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FORMAL REQUEST BY AN EXTERNAL PARTY FOR RECONSIDERATION OF AN EXISTING NCD

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Dear Dr. Chin and Ms. Fulton,

INTRODUCTION:

I have served as the Medical Director of the Cardiac Catheterization Laboratory at Providence Saint John's Health Center for the past 10 years. As a medical professional with extensive practice in cardiac valve replacement I would like to request formal reconsideration of the existing NCD 20.32 released on May 1, 2012 for Transcatheter Aortic Valve Replacement (TAVR) coverage. When TAVR was initially approved, very strict criteria for reimbursement and procedure performance by the cardiac team were enumerated in Medicare NCD 20.32. From the date of initial approval, TAVR has now become a safe, commonplace procedure, with indications expanding from high-risk now to intermediate risk patients. However, the current limitations listed in NCD 20.32 limit the ability of lower volume medical centers and hospitals from providing this key service to Medicare beneficiaries, even if they are high-quality hospitals.

When TAVR was first approved, individual hospital program approval was based on the volumes of non-TAVR procedures, e.g., number of surgical aortic valve replacements, cardiac

catheterizations, and coronary interventions (PCIs). Procedural volume was used as a surrogate for program quality, in the decision to allow a TAVR program to open. After opening a TAVR program, quality parameters are measured. Understanding that at the time of initial CMS approval, few hospitals had extensive experience with TAVR, the reasoning for the NCD restrictions was understandable.

Today, TAVR has become a commonplace and safe procedure, with indications now expanded from high risk to intermediate risk patients as well. Procedural volumes across the country are increasing, with excellent outcomes.[1] Thus, the early motivation for the NCD, insuring quality for a new and high risk procedure, is no longer relevant.

Clearly, CMS is correct in ensuring that delivery of care for Medicare beneficiaries is of the highest quality. Monitoring TAVR outcomes for quality should drive decisions as to whether a TAVR center should continue to operate. Such quality measures should relate to TAVR, and not non-TAVR procedures used as a surrogate for TAVR quality.

Historically, procedural volume has been used as a surrogate for quality. Now, with electronic medical records and registry reporting of such procedures as TAVR, coronary intervention, Watchman, etc., we can and should measure quality directly. Procedural volume criteria can promote and increase unnecessary procedures, while measuring and requiring quality will promote patient-focused population care.

Several factors should be considered in the decision to initially approve a hospital as a TAVR center:

1) As TAVR volume expands across the US, aortic valve surgical volume becomes limited. Lower volume hospitals will be unable to meet a surgical volume of 50 aortic valve replacements per year, as cases are increasingly done percutaneously.
2) TAVR is a catheterization laboratory procedure, commonly done with moderate sedation, in many cases and in many hospitals. This procedure is dependent on physician operator and cath lab structural heart expertise, not open surgical technique.
3) TAVR quality is not affected by procedural volume of non-TAVR procedures. Thus, whether a hospital does 200 or 400 coronary interventions per year should not have a meaningful effect on TAVR outcomes.
4) Coronary interventional procedures are appropriately dropping across the nation, but using coronary procedural volume in the NCD has not been re-thought. This, too, penalizes programs which deliver appropriate care. In fact, the volume criteria could, in some instances, promote unnecessary catheterization or aortic valve surgery procedures, so that a hospital can meet TAVR criteria.
5) The TAVR NCD specifically excluded some structural cases from being used as a quality indicator, such as patent foramen ovale (PFO) and atrial septal defect (ASD) closure device implantation, although they are a better indicator of the ability of a team and lab to

correlate cardiac cath / fluoroscopic imaging, transesophageal imaging, and 3-D CT data than is performance of coronary angiography or intervention.

6) The TAVR NCD does not even consider Watchman implantation as a quality measure, although this is a technically challenging structural heart procedure, similar in some ways to TAVR, and requiring similar correlation of X-ray and ultrasound imaging.
7) Inclusion of PFO, ASD and Watchman quality measures as criteria for opening a TAVR center would actually be more relevant to predicting quality of TAVR than volume of coronary catheterizations or coronary interventions.
8) Thus, NCD 20.32 overly emphasizes volume of non-TAVR services as a proxy for quality of care and clinical expertise in structural heart.

Given the widespread use of electronic health record (EHR) systems, quality of care can now be directly measured, and therefore use of indirect measures, is obviated. CMS approval and reimbursement for TAVR should be based on TAVR quality.

ADDITIONAL SCIENTIFIC EVIDENCE TO SUPPORT RECONSIDERATION

1) NCD determinations can adversely affect patient care and outcomes:

After release of the CMS NCD for TAVR on May 1, 2012, "the non-transfemoral access program was put on hold due to lack of reimbursement."[2] Transfemoral access, that is, valve delivery via catheter placement in the femoral artery, requires a certain minimum artery diameter. Non-transfemoral access is used if the iliofemoral arteries are too small—TAVR valve delivery is accomplished either through alternate arterial access (e.g., subclavian artery or direct aortic puncture) or directly via left ventricular apex puncture. O'Neill, et al. describe 21 patients in their practice who were unable to undergo TAVR due to the NCD limitation, four of whom died. This effect was more pronounced in women, who statistically have smaller iliofemoral vessels.

