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## Metrics for Measuring Quality of Care in Comprehensive Stroke Centers: Detailed Follow-Up to Brain Attack Coalition Comprehensive Stroke Center Recommendations

### A Statement for Healthcare Professionals From the American Heart Association/American Stroke Association

*Endorsed by the Society of Vascular and Interventional Neurology*

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**Background**—Stroke is a major cause of disability and death. The Brain Attack Coalition has proposed establishment of primary and comprehensive stroke centers to provide appropriate care to stroke patients who require basic and more advanced interventions, respectively. Primary stroke centers have been designated by The Joint Commission since 2003, as well as by various states. The designation of comprehensive stroke centers (CSCs) is now being considered. To assist in this process, we propose a set of metrics and related data that CSCs should track to monitor the quality of care that they provide and to facilitate quality improvement.

**Methods and Results**—We analyzed available guideline statements, reviews, and other literature to identify the major features that distinguish CSCs from primary stroke centers, drafted a set of metrics and related data elements to measure the key components of these aspects of stroke care, and then revised these through an iterative process to reach a consensus. We propose a set of metrics and related data elements that cover the major aspects of specialized care for patients with ischemic cerebrovascular disease and nontraumatic subarachnoid and intracerebral hemorrhages at CSCs.

**Conclusions**—The metrics that we propose are intended to provide a framework for standardized data collection at CSCs to facilitate local quality improvement efforts and to allow for analysis of pooled data from different CSCs that may lead to development of national performance standards for CSCs in the future. (*Stroke*. 2011;42:849-877.)

**Key Words:** AHA Scientific Statements ■ cerebrovascular disorders ■ cerebral hemorrhage ■ ischemic stroke ■ healthcare systems ■ patient care ■ university medical centers

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**S**troke is the third-leading cause of death in the United States and a leading cause of disability. Its manifestations are extremely variable and often profoundly and permanently change a patient's quality of life or even lead to death. Each year,  $\approx 795\,000$  people experience a new or recurrent stroke. Approximately 610 000 of these are first attacks, and 185 000 are recurrent attacks.<sup>1</sup> To assist in ensuring adequate care for stroke patients, the Brain Attack Coalition (BAC) has proposed 2 levels of hospitals for the treatment of stroke patients: Primary stroke centers (PSCs) and comprehensive stroke centers (CSCs).<sup>2,3</sup> In addition, the concept of stroke systems of care that facilitate treatment of stroke patients at the most appropriate type of hospital has been suggested.<sup>4,5</sup> Most stroke patients can be treated appropriately at PSCs. Some patients, however, require intensive care and specialized techniques that are not available at most PSCs but constitute the key features of CSCs.<sup>3</sup> Given this background, the success of the multilevel system of care for trauma patients<sup>6</sup> suggests that there may be similar benefits to establishing such a system for stroke patients.

After the PSC concept was proposed, The Joint Commission and several states independently<sup>6-13</sup> established programs for certification of PSCs. Metrics for measuring performance of PSCs were defined and underwent several cycles of modification as experience in implementing them was obtained.<sup>10,11</sup> Analysis of PSC performance has indicated that establishment of PSCs with concomitant development of formal protocols for stroke care and measurement of adherence to the metrics has been associated with improvement in stroke care.<sup>12-15</sup> Several states have now moved ahead with plans to certify CSCs.<sup>7-9</sup>

In this setting, to help in the development of CSCs, we now propose a set of metrics and associated data elements that cover the major types of care that distinguish CSCs from PSCs. We intend that these metrics will assist in the establishment of CSCs, facilitate quality improvement activities at individual centers, and ultimately permit comparison of practices at different CSCs and ensure that hospitals designated as CSCs provide high levels of care. Quality improvement is an essential element of all medical care<sup>16</sup> but is especially important in a CSC where new techniques are being developed and refined for the care of critically ill patients with complex diseases.<sup>3</sup>

We anticipate that these metrics will undergo modification as experience is gained at CSCs. We want to emphasize that the proposed metrics are not performance measures in the sense that performance measures can be used for direct comparison of the quality of care at different institutions, but rather the proposed metrics should be viewed as quality measures that can facilitate improvement of care and may ultimately lead to the adoption of formal performance measures.<sup>17</sup> Some of the metrics have stronger evidence to support them or have greater clinical significance, and we have designated these as core metrics and the others as supplemental metrics. We anticipate that as the CSC concept is implemented, it may be appropriate to expect CSCs to measure the core metrics and a subset of supplemental metrics. This approach of requiring initial monitoring of only a partial set of metrics was used successfully by The Joint Commission when its PSC program was started.

## Methods

We began by reviewing the key components of CSCs as set forth in the BAC report.<sup>3</sup> We conducted an extensive literature review related to these elements and then drafted a set of metrics and related additional data elements to cover the distinguishing features of CSCs. In designing the metrics, our underlying assumption was that CSCs will be expected to meet all standards required for PSCs by the organization or authority certifying them. The initial draft underwent repeated revisions through cycles of conference calls and e-mail correspondence. Members of the writing committee specifically provided input in drafting metrics related to their areas of expertise and had opportunities to comment on all the metrics repeatedly until consensus was reached. We also obtained opinions from outside stroke experts during this process (see Acknowledgments). In drafting our recommendations, we sought to rely most strongly on formal guideline statements prepared under the auspices of the American Heart Association (AHA) and, when appropriate, other organizations. We particularly relied on items that the guideline statements ranked highest (Tables 1 and 2). We supplemented these with data from other reports and also considered the types of outcomes and complications that were monitored in important clinical trials in our efforts to define metrics related to individual processes of care. We sought to develop a consensus to achieve metrics that are evidence based and in keeping with clinical practice. We also sought to develop metrics that would be feasible to collect in a reproducible way and recognized that in some cases, the data that would be the most desirable might not be reliably collected in routine clinical practice.

In the course of our work, it became clear that some of the metrics had stronger support in the literature or more significant implications for quality of care. On the basis of these considerations, we reached a consensus about designating some of the metrics as core metrics, and we have designated the others as supplemental metrics. We have also identified additional data elements that we encourage CSCs to collect to facilitate interpretation of the data collected for the metrics and to provide additional information for quality improvement. We do not want to imply that this is a complete list of data elements, nor do we intend to suggest that CSCs should be required to collect all of these elements, at least not initially. We intend that the core metrics will be required initially and that CSCs may have some choice about which of the other metrics to record initially, and that over time, this requirement may be revised.

In formulating the metrics, we have divided the patients who will be cared for at a CSC into 3 categories that include the major stroke-related diseases: (1) ischemic cerebrovascular disease; (2) aneurysmal subarachnoid hemorrhage (SAH) and unruptured aneurysms; and (3) nontraumatic intracerebral hemorrhage (ICH; including hemorrhages from arteriovenous malformations [AVMs] and nonhemorrhagic AVMs). We have proposed process metrics and metrics that monitor complication rates and outcomes.

We have also proposed metrics that pertain to the documentation of the initial severity of stroke, aspects of intensive care unit (ICU) treatment and of rehabilitation care, transfer of patients from outside hospitals to a CSC, and participation in research. We also considered the risk adjustment that will be necessary to fully interpret data collected for some of the

Table 1. Applying Classification of Recommendations and Level of Evidence

		SIZE OF TREATMENT EFFECT <span style="float: right;">→</span>			
		<b>CLASS I</b> <i>Benefit &gt;&gt;&gt; Risk</i> Procedure/Treatment <b>SHOULD</b> be performed/administered	<b>CLASS IIa</b> <i>Benefit &gt;&gt; Risk</i> <i>Additional studies with focused objectives needed</i> <b>IT IS REASONABLE</b> to perform procedure/administer treatment	<b>CLASS IIb</b> <i>Benefit ≥ Risk</i> <i>Additional studies with broad objectives needed; additional registry data would be helpful</i> Procedure/Treatment <b>MAY BE CONSIDERED</b>	<b>CLASS III</b> <i>Risk ≥ Benefit</i> Procedure/Treatment should <b>NOT</b> be performed/administered <b>SINCE IT IS NOT HELPFUL AND MAY BE HARMFUL</b>
ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT	<b>LEVEL A</b> Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	<ul style="list-style-type: none"> <li>■ Recommendation that procedure or treatment is useful/effective</li> <li>■ Sufficient evidence from multiple randomized trials or meta-analyses</li> </ul>	<ul style="list-style-type: none"> <li>■ Recommendation in favor of treatment or procedure being useful/effective</li> <li>■ Some conflicting evidence from multiple randomized trials or meta-analyses</li> </ul>	<ul style="list-style-type: none"> <li>■ Recommendation's usefulness/efficacy less well established</li> <li>■ Greater conflicting evidence from multiple randomized trials or meta-analyses</li> </ul>	<ul style="list-style-type: none"> <li>■ Recommendation that procedure or treatment is not useful/effective and may be harmful</li> <li>■ Sufficient evidence from multiple randomized trials or meta-analyses</li> </ul>
	<b>LEVEL B</b> Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	<ul style="list-style-type: none"> <li>■ Recommendation that procedure or treatment is useful/effective</li> <li>■ Evidence from single randomized trial or nonrandomized studies</li> </ul>	<ul style="list-style-type: none"> <li>■ Recommendation in favor of treatment or procedure being useful/effective</li> <li>■ Some conflicting evidence from single randomized trial or nonrandomized studies</li> </ul>	<ul style="list-style-type: none"> <li>■ Recommendation's usefulness/efficacy less well established</li> <li>■ Greater conflicting evidence from single randomized trial or nonrandomized studies</li> </ul>	<ul style="list-style-type: none"> <li>■ Recommendation that procedure or treatment is not useful/effective and may be harmful</li> <li>■ Evidence from single randomized trial or nonrandomized studies</li> </ul>
	<b>LEVEL C</b> Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	<ul style="list-style-type: none"> <li>■ Recommendation that procedure or treatment is useful/effective</li> <li>■ Only expert opinion, case studies, or standard of care</li> </ul>	<ul style="list-style-type: none"> <li>■ Recommendation in favor of treatment or procedure being useful/effective</li> <li>■ Only diverging expert opinion, case studies, or standard of care</li> </ul>	<ul style="list-style-type: none"> <li>■ Recommendation's usefulness/efficacy less well established</li> <li>■ Only diverging expert opinion, case studies, or standard of care</li> </ul>	<ul style="list-style-type: none"> <li>■ Recommendation that procedure or treatment is not useful/effective and may be harmful</li> <li>■ Only expert opinion, case studies, or standard of care</li> </ul>
Suggested phrases for writing recommendations†		should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	is not recommended is not indicated should not is not useful/effective/beneficial may be harmful

\*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as gender, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use. A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Even though randomized trials are not available, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

†For recommendations (Class I and IIa; Level of Evidence A and B only) regarding the comparative effectiveness of one treatment with respect to another, these words or phrases may be accompanied by the additional terms "in preference to" or "to choose" to indicate the favored intervention. For example, "Treatment A is recommended in preference to Treatment B for . . ." or "It is reasonable to choose Treatment A over Treatment B for . . ." Studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

metrics, additional data collection related to in-hospital complications, and participation in registries that may facilitate standardized data collection.

