public Health Sciences in Detroit, Michigan. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies. A specific database was created solely for NCSI in September 2017. The REDCap database that was custom-built for this study includes only the specific data fields that pertain to the data points being collected in the study, which are present on the case report form (CRF) (see Appendix 3).

For patients who present to affiliated hospitals with AMICGS but are excluded from entry into the registry, a Patient Exclusion Form will be sent to track the reasons for exclusion (see Appendix 4).

The CRFs and Patient Exclusion Forms from an individual site will be transmitted to the lead site, Henry Ford Hospital, via secure email and accessed only on hospital-approved, password-protected computers and stored on a password-protected and encrypted OneDrive system by Microsoft. Access to the OneDrive system and the REDCap database will be managed at the lead site by the NCSI coordinator and the investigators of the study via hospital-approved, password-protected computers inside locked offices in Henry Ford Hospital.

Access to Patient Information

The following will have access to the de-identified patient medical information, and any necessary research contracts and Data Use Agreements will be completed for each participating site.

Henry Ford Hospital – Detroit, Michigan:

- The NCSI team:
    - PI
    - Co-Investigator
    - NCSI Coordinator
    - Research Nurse
    - Research Assistant
    - Data Coordinator
- Statistician, based at Henry Ford Hospital

Analysis and Publication of Data

There will be planned interim analysis of the data for the purpose of presentation as well as a final analysis and submission for publication of all data at the end of the study enrollment and follow-up.

References

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5. Thiele H., Zeymer U., Neumann F.J., et al.(2012) Intraaortic balloon support for myocardial infarction with cardiogenic shock. N Engl J Med 367:1287–1296

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7. Killip, T., & Kimball, J. T. (1967). Treatment of myocardial infarction in a coronary care unit: a two year experience with 250 patients. *The American journal of cardiology*, *20*(4), 457-464.

8. Stretch R, Sauer C.M., Yuh D.D., Bonde P.(2014) National trends in the utilization of short-term mechanical circulatory support: incidence, outcomes, and cost analysis. J Am Coll Cardiol 64:1407–1415.

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APPENDIX 1

NSCI Treatment Algorithm

1. Confirmation of AMI Shock

The diagnosis of AMI is confirmed by electrocardiographic changes indicative of new or presumed new ischemia (new ST-T wave changes), detection of elevated cardiac biomarkers or angiographic findings of an infarct related artery on coronary angiogram in the presence of ischemic symptoms.

Cardiogenic shock is defined as the presence of at least two of the following:

1. Hypotension (systolic blood pressure ≤90 mm Hg, or inotropes/vasopressors to maintain systolic blood pressure ≥90 mmHg)
2. Signs of end organ hypoperfusion (cool extremities, oliguria or anuria, or elevated lactate levels)
3. Hemodynamic criteria represented by a cardiac index of <2.2 L/min/m^2 or a cardiac power output ≤0.6 watts.

2. Access, Baseline Invasive Hemodynamics

Due to the heterogeneous cohort of patients who present with AMICS, any diagnostic steps to ensure the presence of AMI or CS are left to the discretion of the primary operator (ie: timing of right heart catheterization, coronary angiogram and placement of MCS). We do recommend obtaining femoral access to ensure adequate vessel size for MCS. If a right heart catheterization has not been performed prior to MCS placement we recommend measuring a LVEDP prior to placement of MCS. In the event a LVEDP ≤15 mmHg, an alternate diagnosis should be suspected and right heart catheterization should be performed prior to MCS to confirm presence of cardiogenic shock. Following placement of large-bore access and administration of systemic anticoagulation an Impella catheter will be inserted and manipulated to obtain maximum

forward flow. Right heart catheterization (RHC) will be performed for calculation of cardiac power output (CPO), SVR and PCWP/RA ratio and pulmonary artery pulsatility index (PAPi), during the index procedure.

3. Intervention

PCI of the culprit lesion(s) should be performed, per national recommendations. We recommend against non-culprit PCI unless flow is impaired in the involved artery (ie. less than TIMI 3 flow and excluding chronic total occlusions); however the ultimate decision of multi-vessel PCI lies with primary operator. PCI can be performed with thrombectomy if a heavy thrombus burden is present. Once appropriately sized stents have been implanted angiography will be performed to assess TIMI flow. If TIMI III flow is not present, intracoronary vasodilatory should be administered at the discretion of the primary operator.

