ST-Elevation Myocardial Infarction
Which Patients Do Quality Assurance Programs Include?

Alex R. Campbell, MD*; Daniel Satran, MD*; David M. Larson, MD; Ivan J. Chavez, MD; Barbara T. Unger, RN; Barbara P. Chacko, RN; Christopher Kapsner, MD; Timothy D. Henry, MD

Background—In the United States, efforts are underway to improve timely access to percutaneous coronary intervention in ST-elevation myocardial infarction (STEMI). The Joint Commission (TJC) and the American College of Cardiology National Cardiovascular Data Registry (NCDR) have developed standardized definitions and clinical performance measures for STEMI. The purpose of this study was to determine differences in 3 quality-assurance registries for STEMI patients.

Methods and Results—STEMI patients presenting to the Minneapolis Heart Institute at Abbott Northwestern Hospital (Minneapolis, Minn) are tracked by 3 distinct quality assurance programs: NCDR, TJC, and the level 1 MI registry (a regional system for percutaneous coronary intervention in STEMI which includes transfer patients). Over 1 year, we examined consecutive STEMI patients in level 1 and compared them with individuals meeting NCDR and TJC inclusion criteria. Of 501 STEMI patients treated using the level 1 MI protocol, 422 patients had a clear culprit (402 percutaneous coronary intervention, 13 coronary artery bypass grafting, 7 medical management). In the same period, 282 patients met inclusion criteria for NCDR (56% of the level 1 population), and 66 met inclusion criteria for TJC (13% of the level 1 population). Transfer patients (n=380) accounted for 87% of the discrepancy between level 1 and TJC. Pharmacoinvasive percutaneous coronary intervention (n=102) accounted for 47% of the discrepancy between level 1 and NCDR.

Conclusions—Current inclusion criteria for enrollment in STEMI registries are not uniform. This may lead to variable quality assurance outcomes for the same patient cohort and has important implications for standardized quality measurement. (Circ Cardiovasc Qual Outcomes. 2009;2:648-655.)

Key Words: myocardial infarction ♦ quality assurance, health care

Quality of care in ST-elevation myocardial infarction (STEMI) has become a focus for physicians, hospitals, payers, and medical organizations. Door-to-balloon time has emerged as the standard metric of clinical performance for percutaneous coronary intervention (PCI) in STEMI because of its association with patient outcome.1,2 The American College of Cardiology (ACC) D2B Alliance has focused on reducing door-to-balloon time in PCI hospitals.3 The American Heart Association (AHA) “Mission: Lifeline” initiative has been launched to improve timely access to reperfusion in STEMI.4 Integrated systems of care for STEMI including transfer from non-PCI hospitals represent one strategy to achieve this goal.5 The ACC/AHA have developed standardized definitions and clinical performance measures for STEMI and have recently published a statement which includes recommendations for additional performance measures for reperfusion therapy.6,7 The National Cardiovascular Data Registry (NCDR) is intended to serve as a means of internal STEMI program quality improvement.8 The Joint Commission (TJC) and the Center for Medicare and Medicaid Services (CMS) track door-to-balloon time as the key clinical performance measure specific to STEMI at institutions performing primary PCI.9

Pay for performance programs, which link financial incentives to physician and hospital performance on specific quality measures, have been proposed as a method to improve healthcare quality and efficiency.10–14 Door-to-balloon time benchmarks are currently being incorporated in public reporting and federal pay-for-performance initiatives.10 Accurate and reproducible inclusion criteria for enrollment in STEMI registries are necessary to achieve uniform performance measurement and are implicit in standardized quality assurance. Despite the implications of performance measurement for physicians and hospitals, the ability of quality-assurance registries to identify cohorts of patients with STEMI has not been evaluated. The level 1 MI program is a regional system for STEMI care using a standardized protocol and integrated transfer system for 31 non-PCI hospitals to a PCI center.15,16

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Abbott Northwestern Hospital is a 619-bed tertiary care hospital in Minneapolis, Minn. Three STEMI registries—with 3 separate inclusion criteria—track patient quality assurance data (Table 1).