We have also noted additional optional data elements that are related to the metrics and that we encourage CSCs to collect to assist in interpretation of the metric, to help in performance improvement, and to provide additional information for quality improvement for the metrics. Because of the extra resources that would be required to collect these additional data elements, we want to emphasize that it would be reasonable for centers to collect and analyze some of them as part of focused, time-limited quality improvement projects rather than collecting all of them on a continuous basis. We anticipate that centers might decide to conduct such specific projects on the basis of analysis of their performance on the metrics that we have proposed.

In formulating the metrics, we have not set specific performance benchmarks. There is not enough evidence to set

such quantitative standards; nevertheless, it is essential for CSCs to collect data about how quickly or how often they perform certain diagnostic and therapeutic procedures and what their complication rates are, so that they can use this information for quality improvement and so that quantitative standards that CSCs should meet can eventually be set.

## Results

Table 3 summarizes the metrics that we propose for CSCs. Table 3 indicates whether individual metrics are classified as core metrics that we recommend that all CSCs should collect initially and whether the metrics apply only to specific types of patients.

### Ischemic Stroke

#### Metric 1

**Percentage of patients who have an ischemic stroke or who have a transient ischemic attack (TIA) with a**

**Table 2. Definition of Classes and Levels of Evidence Used in AHA Stroke Council Recommendations**

Class I	Conditions for which there is evidence for and/or general agreement that the procedure or treatment is useful and effective
Class II	Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment
Class IIa	The weight of evidence or opinion is in favor of the procedure or treatment
Class IIb	Usefulness/efficacy is less well established by evidence or opinion
Class III	Conditions for which there is evidence and/or general agreement that the procedure or treatment is not useful/effective and in some cases may be harmful
<i>Therapeutic recommendations</i>	
Level of Evidence A	Data derived from multiple randomized clinical trials or meta-analyses
Level of Evidence B	Data derived from a single randomized trial or nonrandomized studies
Level of Evidence C	Consensus opinion of experts, case studies, or standard of care
<i>Diagnostic recommendations</i>	
Level of Evidence A	Data derived from multiple prospective cohort studies using a reference standard applied by a masked evaluator
Level of Evidence B	Data derived from a single grade A study, or $\geq 1$ case-control studies, or studies using a reference standard applied by an unmasked evaluator
Level of Evidence C	Consensus opinion of experts

**deficit at the time of the initial admitting note or neurology consultation note for whom a National Institutes of Health Stroke Scale (NIHSS) score is documented. (Core metric)**

**Numerator:** Number of patients with ischemic stroke or TIA with a deficit at the time of the initial admitting or neurological consultation note for whom an NIHSS is documented. Patients are to be included in the numerator if the NIHSS is recorded in the first admitting note or in the first neurology consultation note, whichever comes first, or in a separate earlier note. Patients with acute ischemic stroke treated with intravenous tissue-type plasminogen activator (tPA) or with an acute endovascular procedure should be included in the numerator only if the NIHSS is performed before the start of these treatments.

**Denominator:** All patients who have an ischemic stroke or TIA with a deficit at the time of the initial admitting or neurology consultation note or who undergo intravenous tPA or acute endovascular treatment with complete resolution of their deficit.

For the purposes of this metric, patients with a TIA should be included if they still have a deficit at the time of the initial admitting or consultation note. In addition, the NIHSS should be performed by a certified examiner.

### *Justification*

The NIHSS is now well established as a reliable and reproducible indicator of ischemic stroke severity. The AHA/American Stroke Association (AHA/ASA) "Guidelines for the Early Management of Adults with Ischemic Stroke" advise the use of a standardized clinical examination for assessing stroke patients, "preferably the NIHSS," as a **Class I, Level of Evidence B** recommendation.<sup>18</sup> The NIHSS has been used in multiple major clinical trials.<sup>19–30</sup> It has been used in all of these trials and others for patient selection. It has been shown to be a strong predictor of outcome<sup>18,31</sup> and therefore is a fundamental factor in risk adjustment.

Ideally, the NIHSS should be administered before initial imaging is performed to establish a baseline and should therefore be administered to both ischemic and hemorrhagic stroke patients, but we recognize that often, this is not done before imaging in clinical practice. We also want to emphasize that imaging should not be delayed to perform the NIHSS. Because the NIHSS is not well established for use in hemorrhagic stroke patients, and because other clinical scales are better established for patients with SAH and ICH, as discussed below under Metric 12, we have not proposed requiring the NIHSS for hemorrhagic stroke patients. Because of the widespread acceptance of the NIHSS, its use in making clinical decisions and in determining eligibility for clinical trials, and the need for quantified measures of initial severity to interpret data about outcomes and other metrics, we have classified this metric as a core metric.

### *Additional Data Elements*

CSCs should also consider recording the size and location of ischemic strokes, the location of any related stenoses or occlusions, and the severity of any related stenoses. In addition, because the NIHSS is not a substitute for a complete neurological assessment by a vascular neurologist, CSCs should consider recording whether each stroke patient is evaluated by a vascular neurologist and the time from admission to evaluation.

### *Metric 2*

**Percentage of ischemic stroke patients eligible for intravenous thrombolysis who receive it within the appropriate time window. (Core metric)**

**Numerator:** Patients who arrive within 3.5 hours of last being known to be at baseline, are candidates for intravenous thrombolysis up to 4.5 hours since last being known to be at baseline, and are treated with intravenous thrombolysis within this time are to be included in the numerator. In addition, the subset of patients who arrive within 2.0 hours of last being known to be at baseline and are candidates for intravenous thrombolysis only up to 3.0 hours of last being known to be at baseline are also to be included in the numerator if they are treated within 3.0 hours.

**Denominator:** Patients who arrive within 3.5 hours of last being known to be at baseline and are candidates for intravenous thrombolysis up to 4.5 hours after last being known to be at baseline are included in the denominator. The subset of patients who arrive within 2.0 hours of last being known to be at baseline and are candidates for intravenous thrombolysis only up to 3.0 hours after last being known to be at baseline are also to be included in the denominator.

**Table 3. Summary of Metrics for Comprehensive Stroke Centers**

Metric	Core Metric	Ischemic Stroke, TIA, or Asymptomatic Cerebrovascular Stenosis	SAH and Nonruptured Aneurysm	ICH and AVM (With or Without Hemorrhage)
Metric 1: Percentage of patients who have an ischemic stroke or who have a TIA with a deficit at the time of the initial admitting note or neurology consultation note for whom an NIHSS score is documented.	Yes	Ischemic stroke, TIA	...	...
Metric 2: Percentage of ischemic stroke patients eligible for intravenous thrombolysis who receive it within the appropriate time window.	Yes	Ischemic stroke seen within 4.5 h of patient last being seen at baseline	...	...
Metric 3: Percentage of patients who are treated for acute ischemic stroke with intravenous thrombolysis whose treatment is started $\leq$ 60 minutes after arrival.	Yes	Ischemic stroke treated with intravenous thrombolysis	...	...
Metric 4: Median time from arrival to start of multimodal CT or MR brain and vascular imaging (MRI/MRA or CT/CTA) for ischemic stroke patients arriving within 6 hours of the time that they were last known to be at baseline, if 1 of these studies is ordered.	Yes	Ischemic stroke seen within 6 h of patient last being known to be at baseline	...	...
Metric 5: Percentage of ischemic stroke patients seen within 6 hours of the time they were last known to be at baseline who have documentation that an endovascular recanalization procedure either was performed or was considered and deemed not to be appropriate or possible. A reason should be documented if an endovascular procedure was not performed.	No	Ischemic stroke seen within 6 h of patient last being known to be at baseline	...	...
Metric 6: Median time from arrival to start of treatment for acute ischemic stroke patients undergoing an endovascular intervention.	No	Ischemic stroke treated with endovascular intervention	...	...
Metric 7: Percentage of patients treated with intravenous thrombolysis who have a symptomatic intracranial hemorrhage within 36 hours of treatment.	Yes	Ischemic stroke treated with intravenous thrombolysis	...	...
Metric 8: Percentage of acute ischemic stroke patients treated with endovascular interventions who develop significant intracranial hemorrhage within 36 hours of treatment.	Yes	Ischemic stroke treated with endovascular intervention	...	...
Metric 9: Percentage of acute ischemic stroke patients who are treated with intravenous thrombolysis or who undergo endovascular interventions for whom there is documentation of a 90-day mRS score.	Yes	Ischemic stroke treated with intravenous thrombolysis or endovascular procedure	...	...
Metric 10: Percentage of patients undergoing CEA, or carotid angioplasty or stenting, with stroke or death within 30 days of the procedure.	No	CEA or stenting	...	...
Metric 11: Percentage of patients undergoing intracranial angioplasty and/or stenting for atherosclerotic disease with stroke or death within 30 days of the procedure.	No	Intracranial angioplasty and/or stenting	...	...
Metric 12: Percentage of SAH, ICH, and AVM patients for whom initial severity measures are documented.	Yes	...	Hunt and Hess scale if SAH	ICH score if ICH (whether or not AVM); Spetzler-Martin for all AVM
Metric 13: Median time from admission to start of procedure intended to obliterate a ruptured aneurysm by surgical clipping or endovascular coiling for patients who arrive within 48 hours of the hemorrhage that led directly to admission.	Yes	...	SAH	...
Metric 14: Percentage of patients with aneurysmal SAH arriving within 48 hours of hemorrhage for whom a coiling or clipping procedure was not started within 36 hours of arrival who have a documented reason for not having undergone coiling or clipping within 36 hours of arrival.	No	...	SAH	...
Metric 15: Percentage of patients with documented aneurysmal SAH for whom nimodipine treatment (60 mg every 4 hours or 30 mg every 2 hours) is started within 24 hours of diagnosis and for whom such treatment is continued until 21 days after the hemorrhage or until discharge if they are discharged $<$ 21 days after the SAH.	Yes	...	SAH	...
Metric 16: Percentage of SAH patients with diminished level of consciousness and ventriculomegaly who are treated with EVD.	No	...	SAH	...
Metric 17: Median frequency of noninvasive monitoring performed for surveillance for vasospasm in patients with aneurysmal SAH during the period between 3 and 14 days after SAH.	No	...	...	...

