National Cardiogenic Shock Initiative (NCSI)

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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%\textsuperscript{1-3}. To date, the only therapy proven to benefit patients in AMICS using data from randomized control trials has been early mechanical reperfusion\textsuperscript{3}. Accordingly, current American and European guidelines confer a class IB indication for reperfusion therapy in the setting of AMICS\textsuperscript{4}. Unfortunately, little progress has been made on improving survival with subsequent therapies, including intra-aortic balloon pump counter-pulsation (IABP)\textsuperscript{5}. This lack of progress is worrisome since the incidence of AMICS appears to be increasing\textsuperscript{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\textsuperscript{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 hospital 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 76% survival to discharge, a significant improvement compared to prior historical controls.

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 phone follow-up. If the patient is discharged prior to obtaining consent, a 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 phone calls)**

- 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 comprised of patients who present with AMICS, we have defined a specific subset of patients from whom outcomes are to be collected. Approximately 400 patients will be approached to participate in the registry at up to 40 sites in the United States. The duration of hospital participation in this research study is anticipated to be approximately two 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. Systolic blood pressure ≤ 90mm at baseline or use of inotropes or vasopressors to maintain SBP ≥ 90
3. Evidence of end organ hypoperfusion
4. Patient is supported with an Impella
5. Patient undergoes PCI
6. Patient signs informed consent document

**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 in 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 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 co-investigator 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 patient medical information, and any necessary 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
  - 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


6. Center for Medicare and Medicaid database, MEDPAR FY14


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 all 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 cardiac index of <2.2 L/min/m2 or left ventricular end diastolic pressure of >15 mmHg.

2. Access, Baseline Invasive Hemodynamics

Femoral artery access and femoral angiography will be performed first. Once access is achieved, a pigtail catheter will be advanced into the left ventricle and LVEDP can be obtained. If LVEDP >15 is present, placement of the large-bore access will occur, followed by systemic anticoagulation. The Impella CP catheter will be inserted and manipulated to obtain > 3 liters/min 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). The timing of RHC is left to the primary operator.
3. Intervention

PCI of the culprit lesion will be performed. Other non-culprit lesions will not be treated unless <TIMI III flow is present in the involved artery. 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 a peripheral angiogram or lower extremities Doppler. 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 Impella suction alarms are happening and CPO < 0.6, right ventricular support with commercially available devices (Impella or Tandem Heart) should be performed. 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 against to maintain arterial pressure leads to decrease forward RV forward 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 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

INCLUSION CRITERIA
- Acute Myocardial Infarction: STEMI or NSTEMI
- Ischemic symptoms
- ECG 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

EXCLUSION CRITERIA
- Evidence of Asystolic Brain Injury
- Unwitnessed out of hospital cardiac arrest or any cardiac arrest in which ROSC is not achieved in 30 minutes
- LAPB placed prior to Impella
- Septic, septicemic, hemorrhagic, and neurologic causes of shock
- Non-infarct 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

ACCESS & HEMODYNAMIC SUPPORT
- Obtain femoral arterial access (via direct visualization with use of ultrasound and fluoroscopy)
- 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): \( \frac{MAP \times CQ}{451} \)
2. Pulmonary Artery Pulsatility Index (PAPi): \( \frac{sPAP - dPAP}{RA} \)

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 >0.9 consider right sided hemodynamic support
- PAPi >0.9 consider right sided hemodynamic support
- Local practice patterns should dictate the next step
- 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.

**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%

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. NCSI contains two prospective data points collected after patient discharge: survival at 30 days and survival at 1 year. Therefore, patients must give informed, written consent prior to being discharged from the hospital (or via mail if already discharged), to collect their data and to agree to a 1-month and 1-year follow-up, to be conducted either by chart review or phone call.

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 the NCSI coordinator. 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**

**National Cardiogenic Shock Initiative**

**Case Report Form**

(Version 1.4)

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.