Prior to discharge from the cath lab, a formal neurovascular check should be performed for assessment of Impella-related limb ischemia. This can be performed either by an in-depth physical examination, peripheral angiogram, or lower extremities doppler studies. If signs of limb ischemia are noted, the peel-away sheath should be removed (if not already done so) with reassessment. If limb ischemia persists, antegrade access should be performed to provide distal lower extremity blood flow.

4. Post-PCI Hemodynamics

After the intervention is completed, right heart pressures, cardiac output, and CPO will be obtained. If CPO is > 0.6, no further intervention is required. If CPO is ≤ 0.6, right heart pressure will be reviewed to identify evidence of right ventricular failure if present (PAPi < 0.9).

If evidence of right ventricular failure are present (PAPi < 0.9), or if the Impella is suctioning, operators should consider right ventricular support with commercially available devices (Impella or Tandem Heart). Irrespective of CPO, evidence of RV shock is a warning not

to increase alpha agonists. These agents dramatically increase pulmonary vascular resistance (PVR) at a time of minimal RV reserve and can cause a lethal spiral as increasing doses of alpha agonists to maintain arterial pressure leads to decrease forward RV flow and worsens hypotension.

If CPO < 0.6 persists and RV shock is not the cause, consideration for the placement of an Impella 5.0 or a durable left ventricular assist device (LVAD) should be considered.