(Continued)



Table 3. Continued

Metric	Core Metric	Ischemic Stroke, TIA, or Asymptomatic Cerebrovascular Stenosis	SAH and Nonruptured Aneurysm	ICH and AVM (With or Without Hemorrhage)
Metric 18: Complication rates for aneurysm coiling and clipping.	No	...	All	...
Metric 19: Median time from arrival to start of treatment to reverse the INR with a procoagulant preparation (eg, fresh frozen plasma, recombinant factor VIIa, prothrombin complex concentrates) for patients with warfarin-associated ICH and an elevated INR (INR >1.4).	Yes	...	...	ICH (if warfarin-associated)
Metric 20: Percentage of patients undergoing surgical or endovascular treatment of an AVM with stroke or death within 30 days of the procedure.	No	...	...	AVM
Metric 21: Percentage of patients with ischemic or hemorrhagic stroke or TIA transferred from another hospital to the CSC with documentation of the time from the first call from the transferring hospital to the CSC (to a member of a stroke program or to a centralized transfer center) to arrival time at the CSC.	No	All patients transferred from another hospital	All patients transferred from another hospital	All patients transferred from another hospital
Metric 22: Percentage of patients admitted to each type of unit to which patients with ischemic or hemorrhagic stroke or TIA are initially admitted (eg, neurological/neurosurgical ICU, medical ICU, surgical ICU, general ICU, coronary care unit, burn ICU, stroke unit, other intermediate-level-of-care unit, neurology floor, or other floor). A separate percentage should be calculated for each type of unit.	No	All	All	All
Metric 23: Percentage of patients with stroke or death within 24 hours of diagnostic neuroangiography.	Yes	If diagnostic angiogram is performed	If diagnostic angiogram is performed	If diagnostic angiogram is performed
Metric 24: Percentage of patients who have a diagnosis of ischemic or hemorrhagic stroke who undergo EVD and then develop ventriculitis.	No	If patient has EVD	If patient has EVD	If patient has EVD
Metric 25: Median number of days from admission to completion of evaluations for physical therapy, occupational therapy, speech-language pathology, and rehabilitation medicine, unless there is documentation on admission that some or all of these evaluations are not needed or that the patient cannot tolerate them because of medical instability.	No	All	All	All
Metric 26: Percentage of patients admitted with diagnoses of ischemic stroke, SAH, AVM, intracranial hemorrhage, extracranial cervical stenosis, intracranial stenosis, or TIA who are enrolled in a clinical research study.	No	All	All	All

TIA indicates transient ischemic attack; SAH, subarachnoid hemorrhage; ICH, intracerebral hemorrhage; AVM, arteriovenous malformation; NIHSS, National Institutes of Health Stroke Scale; CT, computed tomography; MR, magnetic resonance; MRI/MRA, magnetic resonance imaging/angiography; CT/CTA, computed tomography/computed tomography angiography; mRS, modified Rankin Scale; CEA, carotid endarterectomy; EVD, external ventricular drainage; INR, international normalized ratio; CSC, comprehensive stroke center; and ICU, intensive care unit.

For patients with stroke in the hospital, the time of arrival should be taken to be the time that the deficit was first discovered.

Patients who are transferred to the CSC after intravenous thrombolysis is started at another hospital should be excluded from this metric for the CSC.

A reason should be documented if intravenous thrombolysis is not administered. The acceptable reasons for not treating patients with intravenous thrombolysis within 3 hours are listed in the AHA/ASA "Guidelines for the Early Management of Adults With Ischemic Stroke."<sup>18</sup> The acceptable reasons for not treating patients with intravenous thrombolysis within 4.5 hours are the same, with several additional reasons.<sup>32</sup> In addition, in view of the accepted target of a 60-minute door-to-needle time,<sup>33–37</sup> patients are excluded from this metric if they arrive <1 hour before the end of the appropriate time window. Finally, we also think that it is acceptable for centers to consider that patients who meet the published criteria for treatment in the 3- to 4.5-hour window are not eligible for intravenous thrombolysis for the purposes of this metric if there is documentation in the

patient's chart that the risks outweigh the potential benefit or that the patient is to be enrolled in a clinical trial. The reasons for allowing patients who could receive intravenous thrombolysis in the 3- to 4.5-hour window to be dealt with in this way are that intravenous tPA is currently approved by the US Food and Drug Administration only for patients treated within 3 hours, and treatment in the 3- to 4.5-hour window is only a **Class I, Level of Evidence B** recommendation,<sup>32</sup> whereas treatment in the less than 3-hour period is a **Class I, Level of Evidence A** recommendation.<sup>18</sup>

In addition to computing this metric for all eligible patients seen within 3.5 hours, centers should also compute it separately for patients seen within 2 hours and those seen between 2 and 3.5 hours of the time when they were last known to be at baseline.

#### Justification

Intravenous thrombolysis with tPA is still the only intervention that has been approved by the US Food and Drug Administration as a treatment to improve the clinical outcome of acute ischemic stroke patients, and it is a cornerstone of acute stroke treat-

ment.<sup>2,20</sup> Meta-analysis of trials of intravenous thrombolysis has suggested that earlier treatment with intravenous tPA leads to better outcomes,<sup>27,38</sup> so the faster that intravenous tPA is given, the better. Initial analysis of the National Institute of Neurological Disorders and Stroke tPA trial also supported this conclusion,<sup>39</sup> but several subsequent reanalyses of the trial itself have not found a statistically significant effect for earlier treatment.<sup>40–42</sup> Despite the uncertainty raised by these reanalyses, we conclude that the time from arrival to start of treatment should be kept to a minimum. A goal of  $\leq 60$  minutes for the period from time to arrival to initiation of treatment has been proposed to allow adequate time for appropriate clinical and imaging evaluation<sup>33–35</sup> and appears to be feasible.<sup>36,37</sup>

Because of ECASS (European Cooperative Acute Stroke Study) III<sup>28</sup> and the subsequent AHA science advisory that expanded the window for treatment from 3 to 4.5 hours,<sup>32</sup> we propose the inclusion of patients seen at up to 3.5 hours from the time that they were last known to be at baseline.

### **Metric 3**

**Percentage of patients who are treated for acute ischemic stroke with intravenous thrombolysis whose treatment is started  $\leq 60$  minutes after arrival. (Core metric)**

**Numerator:** Patients treated with intravenous thrombolysis for acute ischemic stroke whose treatment is started within 60 minutes of arrival.

**Denominator:** All patients treated with intravenous thrombolysis for acute ischemic stroke.

For patients with stroke in the hospital, the time of arrival should be taken to be the time that the deficit was first discovered.

Patients who are transferred to the CSC after intravenous thrombolysis is started at another hospital should be excluded from this metric for the CSC.

### *Justification*

As noted above in the justification of Metric 2, more rapid initiation of intravenous thrombolysis appears to be beneficial, so we propose that CSCs also track door-to-needle time to aid in quality improvement efforts to reduce this time as much as possible and that they review all intravenous thrombolysis cases to look for ways to reduce this time further. We anticipate that CSCs will record the door-to-needle time itself for Metric 2 (and not just whether or not it was  $< 60$  minutes) to aid in quality improvement efforts.

Although many PSCs track arrival to intravenous thrombolysis times with databases such as Get With The Guidelines,<sup>43</sup> and some states require stroke centers to report door-to-needle time for patients treated with intravenous tPA,<sup>12</sup> door-to-needle time itself is not currently one of the harmonized PSC performance measures established by The Joint Commission, the Centers for Disease Control and Prevention, and the AHA.<sup>44,45</sup> The current harmonized PSC performance measure looks at the percentage of patients arriving within 2 hours and treated within 3 hours. CSCs should be especially vigilant in monitoring the efficiency of delivering care for acute stroke patients, so we recommend that this be a core metric.