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**Demographics**

Record ID #

Date of Impella Insertion

Implanting Physician

Hospital Name

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

Does 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
**Admission Characteristics**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was the patient <strong>transferred</strong> from another hospital?</td>
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</tr>
<tr>
<td>If yes, was the patient on support prior to transport?</td>
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<tr>
<td>What support device was used?</td>
<td>IABP</td>
<td></td>
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<tr>
<td>Was cardiogenic shock present on admission to your institution?</td>
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<tr>
<td>Did the patient experience any of the following <em>(prior to arrival in the Cath Lab)</em>:</td>
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<tr>
<td>Anoxic Brain Injury?</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac Arrest (In Hospital)?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiac Arrest (Out of Hospital)?</td>
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<tr>
<td>Did the patient require CPR prior to Impella implant?</td>
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<tr>
<td>Was the patient undergoing active CPR at the time of Impella implantation?</td>
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<tr>
<td>Was the patient treated with medically-induced hypothermia?</td>
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<tr>
<td><strong>Important Timings</strong> Please estimate if exact timings are unavailable.</td>
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<tr>
<td><strong>Please do not leave blank.</strong></td>
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<tr>
<td>Arrival to Hospital (date and time)</td>
<td>Date ___________________________ Time ___________________________</td>
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<td></td>
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<tr>
<td>Onset of AMI (date and time)</td>
<td>Date ___________________________ Time ___________________________</td>
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<td></td>
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<tr>
<td>Onset of Shock (date and time)</td>
<td>Date ___________________________ Time ___________________________</td>
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<td></td>
</tr>
<tr>
<td>Time of Impella Insertion (date and time)</td>
<td>Date ___________________________ Time ___________________________</td>
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<tr>
<td>Using the above timings, please calculate the following times:</td>
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<tr>
<td>Door to Support Time (mins):</td>
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<tr>
<td>Door to Balloon Time (mins):</td>
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</tbody>
</table>
### Procedural Characteristics (please circle the best choice, if answer is not known please write “N/A”)

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>RHC Placement:</td>
<td>1. Prior to Impella</td>
<td>2. Post Impella</td>
<td>3. No RHC obtained</td>
</tr>
</tbody>
</table>

#### Impella Used:
- 2.5 CP
- 5.0 RP
- Other: __________

#### Impella Access:
- Femoral
- Other: __________

#### AMI Type?
- STEMI
- NSTEMI

<table>
<thead>
<tr>
<th>PCI Attempted?</th>
<th>TIMI FLOW (Pre PCI)</th>
<th>TIMI FLOW (Post PCI)</th>
<th># of Diseased Vessels?</th>
<th># Vessels Treated?</th>
<th># of Stents?</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>0</td>
<td>0</td>
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<tr>
<td>NO</td>
<td>1</td>
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<tr>
<td>Successful?</td>
<td>2</td>
<td>2</td>
<td>3</td>
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<tr>
<td>YES</td>
<td>3</td>
<td>3</td>
<td>3</td>
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</tr>
</tbody>
</table>

#### Access for PCI?
- 1. Radial
- 2. Femoral
- Was complete revascularization performed?
- YES NO

#### Thrombectomy used?
- YES NO

#### Atherectomy used?
- YES NO

#### PCI Complications?
- YES NO

If Yes, please explain:

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.

<table>
<thead>
<tr>
<th>HR</th>
<th>SBP</th>
<th>DBP</th>
<th>MAP</th>
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</thead>
</table>

### HEMODYNAMIC & LABORATORY VALUES (Pre-Impella)

These values represent the hemodynamics prior to Impella Insertion, at the beginning of the PCI procedure.

<table>
<thead>
<tr>
<th>HR</th>
<th>SBP</th>
<th>DBP</th>
<th>MAP</th>
<th>Troponin</th>
<th>Cr</th>
<th>AST</th>
<th>Hgb</th>
<th>Lactate</th>
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</thead>
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#### RA/CVP

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<tr>
<th>RV</th>
<th>PA</th>
<th>PCWP</th>
<th>CO</th>
<th>CI</th>
<th>CPO</th>
<th>PAPI</th>
<th>LVEDP</th>
</tr>
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</table>

#### PA Sat.

<table>
<thead>
<tr>
<th>Admission Glucose</th>
<th>Norepinephrine</th>
<th>Dopamine</th>
<th>Epinephrine</th>
<th>Vasopressin</th>
<th>Dobutamine</th>
<th>Milrinone</th>
</tr>
</thead>
</table>

#### VASOACTIVE AGENTS:

- Norepinephrine
- Dopamine
- Epinephrine
- Vasopressin
- Dobutamine
- Milrinone

(DOSE):
**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.