John Carroll, MD, Interventional Cardiologist, wrote a follow-up editorial to O'Neill's article making several relevant points.[3] First, there are clinical and ethical consequences to NCD limitations on reimbursement. Second, evolution of NCD, as described in the Federal Register Guidelines[4] should and must evolve with changes in technology and practice patterns. Third, when faced with the NCD limitations, some hospitals proceeded with non-transfemoral cases anyway, with no data reported, since this was done "under the radar." And finally, he stresses the importance of registry data for quality monitoring.

2) **There is no data to support the procedural volume criteria for TAVR in the initial NCD:**

To determine whether there is any data supporting the initial TAVR NCD volume criteria, PubMed searches were performed. PubMed "comprises more than 27 million citations for biomedical literature from MEDLINE, life science journals and online books." It is a service provided by the US National Library of Medicine in the National Institutes of Health. These searches included:

a) "correlation of coronary intervention volume and TAVR quality": 0 (zero) articles found[5]
b) "correlation of TAVR quality and surgical aortic valve replacement volume": 0 (zero) articles found[6]
c) "correlation of cardiac catheterization procedure volume and TAVR quality:": 0 (zero) articles found[7]

In order to be certain that these searches were exhaustive, multiple other searches were performed using synonyms and alternative phrases. For example, for "a)" above, I also searched with phrases such as "TAVR outcome and coronary intervention procedure volume" and still found no articles showing correlation of the quality of TAVR outcomes with hospital procedural volume for non-TAVR procedures.

Thus, the initial criteria for TAVR approval, as outlined in the NCD, have no evidence basis in the literature.

3) **Procedure volume is not an absolute predictor of quality:**

Many research studies have examined the relationship of procedural volume and procedure quality outcome (for the same procedure, not a fundamentally different procedure). These studies show some correlation, however it is frequently weak.

For example, in the State of California, it was found that there is no significant correlation between CABG (coronary artery bypass) procedural volume and mortality rate in various hospitals. From the graph below, comparing CABG procedural volume and mortality, it is clear that while there is a statistical trend, there are low volume programs with low mortality.[8]

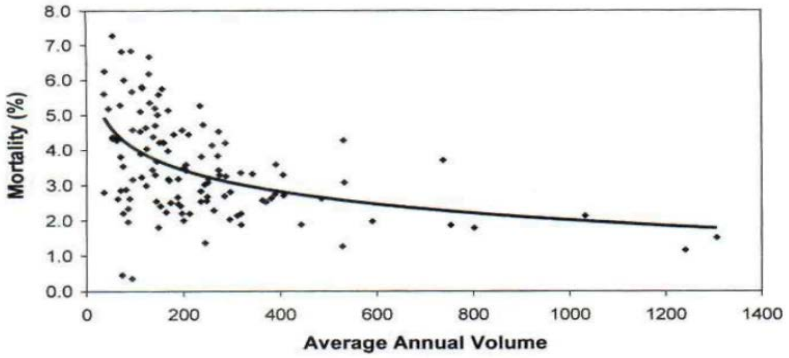

FIG. 1. CABG-only. Scatter plot of average annual volume *versus* 3-year mortality. Logarythmic trendline calculated by MS Excel.

And, in a university-based community hospital network, excellent results for coronary artery bypass surgery were obtained by compliance with quality standards, even in low volume programs, and did not correlate with procedure volume.[9]

In the UK, a large study on 427,467 PCI procedures concluded: "no evidence was found for a relationship between center average annual volume and risk-adjusted 30 day mortality."[10]

Based on the lack of high correlation between procedure volume and quality, many authors have expressed opinions that we need to move on to direct quality outcome measurement, and abandon the usage of procedural volume as a surrogate for quality. An editorial published in the lay press expresses this opinion[11], but more importantly, medical researchers argue for the importance of quality and not volume measurement. Khumbani stresses that PCI volume benchmarks are no longer as relevant as they were, and that improvement in technology has allowed procedure evolution. This, in turn, makes quality, and not procedure volume, important, and also allows high quality without necessarily high volume.[12] Finally, field leaders argue TAVR should not be restricted to high-volume surgical centers citing data that "high surgical volume does not ensure good interventional outcomes, that centers with low or no surgical volume can have excellent interventional results, and that group learning can attenuate the learning curve."[13]

Thus, using volume as a surrogate for quality, even for the same procedure, is not predictive of outcome. And, as shown above, no correlation whatsoever of non-TAVR procedure volumes (e.g., PCI, surgical aortic valve replacement, cardiac cath) with TAVR quality has been described in the literature.