The goal of starting intravenous thrombolysis within 60 minutes of arrival has become an accepted target for stroke centers, as noted in the discussion of Metric 2,<sup>12,33–37</sup> although it

remains difficult to achieve in all cases. In addition, the AHA has recently launched a national campaign focused on reducing door-to-needle times to  $< 60$  minutes in 50% of all treated patients.<sup>47</sup>

### *Additional Data Elements*

In view of the ECASS III study,<sup>32</sup> which found a benefit to the use of intravenous tPA for patients treated within 3 to 4.5 hours of stroke onset, we would encourage CSCs to analyze data about such patients separately from data for patients treated within 3 hours of onset.

Because of concern that performance of multimodal computed tomography (CT) and magnetic resonance imaging (MRI) could delay treatment with intravenous tPA, centers should analyze the data collected under this metric and Metrics 2 and 4 to determine whether performance of multimodal imaging before intravenous tPA administration prolongs the door-to-needle time and whether the information obtained was needed to make a decision about the use of intravenous tPA (as might be the case, for example, if there was uncertainty about the diagnosis of stroke in a patient with seizure at onset of symptoms or hypoglycemia at onset).

### *Metric 4*

**Median time from arrival to start of multimodal CT or magnetic resonance (MR) brain and vascular imaging (MRI/MR angiography or CT/CT angiography [CTA]) for ischemic stroke patients arriving within 6 hours of the time that they were last known to be at baseline, if 1 of these studies is ordered. (Core metric)**

Multimodal CT may include noncontrast CT, CT perfusion, and CTA studies.<sup>18</sup> Multimodal MRI may include diffusion-weighted imaging, perfusion-weighted imaging, MR angiography, gradient echo, and fluid-attenuated inversion recovery or T2-weighted sequences.<sup>18</sup>

The start time for multimodal imaging should be the time recorded on the first vascular or perfusion imaging sequence. If multimodal imaging was performed as part of the same study that included routine anatomic imaging and a separate time cannot be identified for the first vascular or perfusion sequence, then the start time for the entire study should be used.

Patients should be excluded from this metric if there is a documented reason for not performing multimodal imaging quickly (eg, a patient with a mild clinical deficit judged too small to warrant endovascular intervention, a patient enrolled in a clinical trial that precludes emergency vascular imaging, a patient deemed medically too unstable, a patient deemed to have a deficit that is too large or too long established for these procedures, or a patient who proceeds directly to angiography without having any of these studies performed). This metric does not include patients who are only undergoing simple noncontrast CT scans to assess eligibility for intravenous tPA without performance of multimodal imaging (which may include CTA or perfusion studies). Noncontrast CT, when appropriate, should be completed within 25 minutes, as expected for PSCs,<sup>2</sup> whether or not other imaging is also performed emergently.

We also note that these brain and vascular imaging studies may be delayed in some centers in some patients who receive intravenous tPA if the intravenous tPA is given before the studies are performed, so it will be important for centers to



monitor their performance on this measure separately for patients who receive intravenous tPA before the studies are performed.

For patients with stroke in the hospital, the time of arrival should be the time that the deficit was first discovered.

The intent of this metric is to monitor the time that it takes to perform these studies when needed emergently for the care of acute ischemic stroke patients and not to imply that they should be performed on all such patients.

For purposes of this metric, if vascular imaging is performed immediately after noncontrast imaging without removing the patient from the scanner, the time the multimodal procedure was started should be used as the time the noncontrast brain study was begun.

#### *Justification*

The AHA/ASA "Guidelines for the Early Management of Adults With Ischemic Stroke" state that multimodal CT and MRI "may provide additional information that will improve the diagnosis of ischemic stroke" (**Class I; Level of Evidence A**).<sup>18</sup> This additional information includes location and severity of ischemia and location of vascular occlusions and stenoses. Potentially, the additional information may lead to refinement of care for some patients with acute stroke. The new AHA Recommendations for "Imaging of Acute Ischemic Stroke" note that vascular imaging may help in deciding between intravenous and intra-arterial thrombolytic therapies (**Level of Evidence B**) but should not delay intravenous thrombolysis. Vascular imaging should be performed if intra-arterial therapy is being considered in patients >3 hours after onset of stroke (**Level of Evidence A**).<sup>48</sup> Because of the strengths of these recommendations and the need for rapid evaluation of acute ischemic stroke patients, we propose that the time to multimodal imaging when it is ordered for acute stroke patients should be a core metric for CSCs.

The BAC CSC report emphasized the importance of rapid performance of brain and vascular imaging studies in acute ischemic stroke patients. The report proposed a 2-hour standard for time from ordering MR studies to their completion, but we have chosen the time from arrival to start of imaging as the primary measure because of concerns that the time of ordering often cannot be determined reliably and concerns that the time the studies were begun can be obtained more consistently from currently available scanners than the time of completion. In addition, we believe that a 2-hour delay to imaging is unacceptably long for many acute stroke patients, so rather than proposing a specific benchmark, we propose that centers should document the time that it takes to complete imaging and use these data as part of a continuous quality improvement effort to improve and, when appropriate, speed up care of acute stroke patients. We have expanded this metric to include multimodal CT because we recognize that in many centers, CTA and sometimes CT perfusion studies are performed in preference to MR, because CT can be performed more quickly and on more patients. Despite concerns about contrast-induced renal failure with CTA and CT perfusion, the incidence of this complication is extremely low.<sup>49</sup> We recognize that in many centers, MR or CT perfusion studies are performed, but we do not require them for studies performed under this metric, because the evidence

supporting their use is weaker than that for the other studies that are included in this measure.<sup>3</sup>

The additional information obtained by multimodal imaging with regard to prognosis, severity, cause of stroke, and possible therapeutic options justifies its use for evaluation of acute stroke patients (typically those within a 6-hour window) in a CSC. Although it is not yet certain how this information may be applied, many reports have proposed using these types of data to choose patients for endovascular reperfusion procedures.<sup>50–53</sup> If these studies are performed for this purpose, they should be performed quickly. Although multimodal CT currently can be performed more quickly than MR, some investigators report that multimodal MR can also be performed in some circumstances without preventing rapid administration of intravenous tPA.<sup>54</sup> However, multimodal brain and vascular imaging studies should not delay emergency treatment of stroke (ie, treatment with intravenous tPA), as noted in a **Class I; Level of Evidence C** recommendation in the AHA/ASA "Guidelines for the Early Management of Adults With Ischemic Stroke."<sup>18</sup>

#### *Additional Data Elements*

CSCs should consider tracking the time required for ordering MRI/MR angiography or CTA, times of completion, and time to initial interpretation of the studies as part of their quality improvement efforts.

The BAC PSC and CSC reports both emphasize the importance of having a stroke team with specialized expertise assist in the rapid evaluation and ongoing care of stroke patients. Clinical experience suggests that early involvement of the stroke team is important in starting treatment rapidly, so we also suggest that CSCs should consider carefully monitoring the time from arrival of the patient (or from recognition of a possible acute stroke for strokes in inpatients) to the first call to the stroke team and to arrival of the initial responding member of the team at the patient's bedside.

#### *Metric 5*

**Percentage of ischemic stroke patients seen within 6 hours of the time they were last known to be at baseline who have documentation that an endovascular recanalization procedure either was performed or was considered and deemed not to be appropriate or possible. A reason should be documented if an endovascular procedure was not performed.**

**Numerator:** Number of ischemic stroke patients seen within 6 hours of the time when they were last known to be at baseline who undergo an endovascular revascularization procedure or are documented not to be a candidate for such a procedure.

**Denominator:** Number of ischemic stroke patients seen within 6 hours of the time when they were last known to be at baseline.

Allowable reasons for not performing an endovascular procedure but still including a patient in the numerator may include the following: Enrollment in a clinical trial, arrival time that is too late for treatment, deficits that are too severe or too mild, elevated creatinine, comorbidities, advanced age, lack of major vessel occlusion, rapid improvement, large volume of advanced ischemic injury, refusal of a procedure by the patient or the

patient's family, lack of an appropriate proxy for a patient unable to consent to the procedure, and insufficient evidence to support intervention in the judgment of the treating physicians.

Unavailability of endovascular services is also an allowable reason for including a patient in the numerator for this metric, because even though coverage by endovascular interventionalists 24 hours a day, 7 days a week is expected to be an integral part of CSCs,<sup>3</sup> we recognize that there are some occasions when endovascular intervention is legitimately not available. Reasons for such unavailability include simultaneous emergencies, equipment failure, and unavailability of key staff, for example, for medical- or weather-related reasons. These reasons and their frequency should be tracked carefully and reported separately. Moreover, CSCs must have contingency plans to minimize the chance that services are unavailable. Quality improvement efforts should be directed toward decreasing such unavailability over time. For example, CSCs should develop plans to transfer patients to another center when time permits if there are short periods during which endovascular procedures are not available (or to divert them to another center initially). CSCs should not accept transfers of patients who may be candidates for such procedures during these periods unless there are other overriding reasons for transfer, such as a need for intensive care not available at another center that is within an appropriate distance. Quality improvement efforts should be directed toward decreasing such periods when services are unavailable.

In addition, we want to emphasize that the intent of this metric is to ensure that CSCs are actively considering the endovascular procedures that they are capable of performing for acute ischemic stroke patients, not to encourage indiscriminate use of such procedures, whose benefit for stroke treatment has not yet been established. We also want to emphasize that CSCs should consider active participation in clinical trials for patients who are seen within 8 hours of stroke onset and are monitored under this metric because of the many unanswered questions about the optimum treatment for such patients and the large potential benefits if the damage from their strokes can be limited.