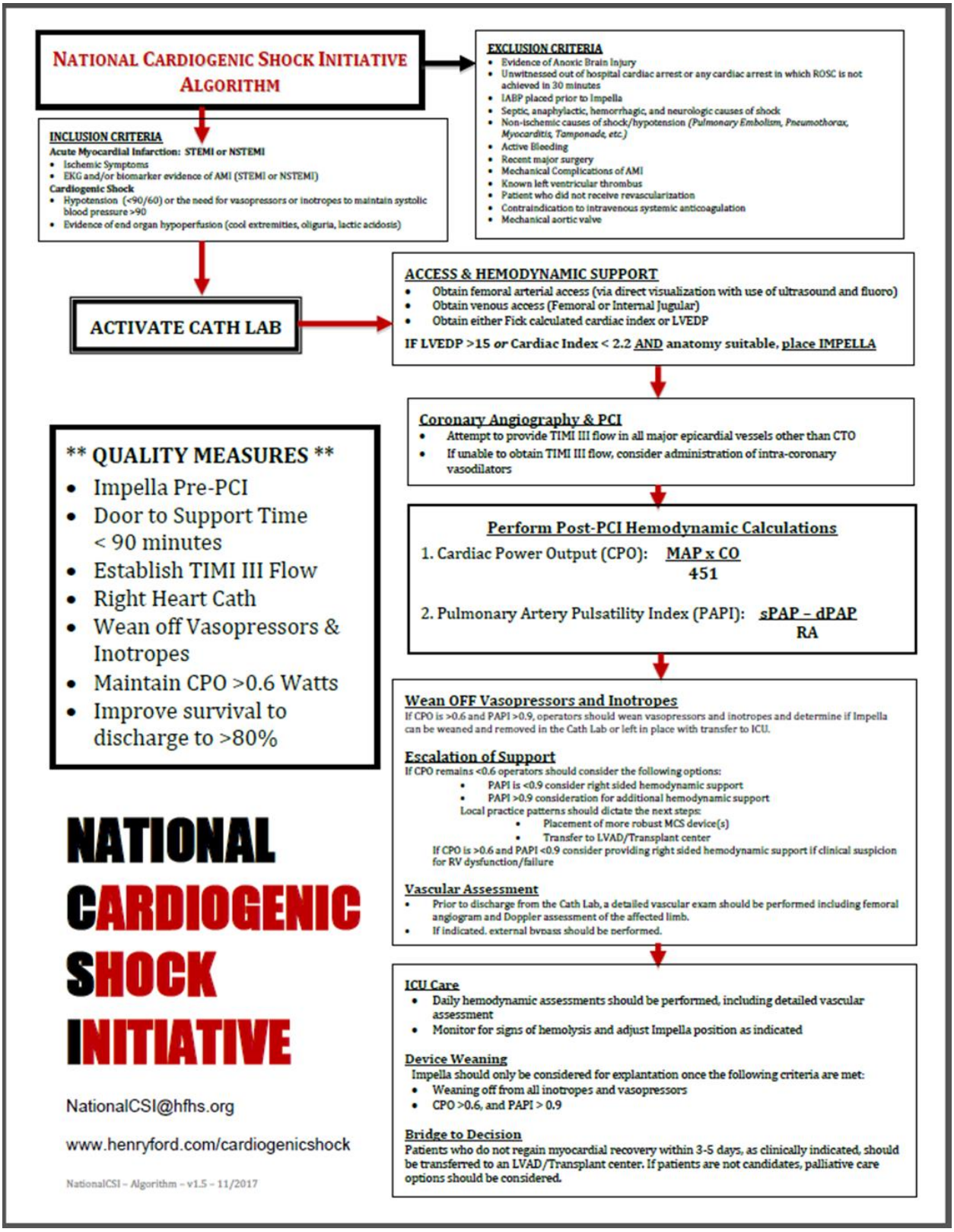
5. Weaning and Explantation

Impella devices should only be considered for explantation once the following criteria have been met:

1. Weaning of all inotropes and vasopressors
2. CPO > 0.6 watts without vasopressors or inotropes, and
3. PAPi > 0.9.

6. Safety and Monitoring

Cautious attention should be paid to the infrequent yet serious complication of limb ischemia with the use of large bore sheaths and devices. Detailed neurovascular checks should be performed while on Impella support. Use of antegrade sheaths to provide flow to the affected limb is strongly recommended in such cases. Prophylactic use antegrade access may also be considered, especially in patients who will likely require >24 hours of support. Although rare hemolysis can also occur, daily hemoglobin level should be obtained while on support. If there are signs of hematuria, Impella positioning should be checked via echocardiography.


NATIONAL CARDIOGENIC SHOCK INITIATIVE ALGORITHM
EXCLUSION CRITERIA
Evidence of Anoxic Brain Injury
Unwitnessed out of hospital cardiac arrest or any cardiac arrest in which ROSC is not achieved in 30 minutes
IABP placed prior to Impella
Septic, anaphylactic, hemorrhagic, and neurologic causes of shock
Non-ischemic causes of shock/hypotension (Pulmonary Embolism, Pneumothorax, Myocarditis, Tamponade, etc.)
Active Bleeding
Recent major surgery
Mechanical Complications of AMI
Known left ventricular thrombus
Patient who did not receive revascularization
Contraindication to intravenous systemic anticoagulation
Mechanical aortic valve
INCLUSION CRITERIA
Acute Myocardial Infarction: STEMI or NSTEMI
Ischemic Symptoms
EKG and/or biomarker evidence of AMI (STEMI or NSTEMI)
Cardiogenic Shock
Hypotension (<90/60) or the need for vasopressors or inotropes to maintain systolic blood pressure >90
Evidence of end organ hypoperfusion (cool extremities, oliguria, lactic acidosis)
ACTIVATE CATH LAB
ACCESS & HEMODYNAMIC SUPPORT
Obtain femoral arterial access (via direct visualization with use of ultrasound and fluoro)
Obtain venous access (Femoral or Internal Jugular)
Obtain either Fick calculated cardiac index or LVEDP
IF LVEDP >15 or Cardiac Index < 2.2 AND anatomy suitable, place IMPELLA
Coronary Angiography & PCI
Attempt to provide TIMI III flow in all major epicardial vessels other than CTO
If unable to obtain TIMI III flow, consider administration of intra-coronary vasodilators
Perform Post-PCI Hemodynamic Calculations
1. Cardiac Power Output (CPO): MAP x CO / 451
2. Pulmonary Artery Pulsatility Index (PAPI): sPAP – dPAP / RA
** QUALITY MEASURES **
Impella Pre-PCI
Door to Support Time < 90 minutes
Establish TIMI III Flow
Right Heart Cath
Wean off Vasopressors & Inotropes
Maintain CPO >0.6 Watts
Improve survival to discharge to >80%
Wean OFF Vasopressors and Inotropes
If CPO is >0.6 and PAPI >0.9, operators should wean vasopressors and inotropes and determine if Impella can be weaned and removed in the Cath Lab or left in place with transfer to ICU.
Escalation of Support
If CPO remains <0.6 operators should consider the following options:
PAPI is <0.9 consider right sided hemodynamic support
PAPI >0.9 consideration for additional hemodynamic support
Local practice patterns should dictate the next steps:
Placement of more robust MCS device(s)
Transfer to LVAD/Transplant center
If CPO is >0.6 and PAPI <0.9 consider providing right sided hemodynamic support if clinical suspicion for RV dysfunction/failure
Vascular Assessment
Prior to discharge from the Cath Lab, a detailed vascular exam should be performed including femoral angiogram and Doppler assessment of the affected limb.
If indicated, external bypass should be performed.
ICU Care
Daily hemodynamic assessments should be performed, including detailed vascular assessment
Monitor for signs of hemolysis and adjust Impella position as indicated
Device Weaning
Impella should only be considered for explantation once the following criteria are met:
Weaning off from all inotropes and vasopressors
CPO >0.6, and PAPI > 0.9
Bridge to Decision
Patients who do not regain myocardial recovery within 3-5 days, as clinically indicated, should be transferred to an LVAD/Transplant center. If patients are not candidates, palliative care options should be considered.
NATIONAL CARDIOGENIC SHOCK INITIATIVE
NationalCSI@hfhs.org
www.henryford.com/cardiogenicshock
NationalCSI – Algorithm – v1.5 – 11/2017