### Level 1 MI Program

The level 1 MI program is a regional system for STEMI care using a standardized protocol and integrated transfer system for 31 non-PCI hospitals to a PCI center. Non-PCI hospitals are stratified into 2 zones based on distance from the PCI center: zone 1 (up to 60 miles) and zone 2 (between 60 and 210 miles). Treatment protocols are identical except zone 2 patients receive half-dose fibrinolytics before transfer. Regardless of whether or not they undergo PCI, patients who present within 24 hours of typical ischemic symptoms with ST-elevation or new LBBB on the ECG are included in a prospectively maintained Registry with detailed time to treatment measures. A cardiologist (T.D.H.) and emergency medicine physician (D.M.L.) independently review all cases to ensure that inclusion criteria are met.

### National Cardiovascular Data Registry

The NCDR maintains a voluntary cardiac catheterization laboratory registry at more than 600 institutions in the United States. STEMI patients are eligible for door-to-balloon time measurement if they meet the ACC/AHA inclusion criteria (Table 1). Baseline patient characteristics and door-to-balloon times are collected retrospectively and submitted to the ACC. Confidential outcome reports for participating institutions are generated as a means of internal quality improvement. At Abbott Northwestern, a registered nurse (B.C.) completes NCDR data for all cases, and an interventional cardiologist is available for oversight review (I.J.C.).

### The Joint Commission

TJC defines STEMI as any patient discharged with an ICD-9 code for acute myocardial infarction with appropriate ECG changes based on abstraction algorithms. TJC abstractors do not interpret ECGs; computerized ECG wording is analyzed for specific inclusion and exclusion phrases indicating ST-segment elevation or new LBBB. If computerized wording is inadequate to adjudicate STEMI, abstractors may use physician documentation, but only if the initial ECG is specifically referenced by time and date with appropriate inclusion phrases. Inclusion and exclusion criteria for ST-elevation and LBBB are periodically updated and have changed frequently since 2002 (Table 2). TJC tracks door-to-balloon time data for STEMI patients meeting inclusion criteria (Table 1). Data obtained by the independent abstractors were reviewed by a cardiologist (T.D.H.).

For a 1-year period, we examined consecutive STEMI patients in the level 1 Registry and compared them to patients who met inclusion criteria for NCDR and TJC. Median door-to-balloon times and in-hospital mortality were determined for each quality assurance program. For the 63 individuals in all 3 registries, registries were compared according to door-to-balloon time using repeated-measures ANOVA.

### Results

From October 2005 to September 2006, 501 patients with STEMI were treated using the level 1 MI standardized protocol. Although all patients had STEMI based on emergency room physician diagnosis, 422 (84.2% of 501) had a clear culprit on angiography. Of the 79 without a clear culprit, 25 (5.0% of 501) had elevated cardiac biomarkers consistent with myocardial infarction. Therefore, 54 (10.8% of 501)
<table>
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<tr>
<th>Date Range</th>
<th>Inclusion</th>
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<tr>
<td>7/2002–6/2003</td>
<td>ST-segment elevation AMI or MI with any mention of location (anterior, apical, inferior, lateral, posterior, or combination)</td>
<td>ST-segment elevation Non-Q-wave MI</td>
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<td>Q-wave AMI</td>
<td>Non-STEMI</td>
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<td></td>
<td>Q wave MI</td>
<td>ST elevation attributable to early repolarization, LVH, normal variant, pericarditis, or Printzmetal variant</td>
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<td>ST elevation</td>
<td>ST-segment elevation, or any of the other ST segment elevation inclusion terms, described as old or previously seen</td>
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<td></td>
<td>ST consistent with injury, infarct, or acute MI</td>
<td>ST-segment elevation, or any of the other ST segment elevation inclusion terms, described using one of the following qualifiers: cannot rule out, may have, may have had, may indicate, possible, suggestive of, suspect, or suspicious</td>
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<td>ST changes consistent with injury, infarct, ischemia, or MI</td>
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<td></td>
<td>STEMI</td>
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<td></td>
<td>ST segment noted as $\geq 0.10$ mV</td>
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<td></td>
<td>Transmural AMI</td>
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<td>Transmural MI</td>
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<td></td>
<td>LBBB</td>
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<td>Intermittent LBBB</td>
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<td>Intraventricular conduction delay of LBBB type</td>
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<td>Variable LBBB</td>
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<td>7/2003–6/2004</td>
<td>Added</td>
<td>ST abnormality, ST changes, or ST segment described as consistent with ischemia</td>
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<td>LBBB described as old</td>
<td>ST elevation or LBBB with the qualifier “cannot exclude”</td>
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<td>ST segment elevation, or any of the other ST-segment elevation inclusion terms, described as old or previously seen</td>
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<td>MI with any mention of location or combinations of locations (anterior, apical, basal, inferior, lateral, posterior, or combination), if described as acute (eg. “posterior AMI”)</td>
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<td></td>
<td>Q-wave MI, if described as acute</td>
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<td></td>
<td>Transmural MI, if described as acute</td>
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<tr>
<td>7/2004–12/2004</td>
<td>No Changes</td>
<td>No Changes</td>
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<tr>
<td>1/2005–12/2005</td>
<td>Changed</td>
<td>Added</td>
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<td></td>
<td>MI with any mention of location or combinations of locations (anterior, apical, basal, inferior, lateral, posterior, or combination), if described as acute (eg. “posterior AMI”) or evolving</td>
<td>MIs specified as old or noted as previously seen</td>
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<td>Q-wave MI if described as acute or evolving</td>
<td>MIs where the age is documented as undetermined or is not addressed</td>
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<td>ST changes/abnormalities consistent with injury, infarct, acute or evolving MI</td>
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<td>Transmural MI, if described as acute or evolving</td>
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<td></td>
<td>LBBB described as old</td>
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<tr>
<td>1/2006–6/2006</td>
<td>Added</td>
<td>ST elevation, or any of the other ST segment elevation inclusion terms, with mention of pacemaker/pacing (unless atrial only)</td>
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<tr>
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<td>ST segment noted as $\geq 1$ mm</td>
<td>LBBB, or any of the other LBBB inclusion terms, with mention of pacemaker/pacing (unless atrial only)</td>
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(Continued)
were false-positive cardiac catheterization laboratory activations. Of 422 patients with a clear culprit, 402 (80.2% of 501) underwent PCI, 13 underwent coronary artery bypass grafting, and 7 were managed medically. In the same period, 282 patients met inclusion criteria for NCDR (56% of the level 1 population), and 66 met inclusion criteria for TJC (13% of the level 1 population).