#### *Justification*

The AHA/ASA "Guidelines for the Early Management of Adults With Ischemic Stroke" state that endovascular thrombolysis (**Class I; Level of Evidence B**) and mechanical clot retrieval with Merci or Penumbra devices (**Class IIb; Level of Evidence B**) are options for treatment of some ischemic stroke patients,<sup>18</sup> and endovascular procedures should be available at a CSC.<sup>3</sup> Both the American College of Chest Physicians Evidence-Based Clinical Practice Guidelines and the AHA *ACLS Provider Manual* have also stated that endovascular thrombolysis has a role in the treatment of some acute ischemic stroke patients.<sup>33,35</sup> In this setting, we recommend that CSCs should consider endovascular interventions for acute stroke, but because of limited data about the actual efficacy of endovascular procedures,<sup>55-57</sup> we do not think that a metric that specifically prescribes endovascular interventions for any group of patients is appropriate yet, nor do we think that there is enough evidence to limit this metric to patients with strokes of any specific severity. In addition, because of these issues, we have not classified this metric as a core metric. Finally, because mechanical clot-

retrieval devices have been approved for use up to 8 hours from the time of stroke onset, we propose the inclusion of patients seen within 6 hours, to allow 2 hours for noninvasive evaluation, diagnostic angiography, and endovascular treatment.

#### *Additional Data Element*

CSCs should consider tracking whether patients who present with posterior circulation strokes up to 24 hours from last being known to be at baseline are considered for endovascular treatment and whether a reason for not treating them is documented if they do not undergo a procedure. The window for treating such patients may be considerably longer than 6 hours.<sup>18,58</sup>

#### *Metric 6*

### **Median time from arrival to start of treatment for acute ischemic stroke patients undergoing an endovascular intervention.**

The start of treatment is defined here as the start of intra-arterial infusion of a thrombolytic drug or the first pass with a device such as a Merci or Penumbra catheter.<sup>26,55</sup> If the time that treatment was started cannot be determined accurately, centers may use the time halfway between groin puncture and completion of the procedure. For patients who have a stroke in the hospital, the time of arrival should be taken to be the time that the deficit was first discovered.

#### *Justification*

Although a consensus does not exist about the efficacy of endovascular interventions for acute ischemic stroke, it is clear that the sooner reperfusion is achieved, the more likely it is to be beneficial.<sup>59,60</sup> We have chosen this metric as the best way to measure the overall speed of the process. It is closer to the physiologically relevant time of reperfusion than the time of puncture. Time of reperfusion, however, may be difficult to determine, because partial recanalization is often achieved before maximal recanalization, and different branches may be opened at different times.

If and when additional evidence becomes available to support the efficacy of endovascular treatment for ischemic stroke, a metric related to the speed of performing endovascular procedures should be considered for inclusion in the set of core metrics. For now, however, we have classified this measure as a supplemental metric. In addition, as experience is gained with this metric, establishment of a benchmark time from arrival to start of treatment should be considered. In view of current cardiology guidelines for door-to-angioplasty time for acute myocardial infarction, for which the goal is 90 minutes,<sup>61</sup> we encourage CSCs to at least aim for a goal of 2 hours, given that stroke patients need to undergo imaging before any endovascular procedure.

#### *Additional Data Elements*

To assist in quality improvement, centers should also consider collecting information about time of arrival in the angiography laboratory, time of groin puncture, time of diagnostic angiographic injection in the vessel supplying the region of the stroke, and time of initial reperfusion and final attempts at reperfusion. The effects of intravenous thrombolysis and of the performance of CTA/CT perfusion or MRI/MR angiography on times of angiography and on outcome should be analyzed as appropriate for quality improvement efforts. Centers should also consider

monitoring the time of arrival in laboratory, the time of puncture, and the time of diagnostic injection for acute stroke patients who do not undergo an intervention.

Centers should also consider monitoring the extent of initial perfusion and of reperfusion at the end of the procedure, as well as degree of reperfusion, using a validated metric. Metrics could include the Thrombolysis in Cerebral Ischemia scale, the Thrombolysis in Myocardial Infarction scale adapted for the cerebral circulation, the Arterial Occlusive Lesion scale, and/or the Qureshi Site of Occlusion Scale.<sup>29,30,62–65</sup>

#### **Metric 7**

#### **Percentage of patients treated with intravenous thrombolysis who have a symptomatic intracranial hemorrhage within 36 hours of treatment. (Core metric)**

**Numerator:** Patients treated with intravenous thrombolysis who have a symptomatic intracranial hemorrhage in the first 36 hours after treatment.

For the purposes of this metric, symptomatic intracranial hemorrhage is defined by the presence of a new intracranial hemorrhage on a CT or MRI that is performed within 36 hours of the end of treatment, with documentation in the medical record that there has been a clinical deterioration, in the absence of documentation that an alternate mechanism caused the deterioration. Acceptable alternate mechanisms may include infection, new stroke or increased swelling of ischemic tissue, seizures, and metabolic and toxic encephalopathy.

Any hemorrhage seen on CT and not identified on a pretreatment scan should be considered new. For patients who have a posttreatment MRI that shows a hemorrhage and only pretreatment CT imaging that did not show the hemorrhage, the hemorrhage should be considered old if its imaging characteristics suggest that it occurred before treatment. If clinically appropriate, a posttreatment CT in addition to the MRI may help determine the age and significance of the hemorrhage. Evidence from older scans performed before the acute presentation, a history of intracranial hemorrhage in the appropriate location, or other relevant clinical information may be used to help determine whether a hemorrhage seen on MRI is new or old. We also note that in general, hemorrhagic transformation with parenchymal hematoma, rather than petechial hemorrhage,<sup>28,66</sup> is expected when brain hemorrhage produces neurological deterioration.

Neurological deterioration is defined as any increase in the patient's NIHSS score, if the score was documented. If it was not documented, neurological deterioration is defined as any documentation of neurological worsening. In addition, even if the NIHSS does not increase, a patient should be included in this metric if the clinicians caring for the patient document that there is worsening that they believe was caused by the hemorrhage. Isolated headache, however, should not be considered evidence of neurological worsening. To determine whether a hemorrhage occurred within 36 hours of treatment, the time to be calculated is the interval from the conclusion of treatment to the time of the last assessment before the one in which the clinical deterioration associated with the hemorrhage was first noted.

**Denominator:** All patients treated with intravenous thrombolysis. If a center uses a "bridging" protocol and treats

some patients with intravenous thrombolysis followed by an endovascular procedure, these patients should be included in the primary metric calculated here, but centers should also track symptomatic intracranial hemorrhage rates separately for patients treated only with intravenous thrombolysis and those treated with a bridging protocol and should consider whether particular types of endovascular therapy are associated with higher rates of intracranial hemorrhage.

#### *Justification*

The risk of intracranial hemorrhage is one of the most serious complications associated with the use of intravenous tPA. In the National Institute of Neurological Disorders and Stroke trial,<sup>20</sup> there was a 6.4% risk of symptomatic hemorrhage among those treated with intravenous tPA compared with a 0.6% risk for control patients ( $P < 0.001$ ). As stated in the AHA/ASA "Guidelines for the Early Management of Adults With Ischemic Stroke," "It is now clear that the risk of hemorrhage is proportional to the degree to which the NINDS protocol is not followed."<sup>18,67–69</sup> Given this background, we recommend that the rate of hemorrhage be tracked as a metric by CSCs and that quality improvement efforts be directed to analyze any protocol deviations in patients who have a symptomatic intracranial hemorrhage after intravenous thrombolysis and to identify other factors that may have contributed to intracranial hemorrhage.<sup>70,71</sup> Given the potentially devastating consequences of intracranial hemorrhage after thrombolysis, this should be a core metric, because it is essential for the assessment of CSC performance.

We recognize that the use of a 36-hour window for inclusion of hemorrhages is somewhat arbitrary, but we have chosen this in keeping with the ECASS III trial, in which routine follow-up scans were performed up to 36 hours after treatment.<sup>28</sup> We have defined the window in terms of the time of clinical deterioration rather than the time of scanning, however, so that hemorrhages are included even if the scan is delayed because a patient is too unstable to be scanned.

We have not specifically excluded petechial hemorrhages from the numerator because we are concerned that hemorrhages may not be classified reliably in clinical practice. However, minor hemorrhages that are not associated with any worsening will not be included in the numerator whether they are only petechial or not.

We recognize that the hemorrhage rates from this metric may differ from those obtained in previous clinical trials, but we think that the definition we are proposing is a more feasible one to implement in clinical practice, and it will be possible to develop expected norms for this metric by comparing data from different centers.

#### *Additional Data Elements*

CSCs should also consider tracking asymptomatic hemorrhages and delayed symptomatic hemorrhages, the size and location of any postthrombolysis hemorrhages, and the type of hemorrhage (eg, hemorrhagic infarction or parenchymal hematoma as defined in the ECASS trials).<sup>28,66</sup> We also encourage CSCs to record the NIHSS score whenever a deterioration occurs after thrombolysis and to consider the effects of the time from onset to treatment on the rate of hemorrhage.

**Metric 8****Percentage of acute ischemic stroke patients treated with endovascular interventions who develop symptomatic intracranial hemorrhage within 36 hours of treatment. (Core metric)**

**Numerator:** Patients who undergo endovascular intervention for acute ischemic stroke and have a symptomatic intracranial hemorrhage in the first 36 hours after treatment. Symptomatic intracranial hemorrhage should be defined as in Metric 7.

**Denominator:** All patients who undergo endovascular intervention for acute ischemic stroke. If a center uses a “bridging” protocol and treats some patients with intravenous thrombolysis followed by an endovascular procedure, these patients should be included in the primary metric calculated here, but as noted under Metric 7, centers should also track symptomatic intracranial hemorrhage rates separately for patients treated only with endovascular thrombolysis and those treated with a bridging protocol.

