

Appropriateness of Percutaneous Coronary Intervention: Appropriate Use Criteria Outperform Certificate of Need

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The underlying concept behind certificate of need (CON) laws is that government regulation and restriction of certain costly services will result in fewer facilities offering that service, but those facilities will perform more of the procedures and thus be able to distribute the costs over more cases, thereby lowering the cost per individual case. This approach arises from a “cost containment” attitude, seeking to prevent the spread of presumably costly technologies. Cardiovascular services and procedures, especially cardiac catheterization as well as revascularization by either surgery (coronary artery bypass grafting) or percutaneous coronary intervention (PCI), are almost always included in the group of higher-cost technologies. The CON theory also implicitly accepts the volume–outcome hypothesis: larger volumes result in better outcomes with fewer adverse events. Mixed into these ideas is the added belief, or hope, that CON laws can help reduce “unnecessary procedures,” although the laws themselves do not define what an unnecessary procedure is or provide any mechanisms for quantitatively analyzing procedure appropriateness. CON is a macroeconomic approach.

In contradistinction to the CON concept, the appropriate use criteria (AUC) are a set of clinical elements that can be determined for each patient undergoing a procedure. These prespecified criteria, developed by professional societies, usually can be applied either prospectively before the procedure or retrospectively after the procedure, which is a great advantage. The current appropriateness categories in most formulations are tripartite: appropriate, may be appropriate, and

rarely appropriate. The underlying idea here is that reducing the rarely appropriate category to a vanishingly small number is a desirable goal, and in this way unnecessary procedures and the attendant unnecessary costs can be avoided. There is no explicit or implicit concern with procedure volumes or quality in the AUC concept. However, the parallel and complimentary actions of AUC and guidelines-directed care are viewed as dual mechanisms to help reduce adverse events and improve clinical outcomes. The AUC corresponds to a microeconomic approach.

Attempting to examine the effects of either CON or AUC in the cardiovascular area has been a complicated and difficult undertaking. Partly this is attributable to the uncertainty of what variables to examine as the “outcomes” in the analyses, and the relevant time points to ascertain the outcomes. It is also partly attributable to lack of high-quality clinical data on patients undergoing the procedures, to be certain that clinical risk adjustments are adequate or even possible. This has been a greater problem for CON because much of the data analyzed come from administrative codes in hospital records or billing data, which are much weaker on clinical information. Yet even the AUC, presumably calculated at the individual patient level from the most granular data available, do not always capture all relevant elements for the most precise risk assessments. Furthermore, for all analyses under either mechanism, demonstrating a mathematical correlation between certain variables does not prove causation. For these and many other reasons, meaningful analyses of CON and AUC in the cardiovascular realm are regrettably few. Those that are available are equivocal at best.^{1–7} This severely limits the ability to propose or advocate any systemic changes.

In this issue of the *Journal of the American Heart Association (JAHA)*, Chui et al undertake an important step by combining both CON and AUC.⁸ This is the first study to link the 2 concepts in a formal analysis. They do this by examining the world’s largest database on PCI, the CathPCI database of the National Cardiovascular Data Registry. The PCI data come from 1.2 million patients treated at almost 1300 centers in 2010 to 2011, years when the status of statewide CON regulations could be validated. Patients were divided into 2 groups: those treated in 26 states with CON programs covering cardiovascular services (594 411 patients;

The opinions expressed in this article are not necessarily those of the editors or of the American Heart Association.

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J Am Heart Assoc. 2019;8:e011661. DOI: 10.1161/JAHA.118.011661.

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47%) and those treated in states without CON (674 384 patients; 53%). Both acute and nonacute PCI indications were included. Not surprisingly, most PCI procedures performed for acute indications were categorized as appropriate or maybe appropriate both in CON states and states without CON (99.4% in both), whereas those categorized as rarely appropriate were negligible (0.6% in both). This corroborates other published data suggesting that most acute PCI is performed appropriately.⁹

It is in nonacute or elective PCI procedures that appropriateness can and should be examined carefully. Previous work by this same group of investigators has suggested that inappropriate (rarely appropriate) PCI for nonacute indications has been declining in recent years, possibly as a result of the publication, widespread dissemination, and local application of the AUC criteria.¹⁰ The important finding in this present work is that any decline in inappropriate nonacute or elective PCI is unlikely to be attributable to CON laws. In states with CON laws for the years examined herein, 77% of nonacute PCI was categorized as appropriate or maybe appropriate, compared with 75% in states without CON. Categorization of nonacute PCI as rarely appropriate was 23% in CON states and only slightly higher at 25% in states without CON, a clinically unimportant 2–percentage point difference, but with a calculated $P < 0.0001$ because of the large numbers.⁸ Furthermore, the stringency of the CON laws was not related to either appropriateness or clinical outcomes to any remarkable degree. Taken altogether, these findings suggest that the greater impact on PCI procedure appropriateness comes from AUC and not from CON.

The authors of the present work suggest that from a public policy perspective, their findings should raise questions about and give pause to efforts to control use of PCI through the mechanism of CON regulation. They further suggest that a periodic reevaluation of CON laws is necessary in those states that have them. In my opinion, it is possible that CON laws may have outlived their usefulness altogether, if there ever was any. Just as important, though, as a necessary corollary, are the responsibilities of professional societies to periodically reevaluate PCI guidelines, performance measures, and AUC. It would be most helpful all around if reevaluations of these 3 areas could be coordinated and synchronized to prevent overlap and confusion. It is then the obligation of all clinical centers and their professional staffs to implement all 3 mechanisms at their local facilities at every revision. As has been pointed out, physicians have the privilege as well as the responsibility of self-regulation to a remarkable degree.¹¹ These 3 mechanisms (guidelines, performance measures, and

AUC) are the tools for exercising this self-regulation. On the other hand, CON is a regulatory and bureaucratic approach that is imposed from outside and is the antithesis of self-regulation. Implementing this periodic self-review process using these 3 mechanisms will help fulfill the vision outlined by the Institute of Medicine in its proposal for a “learning healthcare system.”¹² Furthermore, the hard work of quality improvement, reducing adverse events and reducing unnecessary procedures, must be focused on the local, individual level. CON laws cannot do this, but AUC in conjunction with guidelines and performance measures may be able to.

Disclosures

None.

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Key Words: Editorials • appropriateness criteria • outcomes research • percutaneous coronary intervention