**Level 1 Compared With TJC**

Level 1 reported 501 patients with STEMI, whereas TJC reported 66. Of 501 patients presenting per the level 1 protocol, 380 were transferred for PCI and excluded by TJC criteria. Of 121 patients presenting directly to the PCI center, 97 underwent PCI (19 had no clear angiographic culprit and 5 underwent coronary artery bypass grafting, excluding them by TJC criteria). Of the 97 patients who underwent PCI, only 66 were included in TJC’s door-to-balloon time metric. Figure 1 shows the discrepancies between the 2 registries. Figure 2 shows an example of TJC’s ECG wording exclusions in a confirmed STEMI.

**Level 1 Compared With NCDR**

Level 1 reported 501 patients with STEMI, whereas NCDR reported 282 with 274 patients common to both registries. Figure 3 shows discrepancies between the 2 registries. Of 501 patients in level 1, 227 were excluded by NCDR criteria: 99 received fibrinolytics from zone 2, 3 received fibrinolytics from zone 1 (2 weather delay, 1 time delay), 88 had no angiographic culprit, 13 underwent coronary artery bypass grafting, 7 were managed medically, and 1 transfer with cardiac arrest died before angiography. NCDR did not capture 16 patients with STEMI who underwent PCI and met NCDR criteria. Level 1 did not capture 8 patients included by NCDR with confirmed STEMI (all transferred in from emergency departments not participating in the level 1 Program).

**NCDR Compared With TJC**

NCDR reported 282 patients with STEMI, whereas TJC reported 66 with 63 patients common to both registries. Figure 4 shows discrepancies between the 2 registries. Of 282 patients in NCDR, 194 were transferred for PCI and excluded by TJC criteria. Of the remaining 88 patients presenting directly to the PCI center who underwent PCI, TJC included 63 with 25 excluded for reasons outlined in Figure 4. NCDR did not capture 3 patients included by TJC with confirmed STEMI who met criteria for both registries.