*Justification*

The risk of ICH is the most serious problem associated with endovascular procedures for treatment of acute ischemic stroke, just as it is with intravenous tPA. Especially in view of the lack of proof for the efficacy of endovascular procedures, it is important for CSCs to monitor patients who undergo these procedures carefully for the development of hemorrhage. CSCs should track the development of postprocedural hemorrhages and subject these to rigorous quality improvement analysis to identify potential contributing factors.<sup>70,71</sup> Given the potentially devastating consequences of intracranial hemorrhage after endovascular interventions, this should be a core metric, because it is essential for assessment of CSC performance.

*Additional Data Elements*

CSCs should also consider tracking the same additional data elements suggested for treatment with intravenous thrombolysis under Metric 7.

**Metric 9****Percentage of acute ischemic stroke patients who are treated with intravenous thrombolysis or who undergo endovascular interventions for whom there is documentation of a 90-day Modified Rankin Scale (mRS) score. (Core metric)**

**Numerator:** All patients with ischemic stroke acutely treated with intravenous thrombolysis or with an endovascular recanalization procedure who had an mRS performed at approximately 90 days after the stroke, either in person or by telephone if it was not possible to perform in person. The mRS should be conducted by an appropriately trained individual using a standardized interview. The mRS may be based on information obtained from the patient or from an appropriate family member or caregiver. The mRS should be performed within 2 weeks of the date at which it has been 90 days since stroke onset; it may be performed over the telephone if necessary.

**Denominator:** All patients admitted with ischemic stroke acutely treated with intravenous thrombolysis or with an endovascular recanalization procedure.

*Justification*

The mRS has been shown to be a reliable and reproducible measure of stroke outcome. Because the mRS considers impairments, functional ability, and role outcomes, it serves as a global functional health index with strong emphasis on physical disability.<sup>72</sup> Its popularity derives both from its face validity, its relative efficiency, and its generally well-accepted dichotomization in categorizing dependent versus independent stroke survivors (mRS score 0 to 2 versus 3 to 6). The mRS at 3 months after stroke has become the accepted standard for assessing recovery from ischemic stroke and has been used in numerous recent large randomized clinical trials.<sup>20–24,73</sup>

Because the mRS categories can be assessed somewhat subjectively, as shown by multiple studies demonstrating lower than desirable interrater reliability, the use of a structured interview by a trained evaluator to assign mRS scores should be standard; this leads to good reproducibility of results.<sup>74–76</sup> The use of a standardized interview to assess the mRS score at 3 months should therefore be a key outcome measure in acute ischemic stroke patients treated with intravenous thrombolysis or acute endovascular recanalization at CSCs. This interview could be conducted over the telephone, if necessary (a **Class I; Level of Evidence B** recommendation of the AHA review of telemedicine for stroke<sup>77</sup>). A family member or caregiver may be interviewed if appropriate.

We recognize that acquiring data after hospital discharge may be difficult, but we believe that such data are essential if CSCs are to monitor the outcomes of their care of acute stroke patients in a meaningful way. Such monitoring is necessary for quality assessment and improvement, which are especially important for patients treated with acute interventions because of the risks associated with these interventions. It is important to track whether success rates with intravenous thrombolysis in clinical practice at each CSC match those reached in clinical trials,<sup>18,67–69,78–82</sup> and close monitoring of the outcomes of endovascular procedures is also crucial, especially in view of the lack of definitive evidence for the efficacy of these treatments. The importance of these issues to care of acute ischemic stroke patients justifies the classification of this metric as a core metric for CSCs.

In addition, collection of follow-up information provides a mechanism for contact between the CSC and patients that may facilitate long-term follow-up care and compliance with therapy for secondary prevention of stroke. In this regard, collection of follow-up data at 30 days after other procedures, as noted below, may similarly facilitate long-term care.

Because outcome at 90 days will depend heavily on initial stroke severity and may also depend on the quality of care received after discharge from the CSC, and because collection of the score at 90 days may be difficult in some cases, we have proposed that the primary metric involving the mRS simply be whether it is collected. We expect, however, that CSCs will track the mRS data and use these data for quality improvement, as noted above.

*Additional Data Elements*

If the mRS is not obtained, CSCs should record whether attempts were made to obtain it in accordance with an institutionally established protocol. When collecting informa-

tion about the 90-day mRS, CSCs should also consider whether to collect information about compliance with medications prescribed at discharge, such as antithrombotic drugs, statins, and antihypertensive drugs. Outpatient compliance with therapy for secondary prevention is an essential element of care both at CSCs and at PSCs; we raise this issue here because there is as yet no requirement for monitoring outpatient compliance at PSCs, and because part of the overall mission of CSCs is to provide comprehensive high-quality care, they should also consider addressing outpatient compliance. In this regard, the BAC CSC report notes that an outpatient stroke clinic is an optional component of a CSC.

Although we have recommended collecting the mRS only on ischemic stroke patients undergoing intravenous thrombolysis or endovascular procedures, CSCs should also consider collecting the score on all ischemic and hemorrhagic stroke patients. In this regard, the importance of 90-day follow-up data was previously recognized in the proposed design of the Coverdell Stroke Registry.<sup>83</sup> If collecting the 90-day data on the limited set of stroke patients treated acutely proves feasible and useful, we would favor expanding this metric to include all stroke patients in the future.

We also recognize that recovery may continue long beyond 3 months for ischemic stroke patients and may be slower for patients with hemorrhagic stroke (especially SAH). In this regard, the primary end point of the International Subarachnoid Aneurysm Trial (ISAT) was the mRS at 1 year.<sup>84</sup> Given the difficulties inherent in obtaining lengthy follow-up data, however, we suggest a 90-day follow-up assessment as a reasonable outcome. CSCs should consider collecting data on 1-year follow-up as an additional data element, especially for SAH patients.

CSCs should also consider collecting other functional measures of patient status, such as the Barthel Index. In addition, they should consider collecting the NIHSS at selected times after admission, such as 24 hours after acute interventions and at discharge. Changes in the NIHSS score appear to be a useful stroke outcome measure.<sup>85</sup>

#### **Metric 10**

#### **Percentage of patients undergoing carotid endarterectomy (CEA), or carotid angioplasty or stenting, with stroke or death within 30 days of the procedure.**

**Numerator:** Number of patients who have a stroke or die within 30 days of CEA, or who have carotid angioplasty or stenting performed because of atherosclerotic disease.

**Denominator:** Total number of patients who undergo CEA or who undergo carotid angioplasty or stenting because of atherosclerotic disease.

The metric should be calculated for all procedures taken together and separately for the following groups of patients: (1) Symptomatic patients undergoing endarterectomy; (2) symptomatic patients undergoing carotid angioplasty or stenting; (3) asymptomatic patients undergoing endarterectomy; and (4) asymptomatic patients undergoing carotid angioplasty or stenting. Patients should be excluded from this metric if it is not possible to obtain information about their 30-day stroke and mortality status after reasonable efforts in accordance with a locally established protocol have been made. The number of

such failures to obtain follow-up information should be tracked by CSCs and must be documented formally, along with the complication rates whenever these are reported. This proviso will also apply to subsequent metrics about outcomes for other procedures.

Strokes should be included if they meet the clinical definition of a focal neurological deficit that persists for  $\geq 24$  hours without other cause or if there is a focal deficit that lasts for a shorter period of time but is associated with an appropriately located acute ischemic lesion on MRI. Clinically silent acute lesions detected on diffusion-weighted MRI should not be included as complications, because they are likely to be common when MRI is performed, although their incidence and clinical significance are uncertain. Patients with confusion or encephalopathy who have multiple punctate lesions that together may explain their clinical findings should also be included as having had a stroke. Published clinical trials about complications after carotid procedures and other interventions have typically used clinical stroke as the end point,<sup>86,87</sup> and other ongoing trials also are using clinical end points.<sup>88,89</sup> This definition of stroke will apply to this metric and subsequent ones.

This metric is limited to patients with atherosclerotic disease to ensure that the metric encompasses a uniform population of patients.

#### *Justification*

The AHA/ASA guidelines for patients with recent TIA or ischemic stroke within the past 6 months and ipsilateral severe (70% to 99%) carotid artery stenosis recommend endarterectomy by a surgeon with a perioperative morbidity and mortality rate of  $<6\%$  (**Class I; Level of Evidence A**).<sup>90</sup> For patients with recent TIA or ischemic stroke and ipsilateral moderate (50% to 69%) carotid stenosis, CEA is recommended, depending on patient-specific factors such as age, sex, comorbidities, and severity of initial symptoms if the perioperative morbidity and mortality risk is estimated to be  $<6\%$  (**Class I; Level of Evidence B**).<sup>90</sup>

Among patients with symptomatic severe stenosis ( $>70\%$ ) in whom either the stenosis is difficult to access surgically, medical conditions are present that greatly increase the risk for surgery, or other specific circumstances exist such as radiation-induced stenosis or restenosis after CEA, the use of carotid angioplasty and stent placement is not inferior to endarterectomy and may be considered (**Class IIb; Level of Evidence B**).<sup>90</sup> The procedure is reasonable when performed by operators with established periprocedural morbidity and mortality rates of 4% to 6% (**Class IIa; Level of Evidence B**).<sup>90</sup>

The AHA/ASA "Guidelines for the Primary Prevention of Stroke" state that prophylactic CEA can be useful in highly selected patients with high-grade asymptomatic carotid stenosis if performed by surgeons with morbidity/mortality rates  $<3\%$  (**Class IIa; Level of Evidence A**).<sup>91</sup> The threshold of 3% is defined on the basis of the results of the Asymptomatic Carotid Artery Surgery (ACAS) trial,<sup>87,92</sup> which ascertained the rate of any perioperative stroke or death within 30 days. The combined arteriographic and perioperative surgery-related mortality and stroke rates achieved by the carefully

selected surgical teams was low (2.3%). A low rate of any stroke or death is considered necessary to confer benefit of the procedure in patients with asymptomatic carotid artery stenosis.<sup>93</sup>

The role of carotid angioplasty/stenting in asymptomatic patients has not been established. The AHA/ASA “Guidelines for the Primary Prevention of Stroke” state, “The usefulness of CAS [carotid angioplasty/stenting] as an alternative to CEA in asymptomatic patients at high risk for the surgical procedure is uncertain (*Class IIb; Level of Evidence C*).”<sup>91</sup> In this setting, if centers choose to perform carotid angioplasty/stenting on asymptomatic patients, the 30-day rate of stroke and death should be tracked separately for such patients and monitored carefully.

