Should the CMS NCD requirement for surgical and interventional co-operators for TAVR procedures be dropped?

The current requirement that a cardiovascular surgeon must be in attendance during transcatheter aortic valve replacement (TAVR) as a reflection of the heart team seems to me to be unnecessary. The heart team concept is an excellent idea, but it should not necessarily be defined as a surgeon physically present at every TAVR procedure. The proximity of a surgeon theoretically implies that should disaster strike, the surgeon will be able to rescue the situation. In my experience, if care is exercised in patient selection and TAVR planning, along with careful execution of the plan by the operator, disaster seldom strikes, and if it does, a rescue attempt of a cardiac disaster is likely going to be futile.

In my opinion, TAVR could evolve like percutaneous coronary intervention (PCI) if great care is not taken to preserve the concept of the heart team. Expedient unilateral decisions to perform PCI are sometimes made in the heat of battle based on inadequate informed consent and understanding by the patient, which in retrospect do not serve the best interests of some patients. A critical aspect of the heart team is that decisions are made after all the facts are gathered and have been presented openly to all of the team members in order to make a carefully considered treatment decision. In my opinion, the heart team concept is embodied in this aspect of its role in the care of patients.

The heart team is a very important concept to preserve. A joint informed recommendation as to the form of therapy is the critical contribution that the heart team can make in the care of each individual patient. In the past, cardiology and cardiac surgery have too often championed their own therapies without genuine concern for the overall long-term impact of their recommendation. It has progressively become clear that TAVR is the right choice in some patients, and traditional surgical aortic valve replacement is the right choice in others. The gray zone between these polar opposites is fluid and undergoing dramatic and rapid change. The problems with perivalvular leaks have and will continue to improve. The durability of TAVR prostheses continues to surprise all of us. In addition, the devices have progressively gotten smaller and more user-friendly, making access easier and vascular disaster requiring surgery even less likely.

A collaborative unified honest database as the basis for treatment choice should become the standard of care. Such a database can only develop when open cooperation becomes the culture of the heart team. At some point, the very terms “cardiologist” and “cardiac surgeon” will no longer be appropriate. Rather than “us and them,” we need to be professionals who think in a unified way that places the patient at the center of the discussion.

The American College of Cardiology and the American Heart Association recently made the heart team collaboration a class I indication for assessing and treating high-risk patients with aortic stenosis (level of evidence...
C). The collaborative approach to treating diseases is not something new. In medicine, no one person alone can cure human ailments all by themselves. This is more true today than it was 50 years ago. Collaborations have been the way of innovation and progress since the beginning of time.

It took collaborations from all types of innovators to reach the goal of a successful TAVR procedure. The question we have to ask ourselves is whether the technology has matured enough that we move on from the admiration of innovation to letting the technology do its job. This is especially true in the current state of health economics and fiscal responsibility.

I believe in the saying, "It takes a village." Nowhere in medicine, and especially in cardiology, is this statement more true than it is for TAVR. But like everything else, the ways that this technology will flourish and be used effectively should be up to the local operators and not a regulatory agency to dictate how the collaborations should be implemented. The team approach to TAVR is exactly the reason we have been so successful in making strides in its development, but that does not mean there is only one way to implement it and that the alternative should somehow be imputative. There is no doubt that we need to have more than one operator at the table but to assume and impose restrictions on who should be in the room during these procedures is not something the Centers for Medicare & Medicaid (CMS) should be deciding.

For operators who perform TAVR procedures, we all know that the success of this highly complex procedure is very highly dependent on the relationships and understanding of operators at the table, and it should be left up to the local teams to decide who those operators are. If your team works best with two interventional cardiologists or a combination of an interventional cardiologist and a surgeon, or even rarely two surgeons who can do TAVR successfully with acceptable national standards, then so be it. Having said that, it is clear that non-iliofemoral approaches to TAVR need a surgeon’s expertise. So again, the team that does TAVR should depend on the type of approach, and the operators in the room should be a decision made by the heart team rather than by CMS. For CMS to say that this procedure can and should only be done with a surgeon in the room at all times puts unnecessary financial burden on a hospital without any proof that this leads to better outcomes. In fact, it forces people to work together who may not necessarily be a good fit for that particular approach to TAVR, and may actually do more harm than the well-intended good that we want to accomplish.