APPENDIX 2

Adoption of the NCSI Treatment Algorithm & Joining the NCSI

Adoption to the NCSI treatment algorithm is completely voluntary. Deviation from the treatment algorithm can occur without consultation of the primary investigators at the discretion of the primary operator. All AMICS patients, including those with treatment algorithm deviation, can be included in the NCSI registry as there is no formal, nationally accepted or standardized protocol or treatment algorithm for treatment of AMICS. Operators and hospitals are encouraged to review the pilot study data and treatment algorithm to determine if they wish to adopt the NCSI treatment algorithm as their standard of care for the treatment of AMICS.

Multi-hospital collaboration is considered a cornerstone to the success of the NCSI. We are reaching out nationally and encouraging hospitals to work together to collect data and demonstrate the success of regional shock protocols and/or treatment algorithms. Hospitals joining the NCSI group voluntarily agree to share data, post-discharge, including demographics, procedural characteristics and outcomes as detailed in the case report form. Data is de-identified and HIPAA-compliant. Data generated from the index procedure admission to discharge (or death, if prior to discharge) will be collected retrospectively and de-identified. Prior to discharge, surviving patients will be asked to consent to the collection of data at 30 days and 1 year post-index procedure. This data collection can occur via follow up phone call, electronic chart review, or any other method that complies with the site's SOPs.

To formally join and affiliate with NCSI, we request the minimum following requirements of the interested hospitals:

1. Implantation of >10 Impella per year (for any indication)

2. Adoption of the NCSI treatment algorithm as standard of care for patients who present with AMICS
3. Identification of a local Primary Investigator (PI) to coordinate data collection

After the above requirements are met, a hospital may request to join NCSI through Henry Ford Hospital's NCSI website (www.henryford.com/cardiogenicshock). The hospital site will be contacted and interviewed by a member of the NCSI team. Once a hospital is accepted to join NCSI, a formal data-use agreement between the institution and Henry Ford Hospital must be completed.

APPENDIX 3
Case Report Form

National Cardiogenic Shock Initiative
Case Report Form
(Version 2.0)

Please complete the entirety of the worksheet. Upon completion, please email this worksheet [SECURE] to: NationalCSI@hfhs.org. Please email/call if there are any questions or concerns.

Demographics

Date of Impella Insertion _____

Implanting Physician _____

Hospital: Name _____

Hospital: City, State _____

Age of Patient _____

Gender (please circle) Male Female

Race (please circle) White Black Hispanic Other

Medical History

Does the patient have a history of Diabetes?	Yes	No	N/A
Doe the patient have a history of TIA/CVA?	Yes	No	N/A
Does the patient have a history of ESRD?	Yes	No	N/A
Does the patient have a history of CKD?	Yes	No	N/A
Does the patient have a known LVEF <50%?	Yes	No	N/A
Has the patient had a prior CABG?	Yes	No	N/A
Has the patient had a prior PCI?	Yes	No	N/A
Has the patient had a prior Myocardial Infarction?	Yes	No	N/A