The recommended end point to be ascertained after carotid angioplasty and stent placement is any stroke or death within 30 days, to remain consistent with the data collected for CEA. This end point has been used in trials of carotid angioplasty and stenting. For comparable patients, the complication rate for stenting should be similar to that for endarterectomy if stenting is to be a reasonable option. In particular, the complication rate should be expected to be between 4% and 6% for symptomatic >70% stenoses.<sup>90</sup> If carotid angioplasty and stenting are performed, therefore, careful attention must be paid to complication rates, so it is important for CSCs to monitor these rates.

We have not included myocardial infarction among the complications to be tracked for this metric because data from the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) indicated that quality of life was worse for patients whose end point was stroke than for those whose end point was myocardial infarction.<sup>94</sup>

We have not proposed this metric as a core metric because of concerns about how appropriate it is to apply the known thresholds from clinical trials to clinical practice and concerns about how to adjust for baseline risks, but after some initial experience with its use, we anticipate that it may become a required metric.

#### *Additional Data Elements*

In addition to calculating the metric, centers should consider tracking the rates of stroke and death separately and recording the location and other characteristics of any stroke that occurs after endovascular or surgical carotid procedures, as well as the cause of death in patients who died. Centers should also consider monitoring the degree of residual stenosis on an angiogram at the end of the procedure for stenting (or on any postprocedure study if one is performed before discharge or within 30 days of the procedure on CEA patients). In addition, they should consider monitoring other complications such as myocardial infarction and recording whether strokes are ipsilateral or contralateral to the procedure. For CEA, lower cranial nerve palsies could also be tracked. For angioplasty and stenting, centers should also consider tracking the major nonneurological angiographic complications, specifically renal failure, retroperitoneal or thigh hematoma requiring transfusion or surgical evacuation, arterial occlusions requiring thrombectomy or thrombolysis, arteriovenous fistula, and pseudoaneurysm, as detailed by the Joint Standards of Practice Task Force of the Society of

Interventional Radiology, the American Society of Interventional and Therapeutic Neuroradiology, and the American Society of Neuroradiology.<sup>95</sup>

Centers should also track whether patients who undergo stenting are at high risk for complications of endarterectomy, because the available data primarily support stenting in such patients. High risk is defined as (1) patients with severe comorbidities (class III/IV congestive heart failure, class III/IV angina, left main coronary artery disease,  $\geq 2$ -vessel coronary artery disease, left ventricular ejection fraction  $\leq 30\%$ , recent myocardial infarction, severe lung disease, or severe renal disease) or (2) patients with technical or anatomic factors such as prior neck operation or neck irradiation, postendarterectomy restenosis, surgically inaccessible lesions (ie, above C2, below the clavicle), contralateral carotid occlusion, contralateral vocal cord palsy, or the presence of a tracheostomy.<sup>90</sup>

Centers that perform angioplasty without stenting may consider tracking these patients separately from patients who are stented.

Centers should consider monitoring whether patients were pretreated with antiplatelet therapy and whether they were prescribed antiplatelet therapy at discharge, and if so, which drug or drugs. Rapid thrombus formation after endothelial damage is a well-known and understood complication of endovascular stenting.<sup>96,97</sup> Early carotid stenting was associated with high rates of distal embolic events, as well as in-stent thrombosis. Subsequently, studies have demonstrated that dual-antiplatelet therapy with aspirin and a thienopyridine (ticlopidine or clopidogrel) significantly reduces 30-day morbidity.<sup>98,99</sup>

Finally, centers should consider tracking patients who undergo interventions for nonatherosclerotic disease processes such as arterial dissection or fibromuscular dysplasia.

#### **Metric 11**

##### **Percentage of patients undergoing intracranial angioplasty and/or stenting for atherosclerotic disease with stroke or death within 30 days of the procedure.**

**Numerator:** Patients who undergo intracranial angioplasty and/or stenting for atherosclerotic stenosis who die or have a stroke within 30 days of the procedure.

**Denominator:** All patients undergoing intracranial angioplasty and/or stenting because of atherosclerosis.

Patients who undergo these procedures of stenosis with other causes such as vasospasm, arterial dissection, or fibromuscular dysplasia should be excluded from this metric. Centers should consider tracking these patients separately. Patients who are stented as part of a procedure for coiling of an aneurysm should also be excluded. Outcomes of such patients will be recorded under the metric that tracks outcomes of aneurysm treatment. Stroke will be defined as in Metric 10, and patients for whom outcome data cannot be obtained should also be excluded and documented as detailed in Metric 10.

#### *Justification*

Angioplasty and stenting have become options for treatment of intracranial stenosis both within the context of clinical trials and in clinical practice. Because of the lack of definitive data about the efficacy of intracranial angioplasty stenting, it



is especially important to monitor patients for complications of the procedure. For secondary stroke prevention, angioplasty and stenting have been classified as investigational, with a **Class IIb; Level of Evidence C** rating for patients with >50% symptomatic stenosis of a major intracranial artery.<sup>90</sup> For acute ischemic stroke, angioplasty and stenting have also been classified as investigational, again with a **Class IIb; Level of Evidence C** rating.<sup>18</sup>

The end point of any stroke or death within 30 days of the procedure was chosen on the basis of both direct relevance to the procedure and reproducible ascertainment across studies.<sup>100,101</sup> The end point has been used in 2 major prospective registry studies of intracranial stenting, Stenting of Symptomatic Atherosclerotic Lesions in the Vertebral or Intracranial Arteries (SSYLVA) and the Wingspan stent study, which resulted in approval of endovascular devices by the US Food and Drug Administration. Multiple observational studies<sup>102,103</sup> have demonstrated that the end point of any stroke or death within 30 days can be ascertained reliably in multiple centers that perform intracranial angioplasty and/or stent placement.

#### *Additional Data Elements*

In addition to calculating this metric, centers should consider recording the location and other characteristics of any stroke that occurs after angioplasty and/or stenting, as well as the cause of death in patients who die. Centers should consider tracking the same elements that we proposed as additional elements for carotid stenting. In particular, they should consider tracking the degree of residual stenosis on angiogram at the end of the procedure, pretreatment with antiplatelet therapy, discharge with a prescription for antiplatelet therapy, and major nonneurological angiographic complications.<sup>95</sup>

### **Intracranial Hemorrhage**

#### *Metric 12*

#### **Percentage of SAH, ICH, and AVM patients for whom initial severity measures are documented. (Core metric)**

The severity of SAHs should be documented with the Hunt and Hess scale,<sup>104</sup> and the severity of ICHs should be documented with the ICH score, which incorporates the Glasgow Coma Scale (GCS) and the size and location of the hemorrhage.<sup>105</sup> AVMs should be graded according to the Spetzler-Martin scale.<sup>106</sup> A combined ratio should be calculated as the primary metric, but separate ratios should also be calculated for each scale.

**Numerator:** The sum of the number of SAH patients for whom the Hunt and Hess scale is documented, the number of ICH patients without an AVM for whom the ICH score is documented, the number of AVM patients with hemorrhage for whom the ICH score and Spetzler-Martin score are documented, and the number of AVM patients without hemorrhage for whom the Spetzler-Martin score is documented. For a patient to be counted in the numerator, the Hunt and Hess and GCS scores should be documented in the initial neurological or neurosurgical admitting or consultation note or in a separate earlier note and should be evaluated before the start of any endovascular or surgical procedure. The ICH

score and Spetzler-Martin score may be determined later after analysis of imaging.

**Denominator:** Sum of the number of SAH patients, the number of ICH patients without an AVM, and the number of AVM patients.

#### *Justification*

There is less consensus about what scales to use to assess SAH and ICH patients than to assess ischemic stroke patients. For SAH, the AHA/ASA "Guidelines for the Management of Aneurysmal Subarachnoid Hemorrhage"<sup>107</sup> state that scales that rely heavily on the severity of the initial hemorrhage are helpful in planning future care (**Class I; Level of Evidence B**), and the degree of neurological impairment according to an accepted SAH grading system can be useful for prognosis and triage (**Class IIa; Level of Evidence B**).<sup>108</sup> Thus, to capture the clinical state of the patient, we recommend using the Hunt and Hess scale for SAH patients.

The Hunt and Hess scale was developed 40 years ago and is probably still the most commonly used scale in the United States, if not the world, for assessment of risk of repair of ruptured intracranial aneurysms. It remains as accurate as other scales that have been proposed since its development, if not more so. Although the initial Hunt and Hess score should be documented, the score immediately before surgery may be the most accurate. The Hunt and Hess score has been used in clinical decision making and is useful as a predictor of outcome.<sup>104,108–112</sup>

To help stratify severity of illness for ICH patients, an easy-to-use, common scale developed for this purpose should be used and documented. Although there have been many attempts to develop prognostic tools for outcome after ICH, the only clinical scale for this purpose is the ICH score.<sup>105</sup> The ICH score combines the ubiquitously used GCS, the patient's age, the presence of intraventricular hemorrhage, location (infratentorial or supratentorial) of the hemorrhage, and the volume calculated by the ABC method.<sup>105,113</sup> The GCS score, age, hematoma location and volume, and presence of intraventricular hemorrhage have all been shown repeatedly to be predictors of outcome after ICH, as noted in the AHA/ASA "Guidelines for the Management of Spontaneous Intracerebral Hemorrhage."<sup>114</sup> The ICH score, which has been validated in several populations, reliably predicts outcome and 30-day mortality for patients with spontaneous ICH.<sup>105,115–117</sup>

To help stratify the risk of surgery for the AVM patient, an easy-to-use, common scale developed for this purpose should be used and documented. Although there have been many changes in the treatment of AVMs, the only clinical scale developed for the purpose of predicting outcome after AVM surgery is the Spetzler-Martin score. This scale, which is based on characteristics of the AVM, was also validated in surgical populations and in radiosurgery-treated patients.<sup>106,118,119</sup>

Because of the use of these scores in making clinical decisions and because of the need for quantified measures of initial severity to interpret data about outcomes and other metrics, we have classified this metric as a core metric.