If you look at the data from the PARTNER and CoreValve trials, it is clearly evident that the rate of emergent surgical conversion was extremely low. In fact, STEMI patients went to emergent surgery more commonly than the TAVR patients. We do not have a cardiac surgeon in the room while performing percutaneous coronary intervention in STEMI patients.

In closing, I believe that CMS should modify their stance on having the surgeon present in the room for every procedure in the interest of the procedural and fiscal outcomes involved with this already resource-intensive procedure.

Having said that, I do believe that we still need to have a collaborative heart team when we treat patients who have complex valve disease. In fact, based on our learning from the TAVR experience, we should make a concerted effort to extend the team concept to all of the cardiac patients that we treat in our day-to-day practices.
Cardiac interventions generally trend toward more conservative involvement of cardiac surgeons over time. PCI procedures were first introduced more than 30 years ago. As the technology and procedures have changed over time, there has been a decrease in the need for emergency coronary bypass, ranging between 0.4% and 2%. As such, cardiac surgical backup for PCI has evolved from the formal surgical standby in the 1980s to an informal arrangement of first-available operating room. More recently, there has even been a move toward off-site surgical backup with emergency transport available. Although this has been controversial, it has allowed for greater access to primary therapy with PCI and has evidence to support its safety and efficacy.\(^4\)

TAVR is currently approved by the US Food and Drug Administration only for patients with unacceptable surgical risk; however, there are currently ongoing trials assessing its utility in patients with intermediate surgical risk (PARTNER II, SURTAVI). As the procedure is able to be applied to a broader population, there is an opportunity for far more people to undergo the procedure. With a limited number of surgeons and with ever-increasing time constraints placed on them, the requirement to have a surgeon co-operator present limits the availability of the procedure for patients and places undue strain on the surgical community.

Advances in the design of catheter-delivered valves have improved greatly, allowing for improved safety of the TAVR procedure. The Sapien first-generation valve delivery system (Edwards Lifesciences) was a 22- to 24-F delivery system requiring femoral artery cutdown in order to safely deploy the device.\(^2\) Third-generation devices are now approved in Europe and allow for a 29-mm valve to be deployed through a 16-F delivery system,\(^6\) and the Evolut R valve (Medtronic) is able to be delivered through a 14-F delivery system. This reduction in size should improve femoral arterial access site complications. In addition, newer-generation devices currently in trial are retrievable (Lotus valve, Boston Scientific; Evolut R\(^2\)), allowing for repositioning or fully retrieving the valve, again lowering the complication rate and need for emergent surgery. As the procedure becomes safer and available to a larger number of patients, cost savings may also become a more prominent consideration. Two operators incur a higher cost with minimal benefit.

An approach involving multidisciplinary care teams has been shown to improve patient outcomes in a wide variety of cardiovascular disease states. TAVR has been no exception, and providers from many disciplines have played integral parts in the planning and undertaking of each TAVR case. Selection of valve replacement modality and procedural details should continue to be based on collaboration between all providers. These teams would be best able to determine which cases could be safely and effectively performed without direct surgical presence in the case. Valve replacement procedures are not emergent procedures, so there isn’t a need for expanding access beyond facilities where there is direct surgical backup, and thus these procedures should be performed in large facilities capable of providing the resources needed for emergency surgical intervention. The multidisciplinary team could, as they determine the modality of valve replacement, decide which provider(s) would be needed in the procedure. For more complicated access, an interventional cardiologist and surgeon could complete the case successfully, whereas for more straightforward access, a solo interventional cardiologist or surgeon with extensive endovascular experience may be a more appropriate utilization of resources.

CMS requires that “the heart team’s interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intraoperative technical aspects of TAVR.”\(^8\) This requirement is cumbersome and limits the availability of the procedure, especially with the possibility of a substantial increase in the eligible population in the near future; it should be rethought. Co-operators remain an invaluable resource and should be involved in the selection of patients for TAVR and the intraprocedural aspects of more complicated cases, such as patients who are deemed to be at greatest risk for intraprocedural complications or who have difficult vascular access.

