Creating Clinical and Economic Value Through Risk-Sharing Agreements

The Rush University Medical Center Experience: A 360° View of the Vascade Performance Guarantee

Sreekumar Madassery, MD, Assistant Professor of Vascular & Interventional Radiology, Rush University Medical Center, Chicago, Illinois

Hospitals are increasingly under pressure to deliver better care at a lower cost. One of the more recent concepts to accomplish these seemingly opposing goals is through value-based healthcare where a manufacturer and healthcare provider align clinical and financial incentives through risk-sharing arrangements. An appropriately structured risk-sharing agreement links quality metrics (outcomes) and costs, deriving clinical value while managing financial risk. The result of a properly implemented risk-sharing agreement is better care for patients at a lower overall cost.

Dr. Harry Liu, a senior policy researcher at the RAND Corporation, recently published an article[1] in Medical Device & Diagnostic Industry (MD+DI). Dr. Liu describes four characteristics that facilitate successful implementation of a medical device risk-sharing agreement:

1. An easily identifiable patient population;
2. Outcomes of interest are easily identified and measured;
3. The device is effective in addressing a medical problem;
4. Changes in outcomes can be realized in short period of time.[1]

We would like to share the Rush University Medical Center experience with the Vascade Performance Guarantee in light of these four characteristics. First of all, for any medical device risk-sharing agreement to provide value, the product itself has to be safe and effective, and garner the support of the medical staff. Vascade (Cardiva Medical) is commonly and successfully utilized for interventional and diagnostic patients at Rush. It is the right device for many of our patients because it is simple to use and extravascular, making it especially useful for bifurcations and superficial femoral artery (SFA) closure, as well as closing antegrade access sites. Vascade is indicated for both femoral arterial and venous closure, both coronary and peripheral use, and both interventional and diagnostic cases, making it a flexible tool for 5-7 French (Fr) femoral closure. Due to Vascade's versatility in closing a majority of femoral access sites, the patient population includes all that are deemed appropriate under that description, thus satisfying characteristic #1 above in the RAND model.

Our risk-sharing agreement with Cardiva Medical involves measuring complications associated with access closure, so the relevant patient outcome (complication-free femoral access site closure) can be obtained by the time the patient is discharged. We do not have to track the patient longitudinally over time, making the outcome very easy to measure and satisfying characteristic #2 in the RAND model.

The national average complication rate for access site closure is 5.8%[2], while the national average cost to treat access site-related complications is $5,440[3], meaning the cost of managing access site-related complications equals $315,520 per 1,000 patients. By reducing complications just 1%, an institution could theoretically save $54,400 for every 1,000 cases.

Vascade is the only closure device proven safer than manual compression in a randomized clinical trial, demonstrating zero major complications and 1.1% minor complications in the RESPECT clinical trial.[4] In addition, although not from a clinical trial, the outcomes of the Vascade Performance Guarantee accounts across the U.S. (>50 centers and 25,000 patients), have demonstrated a complication rate of 0.1% (1 in 1,000)[5] as defined in the Performance Guarantee agreement. These data show Vascade is effective in addressing a medical (and economic) problem, satisfying characteristic #3 above in the RAND model.

"Implementing the Vascade Performance Guarantee was pretty simple," said Janet Haw, Director of Interventional Services at Rush. A simple program along with a simple device to use were keys to successfully implementing our program, especially since so many specialties work in our labs, including interventional radiology, interventional cardiology, interventional neurology, electrophysiology, and vascular surgery, as well as many fellows. Janet added, "We successfully used Vascade for about two years prior to implementing the program, but the Vascade Performance Guarantee program now serves as an 'early warning' system, because of our heightened awareness of complications associated with vascular closure." Although closure complications are rare, when one is experienced, we closely scrutinize what happened in order to determine what could be done differently moving forward, in an attempt to continuously improve patient outcomes.

When Vascade was originally introduced to Rush three years ago, it was approved by our Value Analysis Committee (VAC), as with all other new products. "When we decided to proceed with the Vascade Performance Guarantee, the legal sign-off process was simple and straightforward, even though it was a new concept and the first risk-sharing agreement we signed," said Elizabeth Diebolt, Strategic Sourcing Manager with Rush. Elizabeth added, "We are trying to build partnerships with vendors that go beyond just a supplier-customer relationship. With Cardiva and the Vascade Performance Guarantee, it means that we are committed to a larger partnership where they are actively involved with the quality of care. As a large urban academic medical center, we treat a high volume of patients, train fellows/residents, and manage costs while delivering high quality care. Based on our experience using Vascade for three years, the successful implementation of the Vascade Performance Guarantee, and the expert support of the Cardiva Medical field team, whose members are 100% focused on vascular closure, we believe Cardiva Medical is helping us accomplish our goals on a daily basis. ■

"The legal sign-off process was simple and straightforward, even though it was a new concept and the first risk-sharing agreement we signed. We are trying to build partnerships with vendors that go beyond just a supplier-customer relationship. With Cardiva and the Vascade Performance Guarantee, it means that we are committed to a larger partnership where they are actively involved with the quality of care."

— Elizabeth Diebolt, Strategic Sourcing Manager

"Implementing the Vascade Performance Guarantee was pretty simple.…The program serves as an 'early warning' system, because of our heightened awareness of complications associated with vascular closure."

— Janet Haw, Director of Interventional Services

References

1. Liu H, Chen C. Where are the Low-Hanging Fruits for Device Manufacturers? Risk-sharing arrangements are becoming part of the norm in the medical device field, but when are they most beneficial? Medical Device & Diagnostic Industry (MD+DI). 2018 April 2. Available online at https://www.mddionline.com/where-are-low-hanging-fruits-device-manufacturers. Accessed February 14, 2019.
2. Rao SV, McCoy LA, Spertus JA, et al. An updated bleeding model to predict the risk of post-procedure bleeding among patients undergoing percutaneous coronary intervention: a report using an expanded bleeding definition from the National Cardiovascular Data Registry CathPCI Registry. *JACC Cardiovasc Interv*. 2013 Sep; 6(9): 897-904.
3. Resnic FS, Arora N, Matheny M, et al. A cost-minimization analysis of the Angio-Seal vascular closure device following percutaneous coronary intervention. *Am J Cardiol*. 2007; 99(6): 766-770.
4. Hermiller JB, Leimbach W, Gammon R, et al. A prospective, randomized, pivotal trial of a novel extravascular collagen-based closure device compared to manual compression in diagnostic and interventional patients. *J Invasive Cardiol*. 2015 Mar; 27(3): 129-136.
5. Data on file at Cardiva Medical.

Sreekumar Madassery, MD, can be contacted at: sreekumar_madassery@rush.edu