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CORRESPONDENCE

Letters to the Editor

The Weasel Clause

Excluding Patients From Door-to-Balloon Analyses

Numerous broad-based studies, including that from the U.S. National Registry of Myocardial Infarction (1), have convincingly shown a direct relationship between door-to-balloon time and in-hospital mortality for patients treated with primary percutaneous coronary intervention for ST-segment elevation myocardial infarction. Presumably, the principal reason for this observation is that ischemic time, and hence infarct size, is limited by early reperfusion (2). Some data suggest, however, that the reduction in mortality is due to greater overall quality of care rather than reperfusion time per se (3).

Fast door-to-balloon times require a multidisciplinary system approach. This has been carefully studied and noted to include, when possible, paramedic electrocardiogram transfer to alert the receiving team, single-page activation of the on-call team, and a quality control program with system feedback, all of which, to a large degree, are under control of the emergency medical services–emergency room–interventional cardiology "system." There are a number of factors that might adversely affect door-to-balloon time that are beyond the control of the team, including difficult consent process, need to exclude serious comorbidities that might influence concomitant drug therapy for primary percutaneous coronary intervention (e.g., intracranial hemorrhage for a patient found down and resuscitated), and cardiac arrest occurring between the time of emergency department arrival and initiation of percutaneous intervention. Some other potential causes for delay are well within the control of the interventionalist team, including weekend/off-hours staffing, skillful vascular access, and rapid cannulation of the infarct-related artery.

Door-to-balloon-time metrics can be appropriately used both for internal quality control and for external comparison. For internal quality control, the hospital might choose to exclude patients with certain comorbidities, and as long as they are consistent in doing so, they can track improvements in outcome and even compare among operators. For external comparison, however, particularly in the "pay for performance" era, the exclusion rules must be applied uniformly. Ideally, reasons for exclusion should not be subjective or easily "gamed." Few, it would seem, would argue with these ground rules.

Therefore, when the most recent ACC NCDR-revised reasons for patient exclusion in door-to-balloon time analysis were announced (4)—most notably difficult vascular access or difficulty in crossing the culprit lesion, both highly subjective and easily used to explain a poor door-to-balloon time—it struck us as inappropriate. In fact, when we heard these exclusions described, our initial commentary was "this would allow for an abrogation of responsibility" or, more colorfully, "this is a weasel clause!"

Physicians are under fire from multiple quarters due to perceived lack of integrity arising from the activities of some of our colleagues. We call for a retraction of such subjective and easily manipulated exclusions immediately. Should that not be possible, or meet with illogical resistance, at a minimum, each site should be required to report the percentage of patients with ST-segment elevation myocardial infarction that were excluded from "reportable" door-to-balloon time.

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Reply

As contributors to the NCDR (National Cardiovascular Data Registry), we read the letter by Ellis and colleagues with interest. The NCDR has long been dedicated to the measurement and improvement in care quality. Undoubtedly, these goals are best promoted when the measures used to characterize quality are as valid as possible.

We agree regarding the distinction between measures used for the purposes of quality improvement and those intended for the purposes of external accountability. Indeed, the American College of Cardiology/American Heart Association (ACC/AHA) Performance Measures Task Force methodology explicitly acknowledges this dichotomy (1). Measures used for the purposes of accountability must rise to a particularly high standard with respect to validity, burden of data collection, and susceptibility to "gaming."

The specific issue Ellis and colleagues raise is the exclusion in the reperfusion measure for patient-centered reasons for delaying therapy in the NCDR CathPCI Registry. Clinically appropriate reasons for delays in reperfusion therapy are numerous. Indeed, enumerating

them completely is impractical. The NCDR CathPCI Registry reperfusion measures allow for exclusions for patient-centered reasons for delay (e.g., the need for a decision-altering diagnostic test prior to possible primary percutaneous coronary intervention). Although the measures may include examples, they do not include specific lists of these reasons. Such exclusions were integrated into the measure to acknowledge the fact that high-quality clinicians providing the best care will, on occasion, face situations where their delivery of reperfusion therapy is delayed for clinically appropriate reasons. As Ellis and colleagues point out, the flexibility intrinsic to this exclusion may create opportunities for gaming.

Although we believe that the high standards of medical professionals protect the integrity of the measures to some extent, we are not so naive to assume that professional integrity alone will eliminate gaming. Unfortunately, however, addressing this issue by removing the exclusion as proposed by Ellis and colleagues raises substantial problems of its own by undermining the clinical face validity of the measure. The absence of such exclusions creates other compelling arguments—namely, that centers that care for particularly complex patients, where clinically reasonable delays are more common—are disproportionately penalized. Indeed, before the Department of Health and Human Services' Centers for Medicare and Medicaid Services/Joint Commission measure incorporated this exclusion, such complaints were among the most common causes for objection to the reperfusion measures (Jo DeBuhr, Colorado Foundation for Medical Care, personal communication, July 2010).

This dilemma, among the many complex issues surrounding measuring reperfusion quality, was addressed explicitly by an ACC/AHA Writing Group comprised of experienced clinicians and experts in performance measurement (2). This writing group concluded that this exclusion is important, despite its limitations. This opinion is reflected in the current ACC/AHA performance measures for acute myocardial infarction (3).

Further, the Writing Group recommended: 1) surveillance for the proportion of cases where exclusions are noted, including the distribution of the exclusions by institution; and 2) audit of the clinical appropriateness of exclusions both in a targeted manner (i.e., among institutions with the highest numbers of excluded cases) as well as randomly.

To this point, NCDR metrics have been used predominantly for quality improvement. Although some of the metrics reported to registry participants are not intended for accountability purposes, others—including the time-to–primary percutaneous coronary intervention metric in question—might reasonably be viewed as useful in this regard. As this occurs, we agree with Ellis and colleagues that greater scrutiny of exclusions, consistent with the recommendations by the ACC/AHA Writing Group is warranted.

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Serial Intravascular Ultrasound Examinations and Clinical Outcome

We read with interest the paper by Nicholls et al. (1) investigating the relationship between intravascular ultrasound (IVUS)–derived measures of atherosclerosis (baseline and change in percent atheroma volume) and cardiovascular outcomes (death, myocardial infarction, and coronary revascularization). Based on the study design, however, it seems difficult to determine the relationship between change in percent atheroma volume and death or myocardial infarction because IVUS examination at follow-up is often missing in patients with such clinical events. To clarify this point, it would be of great help if the investigators would provide data regarding how many patients died or had myocardial infarction and how long patients underwent follow-up for occurrence of cardiovascular outcomes after follow-up IVUS examination.

In addition, Figure 1 of their paper (1) shows a striking increase in cardiovascular events between 500 and 600 days (repeat IVUS examination period), suggesting angiographically/IVUS-driven revascularization (2). Therefore, it remains unclear whether IVUS-derived measures of atherosclerosis are associated with clinical outcomes without routine angiographic/IVUS follow-up.

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