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TAVR has revolutionized the care of high-risk and inoperable patients with severe symptomatic aortic stenosis.\(^1\)\(^5\) For patients to undergo TAVR, a two-step process has to occur: (1) determine which patients are best suited for TAVR as opposed to traditional surgical aortic valve replacement, and (2) once selected, the actual performance of the TAVR procedure.

Although traditional surgical risk scores have been applied to determine eligibility, they have poor calibration and discrimination in predicting outcomes of patients undergoing TAVR.\(^6\) Several dedicated risk scores are being developed but are not yet validated.\(^7\)\(^8\) What has, however, been put into practice and empirically judged to be effective, is the collaborative decision making of an experienced valve surgeon and an interventional cardiologist who are well versed in treating valvular/structural heart disease, which is known as the heart team concept. The idealized heart team brings different types of expertise to bear on the patient’s care to determine whether a traditional surgical approach or a transcatheter technique is best. As such, both cardiology and cardiac surgical societies have recommended that heart teams be the ones to jointly determine eligibility for TAVR.\(^9\)

For commercial TAVR cases, according to CMS and our professional society guidelines, this requires that the patient visit separately with two cardiac surgeons and one interventional cardiologist. The need for three separate risk assessments before TAVR proves unnecessarily burdensome on both patients and the medical system. In practice, this approach often delays the time to treatment for these often very sick and symptomatic patients. With the development of well-validated, TAVR-specific risk scores, determination of candidacy for each approach may become more objective, but subtle technical details not captured by the dedicated risk scores may still require the joint expertise of the heart team.

Nonetheless, whether or not there are patients for whom one or the other approach is clearly best, there will also be a large number of patients for whom either technique will be medically acceptable and in whom shared decision making with the patient, family, and referring physician will likely determine the approach.

In the early TAVR experience, interventional cardiologists brought catheter-based skills, and the cardiac surgeons brought the surgical skills to the procedure. However, as with most technologies, the technology has rapidly evolved,\(^10\) and with iterative evolution, a vast majority of procedures are being performed fully percutaneously through a femoral puncture, and only a minority (< 10%) require surgical access to the femoral, subclavian, axillary, or carotid arteries, or via transapical and direct aortic access.\(^4\)\(^5\)\(^11\) Appropriate valve sizing

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*Figure 1. Proposed streamlined TAVR evaluation and performance of the procedure.*
has also improved with utilization of highly accurate and reproducible CT imaging to determine valve size. Improvement in valve profile has resulted in an infrequent need for balloon aortic valvuloplasty prior to advancement of the TAVR prosthesis across the aortic valve, resulting in fewer complications associated with need for initial aggressive balloon aortic valvuloplasty, which was previously needed in order to deliver a higher-profile prosthesis. The increase in operator experience and the availability of repositionable valves (currently in trial phase in the United States) has made valve malpositioning, coronary compromise, and valve embolization infrequent. Increasing experience is also accruing with the performance of TAVR without intubation and general anesthesia.5,12 As such, the complication rates and need for surgical bailout with TAVR have declined and will continue to decline further. Additionally, many of the complications that do arise, such as paravalvular leak13 or bleeding from the groin access site, albeit infrequent, can increasingly be dealt with using catheter-based procedures rather than surgical approaches. For those of us in the interventional field for many years, there are clear parallels to the evolution of PCI. This technique, of course, evolved from balloon angioplasty with a necessary open operating room and at-the-ready surgical team, to the present era of percutaneous coronary stenting routinely performed without the need for surgical backup and even performed successfully and safely at hospitals without a cardiac surgical team.13

Given that the majority of TAVR procedures can now be performed fully percutaneously and with an infrequent need for surgical bailout, it may be time to rethink the CMS NCD requirement for surgeon and interventional co-operators for TAVR procedures when the procedure can be performed fully percutaneously through the femoral approach. In such cases, the cardiac surgeon’s time is not well utilized by being involved in a fully percutaneous catheter-based procedure with no surgical component other than the infrequent need for a surgical bailout. A joint surgical and interventional cardiology team, however, should remain a requirement when more invasive approaches require surgical access (Figure 1).