Procedure quality should be the key determinant in decisions about approval and reimbursement for a procedure by CMS.

4) **TAVR results in significant reduction in surgical AVR volume:**

One of the criteria listed in the TAVR NCD is that a hospital must maintain a volume of surgical aortic valve replacement cases in order to remain approved for CMS reimbursement for TAVR. However, with the increasing volume of TAVR procedures performed in the US, and with the inclusion of intermediate risk cases rather than just high risk cases, surgical volume is decreasing.[14]

Decreasing surgical volume is thus becoming a Catch-22: increasing TAVR procedure volume will make it further unlikely that hospitals will qualify to perform TAVR, if the current NCD remains unchanged. Per Dr. Wright, from the latest RUC Committee meeting, Medicare fee-for-service surgical aortic valve replacement cases (CPT 33405,33406, and 33410) decreased from 32,860 in 2013 down to 26,351 in 2016. At the same time, TAVR (CPT 33361-33366) dramatically increased from 5,262 to 27,116 cases.

5) **Thought experiment / logical arguments:**

Given the data available in the current medical practice environment, one must consider the following:

a) It is impossible to provide data supporting the absence of correlation between TAVR quality and non-TAVR procedure volume, because:
    a. The TAVR NCD does not permit performance of TAVR in centers which do not meet the non-TAVR procedure volume criteria
    b. If there are centers in the US which are "flying under the radar," performing TAVR without meeting the NCD criteria, they are incentivized not to publish their quality data
b) In the US, surgical aortic valve replacement and coronary interventional volumes are falling, respectively because of the advent of TAVR and the AUC (Appropriate Use Criteria) curtailing the indications for catheterization and PCI. In that world, if a hospital met the NCD criteria for TAVR, and while performing high quality TAVR

procedures finds that their PCI or surgical AVR volume decreases, given the arguments made above, there is no reason to believe that TAVR quality would fall, While the NCD mandates that that hospital cease TAVR procedures the moment their non-TAVR volumes fall below the NCD requirements, this does not make logical sense.

ADDITIONAL MEDICARE PART A AND PART B BENEFIT CATEGORIES IN WHICH THE REQUESTER BELIEVES THE ITEM OR SERVICE FALLS

Medicare Part A and Part B benefits will accrue to patients allowing them to benefit from TAVR in high-quality programs which will be more readily available and accessible to them, both geographically, as well as per availability of schedule times.

Continuous transitioning Medicare from volume-based toward value-based care delivery system and reimbursement will promote culture of quality care and will incentivize caregivers to concentrate not on procedural volumes sometimes not necessary volumes but rather on quality outcomes. In long term perspective, it will lead to reduced overall medical expenses.

SUMMARY OF REQUEST FOR RECONSIDERATION OF TAVR NCD

Based on the above, I believe it is time to reconsider the TAVR NCD. TAVR is no longer a new, experimental and risky procedure. The non-TAVR volume criteria in the NCD are not supported by evidence based research, and are restrictive for any high-quality but not high-volume cardiovascular program. Now that the procedure is streamlined, with excellent outcomes, CMS approval and reimbursement should be based on quality and not non-TAVR procedure volume surrogates for quality.

Therefore, I would request one of two options: 1) Retire the NCD; or 2) remove the volume criteria from the NCD.

If the NCD is modified, and not retired, I respectfully suggest:

1) **TAVR SHOULD BE REIMBURSED BASED ON QUALITY OUTCOME OF THE HOSPITAL TAVR PROGRAM.**
2) **TAVR REIMBURSEMENT SHOULD NOT BE BASED ON MEETING VOLUME CRITERIA OF NON-TAVR PROCEDURES.**
3) **PHYSICIAN OPERATOR EDUCATION, TRAINING AND SKILL SHOULD QUALIFY A PROGRAM FOR TAVR REIMBURSEMENT BY CMS. GIVEN**

THE PROCEDURAL REQUIRMENTS, SUCH PHYSICIANS SHOULD BE CREDENTIALLED AND SKILLED IN

- **a. CARDIAC CATHETERIZATION**
- **b. CORONARY INTERVENTION**
- **c. PERIPHERAL INTERVENTION**
- **d. STRUCTURAL HEART INTERVENTION:**
  - **i. 100 LIFETIME PROCEDURES TO HAVE BEEN COMPLETED, WHICH COULD BE:**
    1. **TAVR**
    2. **MITRACLIP**
    3. **PERCUTANEOUS MITRAL, TRICUSPID OR PULMONARY VALVE REPLACEMENT**
    4. **LEFT ATRIAL APPENDAGE OCCLUDER IMPLANT**
    5. **PFO, VSD, ASD CLOSURE IMPLANTATION**

Sincerely yours,

Electronically signed 10/24/17: Peter Pelikan, MD

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