<table>
<thead>
<tr>
<th>HR</th>
<th>SBP</th>
<th>DBP</th>
<th>MAP</th>
<th>RA/CVP</th>
<th>RV</th>
<th>PA</th>
<th>PCWP</th>
<th>CO</th>
<th>CI</th>
<th>CPO</th>
<th>PAPI</th>
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</table>

**PA Sat.**

**VASOACTIVE AGENTS:**

(DOSE): Norepinephrine Dopamine Epinephrine Vasopressin Dobutamine Milrinone Other:

---

**HEMODYNAMIC & LABORATORY VALUES: 12 hours- Post Impella Implant (with Impella running)**

<table>
<thead>
<tr>
<th>HR</th>
<th>SBP</th>
<th>DBP</th>
<th>MAP</th>
<th>Troponin</th>
<th>Cr</th>
<th>AST</th>
<th>Hgb</th>
<th>Lactate</th>
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</table>

**PA Sat.**

**VASOACTIVE AGENTS:**

(DOSE): Norepinephrine Dopamine Epinephrine Vasopressin Dobutamine Milrinone Other:

---

**HEMODYNAMIC & LABORATORY VALUES: 24 hours- Post Impella Implant (with Impella running)**

<table>
<thead>
<tr>
<th>HR</th>
<th>SBP</th>
<th>DBP</th>
<th>MAP</th>
<th>Troponin</th>
<th>Cr</th>
<th>AST</th>
<th>Hgb</th>
<th>Lactate</th>
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**PA Sat.**

**VASOACTIVE AGENTS:**

(DOSE): Norepinephrine Dopamine Epinephrine Vasopressin Dobutamine Milrinone Other:

---

**POST PROCEDURAL FOLLOW UP**

Time & Date of Impella Explant

Time: __________________ Date: __________________

Total hospital duration

__________________________________________________________________________

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

DID THE PATIENT SURVIVE THE INDEX PROCEDURE?  

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
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Was the patient transferred to VAD/Transplant Center

If “Yes”, DID THE PATIENT SURVIVE TO TRANSFER?

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<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
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Did the patient have any additional support devices implanted post-index procedure?

If “Yes”, which device was used: __________________________________________________________

DID THE PATIENT SURVIVE TO DISCHARGE?  

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<tr>
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<th>Yes</th>
<th>No</th>
<th>N/A</th>
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Was the patient discharged to hospice?  

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<th></th>
<th>Yes</th>
<th>No</th>
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Did the patient experience any significant Impella-related complications (including vascular complications, hemolysis, etc.)?

Please Explain: ___________________________________________________________________

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.)?

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 (anoxic brain injury, worsening cardiogenic shock, patient/family wishes?)

Please Explain: ___________________________________________________________________

Cardiac Medications on Discharge: _________________________________________________

____________________________________

____________________________________

Follow Up Phone Calls: 1 & 12 month(s) from Impella Implant Day:

Did the patient survive 1 month  

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
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Did the patient survive 1 year  

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<tr>
<th></th>
<th>YES</th>
<th>NO</th>
<th>N/A</th>
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APPENDIX 4
National Cardiogenic Shock Initiative

PATIENT EXCLUSION FORM

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

Hospital: ________________________________________________________________
City, State: ________________________________________________________________
Physician: ________________________________________________________________
Date: __________________________
Age: ___________
Gender:  □ Male  □ Female
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:

<table>
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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 did not receive revascularization

☐  ☐ Mechanical aortic valve

Notes:

___________________________________________________________________________

_________________________________________________________________________________

Completed by:

_____________________________________________________________

SIGNATURE

_____________________________________________________________

NAME (PRINTED)

_____________________________________________________________

DATE

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