FOR HFH USE ONLY

NCSI #: _____

Admission Characteristics

Was the patient transferred from another hospital?	Yes	No	N/A
If yes, was the patient on support prior to transport?	Yes	No	N/A
What support device was used?	IABP	Other: _____	
Was cardiogenic shock present on admission to your institution?	Yes	No	N/A
Did the patient experience any of the following (*prior* to arrival in the Cath Lab):			
Anoxic Brain Injury?	Yes	No	N/A
Cardiac Arrest (In Hospital)?	Yes	No	N/A
Cardiac Arrest (Out of Hospital)?	Yes	No	N/A
Did the patient require CPR prior to Impella implant?	Yes	No	N/A
Was the patient undergoing active CPR at the time of Impella implantation?	Yes	No	N/A
Was the patient treated with medically-induced hypothermia?	Yes	No	N/A

** Important Timings ** Please estimate if exact timings are unavailable.
Please do not leave blank.

Arrival to Hospital (date and time)	Date_____Time_____
Onset of AMI (date and time)	Date_____Time_____
Onset of Shock (date and time)	Date_____Time_____
Time of Impella Insertion (date and time)	Date _____ Time _____

Using the above timings, please calculate the following times:

Door to Support Time (minutes): _____

Door to Balloon Time (minutes): _____

Procedural Characteristics (please circle the best choice, if answer is not known please write "N/A")

Impella Placement: 1. Prior to PCI 2. Post PCI 3. Intra-procedural

RHC Placement: 1. Prior to Impella 2. Post Impella 3. No RHC obtained

Impella Used:	Impella Access:	AMI Type?
2.5 CP 5.0 RP Other:_____	☐ Femoral ☐ Axillary ☐ Other: _____	STEMI NSTEMI

PCI Attempted?	TIMI FLOW		Evidence of Thrombus Pre-PCI?	# of Diseased Vessels?	# Vessels Treated?	# of Stents?	Culprit Lesion(s) Location(s)		Other Lesion(s) Location(s)	
YES	Pre-PCI	Post-PCI					1. LM	5. Ramus	1. LM	5. Ramus
NO	0	0		0	0		2.LAD	6. SVG	2.LAD	6. SVG
Successful?	1	1	YES	1	1		3. LCx	7. LIMA	3. LCx	7. LIMA
YES	2	2		2	2		4. RCA	8. RIMA	4. RCA	8. RIMA
NO	3	3	NO	3	3					

Access for PCI?	Was complete revascularization performed?	Thrombectomy used?	Atherectomy used?	PCI Complications? ☐ NO ☐ YES
1. Radial				If YES: ☐ Stent Thrombosis
2. Femoral	YES NO	YES NO	YES NO	☐ Evidence of Residual Thrombus ☐ OTHER:

Was patient taking antiplatelet medication at home? ☐ No ☐ Aspirin ☐ Clopidogrel ☐ Ticagrelor ☐ Prasugrel ☐ N/A
☐ OTHER: _____

Was patient loaded with antiplatelet prior to PCI: ☐ No ☐ Aspirin ☐ Clopidogrel ☐ Ticagrelor ☐ Prasugrel ☐ Cangrelor ☐ Abciximab
☐ Eftifibatide ☐ Tirofiban ☐ N/A ☐ OTHER: _____

If oral antiplatelets were given, what route were they given? ☐ By Mouth ☐ NG/OG Tube ☐ Rectal ☐ N/A ☐ Other: _____

Was the oral antiplatelet crushed? ☐ Yes ☐ No ☐ N/A

When was antiplatelet administered? ☐ EMS ☐ ER ☐ Pre-PCI ☐ Post-PCI ☐ N/A ☐ Other: _____

Anticoagulation used during PCI: ☐ Heparin ☐ Bivalirudin ☐ Other: _____

Please give a brief description of the patient admission:_____

HEMODYNAMIC & LABORATORY VALUES (Pre-procedure & Prior to starting Vasoactive Medications) These values should represent the "worst hemodynamics" that demonstrate level of shock			
HR	**SBP**	**DBP**	**MAP**

HEMODYNAMIC & LABORATORY VALUES: (Pre-Impella) These values represent the hemodynamics prior to Impella Insertion, at the beginning of the PCI procedure								
HR	**SBP**	**DBP**	**MAP**	**Troponin**	**Cr**	**AST**	**Hgb**	**Lactate**
RA/CVP	**RV**	**PA**	**PCWP**	**CO** ☐ Fick ☐ TD ☐ CCO	**CI**	**CPO**	**PAPI**	**LVEDP**
PA Sat.	**Admission Glucose**	***VASOACTIVE AGENTS:*** ***(DOSE):***	Norepinephrine	Dopamine	Epinephrine	Vasopressin	Dobutamine	Milrinone