**Door-to-Balloon Times and Mortality**

Overall, median door-to-balloon time in TJC’s registry (62 minutes) was lower than either NCDR (92 minutes) or level 1 (96 minutes) because of exclusion of transfer patients. Considering only patients common to all 3 registries (n=63), the door-to-balloon time was similar in all 3 registries despite subtle differences in inclusion criteria (P=0.96 from repeated-measures ANOVA; median times in this subset were level 1, 62 minutes; NCDR, 58 minutes; TJC, 61 minutes). 23 patients (4.6%) in the level 1 cohort and 13

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Table 2. Continued

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<td>7/2006–12/2006</td>
<td>Removed</td>
</tr>
<tr>
<td>Intermittent LBBB</td>
<td>Added</td>
</tr>
<tr>
<td>ST elevation clearly described as confined to one lead</td>
<td>ST elevation described as minimal, &lt;0.1 mV, &lt;1 mm, nondiagnostic, or nonspecific in all leads noted to have ST elevation</td>
</tr>
<tr>
<td>MIs where the age is not addressed</td>
<td>Removed</td>
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<tr>
<td>ST segment elevation with the qualifier possible</td>
<td>Added</td>
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<tr>
<td>ST abnormality, ST changes, or ST segment described as consistent with ischemia</td>
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AMI indicates acute myocardial infarction; LVH, left ventricular hypertrophy.
patients (4.6%) in the NCDR cohort died in the hospital. There were no in-hospital deaths in TJC’s cohort.

Discussion

Our results indicate current inclusion criteria for enrollment in STEMI registries are not uniform and can lead to variable quality assurance outcomes for the same patient cohort. Of 501 STEMI patients in level 1 (402 who underwent primary PCI), only 282 (56%) were recognized by NCDR and only 66 (13%) by TJC. The specific inclusion criteria for enrollment in a STEMI registry has important implications for quality of care measurement, and by extension, pay for performance: 87% of STEMI patients presenting to a facility recognized for high quality STEMI care were not eligible for inclusion in TJC’s door-to-balloon time performance metric.

The development of an “ideal” system for STEMI identification, quality of care process, and performance measurement is challenging. Theoretically, all STEMI patients would be included in process measurement: patients who undergo PCI; patients who undergo coronary artery bypass grafting or are managed medically; false-positive cardiac catheterization laboratory activations; patients who receive fibrinolytics and are transferred for rescue PCI; patients who receive fibrinolytics but remain at a non-PCI center; and eligible but untreated patients who receive neither fibrinolytics nor PCI. Important time to treatment measures beyond door-to-balloon time (eg, chest pain onset to first medical contact, first medical contact to hospital arrival, hospital arrival to ECG, in-door/out-door at community hospital, transfer time, chest pain onset to balloon/needle) and

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**Figure 2.** Example of an ECG excluded from TJC’s STEMI population based on the presence of “age undetermined” on the electronic readout.

**Figure 3.** Discrepancies in reported STEMI between the level 1 and ACC-NCDR registries.
outcome measures (adjunctive medication use, bleeding, recurrent ischemia, recurrent revascularization, stroke, myocardial infarction, mortality) would also be tracked.\textsuperscript{19,20} Currently, the exact definitions for door-to-balloon time differ for NCDR and TJC (the level 1 registry uses NCDR definitions), and there continues to be controversy regarding the appropriate measure for reperfusion (wire, first device, balloon, Thrombolysis in Myocardial Infarction grade 3 flow). The recently published ACC/AHA statement on performance measurement and reperfusion therapy recommends a focus on time of first device rather than time of restoration of flow or measurement and reperfusion therapy recommends a focus on time of first device rather than time of restoration of flow or time to first angiography.\textsuperscript{6,7} Finally, a single comprehensive data collection system would avoid the economic and human resource burden of multiple quality assurance programs: the ACC/AHA statement also encourages “alignment” of data registries in an effort to reduce “measurement fatigue.”\textsuperscript{6,7}

