The National Cardiogenic Shock Initiative

Dr. William W. O'Neill shares his experience with launching this initiative at both the regional and national levels.



What led you to begin the Cardiogenic Shock Initiative at the regional level?

The 50% survival rate for cardiogenic shock hadn't changed since the 1980s. Percutaneous coronary intervention (PCI) alone had not been sufficient.

When the US Food and Drug Administration approved the Impella pump (Abiomed, Inc.) for the treatment of cardiogenic shock in 2016, we realized that there was no protocol for systematic use of the device. Starting from scratch in July 2016, we brought together key influential cardiologists from each major health system across the very competitive health care market in southeast Michigan. We came together for the right reason: to save lives.

What obstacles/challenges did you encounter as you rolled the initiative out? How did you get the regional hospitals to join?

I've worked in metro Detroit for more than 30 years, so I'm familiar with many of the cardiologists in our area. The single most important obstacle to overcome is finding a physician leader at each hospital to champion hemodynamic support. They then needed to build a team at their hospital so that a majority of patients showing signs of cardiogenic shock would be treated with early hemodynamic support.

It's challenging for everyone to adopt a similar protocol. The protocol is based on insight gleaned from national shock registries, such as the cVAD Registry. The protocol focuses on identifying shock and unloading before PCI, reducing use of inotropes, and the use of invasive hemodynamic monitoring. We had to overcome the skepticism of trying something new, as well as the lack of a large,

randomized trial. We wanted to determine what the best practice should be before we conducted a randomized trial. Most importantly, we agreed to rigorously collect the outcomes data.

After we had been working together for a few months, we were able to show a survival increase from 50% to 76%. We arranged a press conference at a neutral spot with representatives from all the hospital systems and two ST-elevation myocardial infarction patients whose lives were saved by the protocol. We promoted it to the local media as an unprecedented coming together of area physicians to save lives.

What are the things you wish you had known when beginning this project?

We recognize now that use of the Impella device in the cath lab is not the complete story. There has to be a program for monitoring patients in the intensive care unit after using Impella. That has to be very standardized. We didn't recognize how important it was to have vascular access taken care of before patients left the cath lab.

We also didn't anticipate how quickly the medical community would respond and how many people would be clamoring for a standardized, evidence-based treatment approach. That's why we now include the treatment algorithm on our website (Figure 1).

What facilities should consider adopting this initiative? Where might it be less effective?

Facilities that already have experience using Impella on a commercial basis, performing more than 10 Impella procedures per year, could implement this regional initiative. But really, any hospital that is comfortable using the device can utilize the protocol on an as-needed basis.

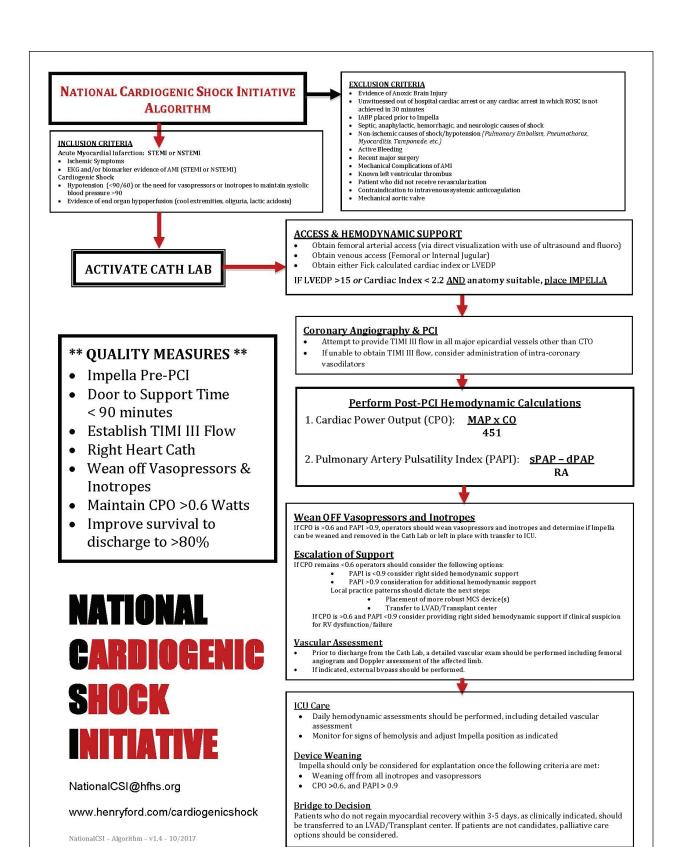


Figure 1. The Cardiogenic Shock Initiative treatment algorithm.

SAINT LOUIS JOINS THE NATIONAL CARDIOGENIC SHOCK INITIATIVE



It struck me during the course of the last year that the real challenge of our time in treating cardiovascular disease is upon us right now—improving treatment and patient outcomes in cardiogenic shock. At Saint Louis University, we were early adopters of the Impella 2.5 device (Abiomed, Inc.) soon after it was introduced and partici-

pated in the PROTECT trial evaluating its use in protected PCI. This experience translated into our facility becoming very comfortable with the device in many different patient conditions, including shock and cardiac arrest. We quickly learned that applying the Impella to patients with out-of-hospital cardiac arrest contributed to our highest mortality cohort in the catheterization lab, and we began trying to think about better utilizing this powerful new tool more effectively.

We extrapolated data from the USPella Registry and other sources that supported outcomes with Impella insertion prior to PCI in hemodynamically unstable patients and adopted this as our standard Saint Louis University practice approximately 2.5 years ago, with good success. However, there is great variability in the Saint Louis community, as there is in many communities across the country, with respect to adopting a doorto-support—themed approach to treating cardiogenic shock.

Interventionalists have widely different practice patterns that they are very attached to in how they treat patients, relying on comfort and experience—things that have promoted a high reliance on intra-aortic balloon pumps and percutaneous intervention as the keys to treating this difficult-to-treat patient population. To really make an impact on the challenge of cardiogenic shock, we don't see any other way but to get together with like-minded interventionalists and show that unloading the ventricle early in the course makes a difference. Thus, the opportunity to partner with Dr. William O'Neill and the Detroit Cardiogenic Shock group and to help them nationalize the approach was a natural next step in the process. For us, the realization that in-hospital mortality for patients with cardiogenic shock remains too high without change mandates that we push forward on this new paradigm of treatment.

We are excited that Saint Louis University can play a role in partnering with the National Cardiogenic Shock Initiative and look forward to having Saint Louis play a prominent role in conquering the issues that have impeded us in the care of cardiogenic shock.

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What does the organizational structure look like when successfully implemented?

We use the hub-and-spoke model. The Impella is inserted at one of the spoke facilities and the patient is then transferred to the hub, a tertiary care hospital, for additional treatment.

What is the protocol that is being used?

The National Cardiogenic Shock Initiative algorithm is on the website and lists the standardized treatment. Anyone can review it at HenryFord.com/cardiogenicshock.

How did the initiative grow beyond the regional level to a national initiative?

I shared our initial data from the Detroit Cardiogenic Shock Initiative on the national stage in March 2017 at the American College of Cardiology annual meeting in Washington, DC. After that, we started getting contacted almost weekly. I call it a "coalition of the willing," those willing to follow a specific protocol to save lives.

Also, we're working with specific regional medical groups that submit data on their early use of mechanical circulatory support in acute myocardial infarctions and cardiogenic shock. We should have some really interesting additional insight in a few months.

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