HEMODYNAMIC & LABORATORY VALUES: Post-PCI, in the Cath Lab (with Impella running) These values represent the Cath Lab hemodynamics post PCI, at the end of the procedure								
HR	**SBP**	**DBP**	**MAP**					
RA/CVP	**RV**	**PA**	**PCWP**	**CO** ☐ Fick ☐ TD ☐ CCO	**CI**	**CPO**	**PAPI**	**LVEDP**
PA Sat.	***VASOACTIVE AGENTS:*** ***(DOSE):***	Norepinephrine	Dopamine	Epinephrine	Vasopressin	Dobutamine	Milrinone	Other:

HEMODYNAMIC & LABORATORY VALUES: 12 hours Post-Impella Implant (ONLY if Impella is running)								
HR	**SBP**	**DBP**	**MAP**	**Troponin**	**Cr**	**AST**	**Hgb**	**Lactate**
RA/CVP	RV	**PA**	**PCWP**	**CO** ☐ Fick ☐ TD ☐ CCO	**CI**	**CPO**	**PAPI**	**LVEDP**
PA Sat.	***VASOACTIVE AGENTS:*** ***(DOSE):***	Norepinephrine	Dopamine	Epinephrine	Vasopressin	Dobutamine	Milrinone	Other:

HEMODYNAMIC & LABORATORY VALUES: 24 hours Post-Impella Implant (ONLY if Impella is running)								
HR	**SBP**	**DBP**	**MAP**	**Troponin**	**Cr**	**AST**	**Hgb**	**Lactate**
RA/CVP	RV	**PA**	**PCWP**	**CO** ☐ Fick ☐ TD ☐ CCO	**CI**	**CPO**	**PAPI**	**LVEDP**
PA Sat.	***VASOACTIVE AGENTS:*** ***(DOSE):***	Norepinephrine	Dopamine	Epinephrine	Vasopressin	Dobutamine	Milrinone	Other:

POST PROCEDURAL FOLLOW UP

Time & Date of Impella Explant: Time:_____Date:_____

WEANING OF HEMODYNAMIC SUPPORT:
Support was weaned according to: ☐ PA Sat ☐ Echo ☐ RHC Hemodynamics
☐ Other: _____

Total hospital duration (Days): _____

Left Ventricle Ejection Fraction (Pre-Impella): _____ (Prior to discharge): _____

DID THE PATIENT SURVIVE THE INDEX PROCEDURE? Yes No N/A

Was the patient transferred to VAD/Transplant Center	Yes	No	N/A
If "Yes", DID THE PATIENT SURVIVE TO TRANSFER?	Yes	No	N/A
Did the patient have any additional support devices implanted post-index procedure?	Yes	No	N/A
If "Yes", which device was used: _____			
DID THE PATIENT SURVIVE TO DISCHARGE?	Yes	No	N/A
Was the patient discharged to hospice?	Yes	No	N/A

Did the patient experience any significant Impella-related complications?

☐ NO ☐ Vascular Complications ☐ Hemolysis

☐ OTHER – Please explain: _____

_____

Did the patient require any blood transfusions? ☐ No ☐ Yes – # of transfusions: _____

Was any external form of vascular bypass performed to provide lower extremity perfusion during Impella (i.e. antegrade access, "up and over" perfusion catheter, etc.)?

☐ No ☐ Yes – Please Explain: _____

_____

_____

Please provide a brief description of the patient's hospital course (including significant complications and discharge circumstances):

Please Explain: _____

_____

_____

_____

_____

If the patient did not survive, please indicate the major cause of death (fatal bleeding, anoxic brain injury, worsening cardiogenic shock, patient/family wishes?)

Please Explain: _____

_____

_____

Cardiac Medications on Discharge (name only): _____

_____

- END OF FORM -

APPENDIX 4

Patient Exclusion Form

National Cardiogenic Shock Initiative

PATIENT EXCLUSION FORM

(Version 2.0)

Please complete and email this form via **[SECURE]** email to: NationalCSI@hfhs.org.
Please email/call if there are any questions or concerns.

Hospital: _____

Hospital - City, State: _____

Physician: _____

Date: _____

Age: _____

Gender: ☐ Male ☐ Female ☐ Other

Race: ☐ White ☐ Black ☐ Hispanic ☐ Other

Patients will be excluded if there is at least one NO response to the inclusion criteria or at least one YES response to the exclusion criteria.