Currently, the accuracy of quality assurance outcomes in STEMI depends on inclusion criteria for enrollment used by a particular registry. The level 1 registry attempts to use comprehensive inclusion criteria. However, patients transferred to other PCI centers and those treated exclusively at community hospitals (individuals not transferred and “eligible but untreated”) are still not captured. The NCDR registry includes only those patients with STEMI who undergo PCI. TJC’s registry—with the most specific inclusion criteria—tracks data exclusively from the PCI center with specific ECG eligibility criteria. From one perspective in our study, the ability of TJC criteria to track patients with STEMI is excellent (66/66, 100%); this actually exceeds the accepted accuracy of the acute myocardial infarction ICD-9 code and TJC/CMS margin of error for abstraction using that ICD-9 code.\textsuperscript{21–24} Viewed from another perspective, the ability of TJC criteria to track patients with STEMI is incomplete: for all individuals presenting directly to the PCI center who underwent PCI, TJC identified only 66/97 (68%). When transfer patients who undergo PCI are included, the ability of TJC criteria to track STEMI patients is poor (66/402, 16%), and it is important to recognize that a significant number of patients with STEMI who do not undergo PCI remain excluded from this denominator. Numerators and denominators in the setting of performance measurement are complex in that there is no “standard” registry, and the concept of sensitivity and specificity in this setting have been partially addressed by the ACC/AHA.\textsuperscript{6,7} The wide variation in quality assurance outcomes in our patient cohort illustrates implications for both quality-of-care measurement and payment for performance.\textsuperscript{25} In TJC’s registry—where a small number of adverse events can dramatically alter a program’s overall outcomes—the potential exists to “game the system” at the expense of overall quality of care. Concern for higher mortality rates in the context of public reporting has previously been highlighted as a possible reason for case-mix differences between New York and Michigan PCI registries and reluctance to treat high-risk patients.\textsuperscript{26,27} Definition-based discrepancies in door-to-balloon time measurement have also recently been recognized: in 2005, agreement in door-to-balloon measures between the Hospital Quality Alliance and NCDR was only fair to moderate across 241 matched hospitals.\textsuperscript{28} This difference resulted in discrepant quality of care rankings for individual hospitals based on the data source.

In our study, the majority of the discrepancy between TJC and level 1 is attributable to patients transferred for primary PCI. Timely transfer of STEMI patients in the United States continues to be an important issue, and studies have recently demonstrated the feasibility of efficient and integrated transfer systems for primary PCI.\textsuperscript{16,29,30} As regional STEMI systems become more widely incorporated, the establishment of uniform registry inclusion criteria to define quality of care will be increasingly important. The opportunity to include transfer patients allows STEMI registries to reflect the efforts of the entire network of care providers. This has the potential to address reimbursement gaps in STEMI care by acknowledging non-PCI transfer facilities.\textsuperscript{31} Increasing timely access to PCI with a coordinated transfer system may dramatically decrease numbers of eligible but untreated patients yet increase overall door-to-balloon times. Therefore, well-integrated systems of STEMI care may substantially impact the “eligible but untreated” population and decrease overall mortality in STEMI, but paradoxically risk higher publicly reported mortality rates. This concept also applies to registries that include high risk patient cohorts (cardiogenic shock and out-of-hospital cardiac arrest), who stand to benefit the most from early PCI. The ACC/AHA has endorsed including transfer patients in performance measurement\textsuperscript{6,7}; however, TJC has not accepted these recommendations and there are no plans for inclusion in the near future.\textsuperscript{23}

In our study, the majority of the discrepancy between NCDR and level 1 is attributable to pharmacoinvasive PCI. Pharmacoinvasive PCI is a broad term that requires rigorous
definition based on dose and type of fibrinolytic, glycoprotein 2B3A inhibitor, and antiplatelet agent. Controversy remains regarding a facilitated/pharmacoinvasive approach when considering transfer for primary PCI. Recently, the CARESS-in-AMI trial demonstrated immediate transfer for PCI in high-risk patients with STEMI treated with half-dose reteplase and abciximab was superior to fibrinolytic plus rescue PCI. The TRANSFER-AMI trial showed similar results with immediate PCI after full-dose tenecteplase. The use of a pharmacoinvasive strategy and the optimal pharmaceutical regimen—particularly for patients transferred from a substantial distance to the PCI hospital—are a matter of ongoing debate. However, it should be acknowledged that for certain “hub-and-spoke” systems, a pharmacoinvasive strategy continues to be used and may be clinically beneficial. Indeed, a substantial percentage of patients from both the Mayo regional and North Carolina statewide systems of STEMI care underwent rescue PCI after full-dose fibrinolitics. As we look to the future with a goal of extending the reach of primary PCI systems, it seems reasonable to account for these patients in an organized fashion. Neither the ACC/AHA nor TJC has recommended that patients who receive fibrinolitics (in any form) be included in future performance measures, and thus these patients remain “uncaptured” by any current quality measure.

In conclusion, current registry inclusion criteria in STEMI are neither uniform nor straightforward: 3 quality-assurance registries (level 1, NCDR, TJC) at a single facility identified vastly different numbers of patients in the same cohort over a 1-year period. Ongoing efforts to improve STEMI care must recognize that registry inclusion criteria vary, with significant implications for quality of care process and performance measurement.

Acknowledgments
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Disclosures
None.

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None.


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