INCLUSION CRITERIA:

YES	NO	
☐	☐	ACUTE MI: Symptoms with ECG and/or biomarker evidence of STEMI or NSTEMI
☐	☐	CARDIOGENIC SHOCK: Defined by the presence of at least two of the following:

- ☐ Hypotension: Systolic blood pressure ≤ 90mm at baseline, or use of inotropes or vasopressors to maintain SBP ≥ 90
- ☐ Evidence of end organ hypoperfusion (cool extremities, oliguria or anuria, or elevated lactate levels)
- ☐ Hemodynamic criteria: Cardiac index of <2.2 L/min/m2 or a cardiac power output ≤0.6 watts.

☐	☐	Patient is supported with Impella
☐	☐	Patient undergoes PCI

Continued on next page →

FOR HFH USE ONLY

NCSI #: _____

EXCLUSION CRITERIA:

YES	NO	
☐	☐	Evidence of Anoxic Brain Injury
☐	☐	Unwitnessed out of hospital cardiac arrest or any cardiac arrest in which ROSC is not achieved in 30 minutes
☐	☐	IABP placed prior to Impella
☐	☐	Septic, anaphylactic, hemorrhagic, and neurologic causes of shock
☐	☐	Non-ischemic causes of shock/hypotension *(pulmonary embolism, pneumothorax, myocarditis, tamponade, etc.)*
☐	☐	Active Bleeding
☐	☐	Recent major surgery
☐	☐	Mechanical Complications of AMI
☐	☐	Known left ventricular thrombus
☐	☐	Patient who did not receive revascularization
☐	☐	Mechanical aortic valve
☐	☐	Patient refused to sign consent for 1M & 1Y follow-up

Notes:

_____

_____

Completed by:

_____

SIGNATURE

_____

NAME (PRINTED)

_____

DATE

APPENDIX 5

30 Day Follow-Up Form

National Cardiogenic Shock Initiative

30 Day Follow-Up

(Version 1.0)

Upon completion, please email this form via [SECURE] email to: NationalCSI@hfhs.org.
Please email/call if there are any questions or concerns.

NCSI #: _____

Hospital: _____

Hospital - City, State: _____

Date of Impella Implant: _____

Date of Follow-Up: _____

Patient Follow-Up – ≥ 30 Days from Date of Impella Implant:

Did the patient survive to 30 Days?

- ☐ YES
- ☐ NO
- ☐ Unknown
- ☐ Patient Unavailable
- ☐ Refused
- ☐ Other: _____

Point of Contact for Follow-up:

☐ Patient ☐ Spouse ☐ LAR/Proxy ☐ Other: _____

Method of Follow-up:

- ☐ Phone Call
- ☐ Electronic Medical Record Review (patient signed-in for visit with ID at 30 or more days)
- ☐ Mail
- ☐ Email
- ☐ Other: _____

NOTES: _____

_____

Follow-up performed by: _____

Title: _____

Signature: _____ Date: _____

National CSI – 30-Day Follow-Up—v1.0 – July, 2018

APPENDIX 6
1 Year Follow-Up Form

National Cardiogenic Shock Initiative

1 Year Follow-Up

(Version 1.0)

Upon completion, please email this form via [SECURE] email to: NationalCSI@hfhs.org.
Please email/call if there are any questions or concerns.

NCSI #: _____

Hospital: _____

Hospital - City, State: _____

Date of Impella Implant: _____

Date of Follow-Up: _____

Patient Follow-Up: ≥ 365 Days from Date of Impella Implant:

Did the patient survive to 1-year?

- ☐ YES
- ☐ NO
- ☐ Unknown
- ☐ Patient Unavailable
- ☐ Refused
- ☐ Other: _____

Point of Contact for Follow-up:

☐ Patient ☐ Spouse ☐ LAR/Proxy ☐ Other: _____

Method of Follow-up:

- ☐ Phone Call
- ☐ Electronic Medical Record Review (patient signed-in for visit with ID at 365 or more days)
- ☐ Mail
- ☐ Email
- ☐ Other: _____

NOTES: _____

_____

Follow-up performed by: _____

Title: _____

Signature: _____ Date: _____

National CSI – 1 Year Follow-Up—v1.0 – July, 2018