*Additional Data Elements*

CSCs should also consider tracking the individual components that lead to the grades for the different scores. For example, for Spetzler-Martin grading of AVMs, AVM size, the presence of deep or superficial drainage, and involvement of eloquent brain areas should be recorded. For the ICH score, hemorrhage dimensions and GCS score should be recorded. Centers may also want to track the Fisher scale,<sup>120</sup> the World Federation of Neurological Surgeons scale,<sup>121</sup> or the GCS for SAH patients.<sup>108</sup> CSCs should also consider recording the location of aneurysms, ICH, and AVM; the size of aneurysms; the procedures used for aneurysm and AVM treatment; the presence of any residual aneurysm or AVM; and rebleeding during admission.

**Subarachnoid Hemorrhage***Metric 13*

**Median time from admission to start of procedure intended to obliterate a ruptured aneurysm by surgical clipping or endovascular coiling for patients who arrive within 48 hours of the hemorrhage that led directly to admission. (Core metric)**

Patients who are not treated should be excluded from this metric, but the reason they were not treated should be recorded, as discussed in Metric 14. Times for this metric should be recorded to the nearest hour, in contrast to the measures for acute ischemic stroke, which should be recorded in hours and minutes.

Patients with sentinel hemorrhage >48 hours before admission and a second hemorrhage within the 48 hours before admission should be included in this metric.

*Justification*

Securing an aneurysm by endovascular coiling or surgical clipping is an urgent goal to prevent rerupture of the aneurysm and to facilitate treatment for vasospasm, if it occurs. Later treatment times are associated with increased rates of preoperative bleeding.<sup>122–124</sup> There is a 3% to 4% or higher risk of rebleeding in the first 24 hours and a 1% to 2% risk per day in the first month,<sup>107</sup> so the AHA/ASA “Guidelines for the Management of Aneurysmal Subarachnoid Hemorrhage” recommend urgent evaluation and treatment of patients with suspected SAH (**Class I; Level of Evidence B**). Given the strength of the evidence in favor of urgent treatment of aneurysms and the catastrophic consequences of rebleeding before treatment, we propose that time to aneurysm treatment should be a core metric.

Because the risk of rebleeding decreases with each day after hemorrhage and the urgency of securing an aneurysm therefore decreases, we have limited this metric to patients who arrive within 48 hours of hemorrhage.

We have not specified a benchmark time from arrival for securing aneurysms because the available evidence does not clearly identify such a time.

*Additional Data Element*

Centers should also consider recording the type of procedure (coiling or clipping) and at least basic procedural details (eg, the specific coils and clips that were used) that are needed for quality improvement purposes.

*Metric 14*

**Percentage of patients with aneurysmal SAH arriving within 48 hours of hemorrhage for whom a coiling or clipping procedure was not started within 36 hours of arrival who have a documented reason for not having undergone coiling or clipping within 36 hours of arrival.**

**Numerator:** Number of patients with aneurysmal SAH who arrive within 48 hours of hemorrhage and whose ruptured aneurysm is not coiled or clipped within 36 hours of arrival for whom the reason for not treating is documented.

**Denominator:** Total number of patients with aneurysmal SAH who arrive within 48 hours of hemorrhage and whose ruptured aneurysm is not coiled or clipped within 36 hours of arrival.

Reasons for not treating may include but are not limited to futility, medical instability, patient or family wishes, and delayed arrival of the patient to the CSC. Problems leading to medical instability may include but are not limited to stunned myocardium with shock, neurogenic pulmonary edema, status epilepticus, septic shock, hypoxemic respiratory failure, uncontrolled or refractory intracranial pressure, poor neurological status, and repeat hemorrhage before treatment.

Unavailability of neurosurgical or endovascular services is also an acceptable reason for this metric, because although coverage by neurosurgeons and endovascular interventionalists 24 hours a day, 7 days a week is expected to be an integral part of CSCs,<sup>3</sup> we recognize that there are some occasions when angiography or surgical clipping is legitimately not available. Reasons for such unavailability include simultaneous emergencies, equipment failure, and unavailability of key staff, for example, for medical- or weather-related reasons. Reasons and their frequency should be tracked carefully and reported separately. Moreover, CSCs must have contingency plans to minimize the chance that services are unavailable. In particular, CSCs should develop contingency plans to transfer patients to another center (or to divert them to another center initially) if there are short periods when endovascular or neurosurgical procedures are not available. CSCs should not accept transfers of patients who may be candidates for such procedures during these periods unless there are other overriding reasons for transfer, such as a need for intensive care not available at another center that is within an appropriate distance. Quality improvement efforts should be directed toward decreasing such periods when services are unavailable.

*Justification*

Because of the risks of rebleeding<sup>107,122–124</sup> and the difficulty in treating vasospasm when a ruptured unsecured aneurysm is present, it is important to document the reason why a ruptured aneurysm is not treated quickly. The reasons why patients are not treated or why treatment is delayed should be reviewed as part of quality improvement efforts.

*Metric 15*

**Percentage of patients with documented aneurysmal SAH for whom nimodipine treatment (60 mg every 4 hours or 30 mg every 2 hours) is started within 24 hours of diagnosis and for whom such treatment is continued until**

**21 days after the hemorrhage or until discharge if they are discharged <21 days after the SAH. (Core metric)**

**Numerator:** Patients with documented aneurysmal SAH treated with nimodipine 60 mg every 4 hours (or 30 mg every 2 hours) within 24 hours of diagnosis and who continue this treatment until 21 days after their hemorrhage, or until discharge if they are discharged <21 days after the SAH, or until they develop a contraindication to nimodipine. Acceptable contraindications include documentation of intractable hypotension or allergy to nimodipine.

**Denominator:** All patients with a diagnosis of aneurysmal SAH.

Patients whose dose of nimodipine is reduced because of hypotension will be considered to be in compliance with this metric. Patients who have a known contraindication to nimodipine and are therefore not treated with it will also be considered to be in compliance with this metric. Patients who arrive at a CSC with documented aneurysmal SAH should receive nimodipine within 24 hours of admission.

*Justification*

The AHA/ASA “Guidelines for the Management of Aneurysmal Subarachnoid Hemorrhage” recommend nimodipine to reduce the risk of poor outcomes after aneurysmal SAH (*Class I; Level of Evidence A*).<sup>107,125</sup> Nimodipine has been shown to be beneficial in randomized controlled trials<sup>126,127</sup> and has been approved by the US Food and Drug Administration for “improvement of neurological outcome by reducing the incidence and severity of ischemic deficits in patients with subarachnoid hemorrhage from ruptured intracranial berry aneurysms.”<sup>128</sup> Given the strength of the evidence in favor of the use of nimodipine, we have classified this metric as a core metric.

*Additional Data Element*

As part of their quality improvement efforts, CSCs should consider monitoring whether patients who are not treated with nimodipine as described above are not treated with it at all, have it stopped prematurely, or are treated with an incorrect dose.

**Metric 16****Percentage of SAH patients with diminished level of consciousness and ventriculomegaly who are treated with external ventricular drainage (EVD).**

**Numerator:** SAH patients with diminished level of consciousness and ventriculomegaly who are treated with EVD.

**Denominator:** SAH patients with diminished level of consciousness and ventriculomegaly.

Patients for whom EVD is recommended but not performed because the patients or their families or proxies refuse permission for it should be excluded from this metric.

*Justification*

The AHA/ASA “Guidelines for the Management of Aneurysmal Subarachnoid Hemorrhage” note that EVD can be beneficial in patients with ventriculomegaly and a diminished level of consciousness after acute SAH (*Class IIa; Level of Evidence B*).<sup>107</sup> Several reports support this conclusion about the value of EVD.<sup>129–132</sup>

**Metric 17****Median frequency of noninvasive monitoring performed for surveillance for vasospasm in patients with aneurysmal SAH during the period between 3 and 14 days after SAH.**

Most studies performed for this purpose will be transcranial Doppler (TCD) studies, but centers may count a single study by another modality (eg, CTA, CT perfusion, MR angiography, MR perfusion, catheter angiography, or electroencephalography) on days when TCD is not performed. Centers that perform surveillance TCD (or another type of study for surveillance) more than once daily would count each of the studies for the purposes of calculating the frequency of monitoring. Additional studies performed on a given day because the first study performed raised suspicion of vasospasm or because of clinical changes that suggest vasospasm should not be included in calculating the frequency of monitoring. Patients will be excluded on days on which there is documentation of a reason not to monitor for vasospasm (eg, patients being treated with comfort care only), on days after discharge or death, and on days before transfer to the CSC.

*Justification*

Cerebral vasospasm after aneurysmal SAH is seen in 30% to 70% of patients.<sup>120,133</sup> Vasospasm can lead to devastating ischemic infarcts, and monitoring for vasospasm is important so that it can be diagnosed early and treated to prevent ischemic injury. Vasospasm usually develops 3 to 5 days after SAH and peaks between 5 and 14 days after SAH.<sup>107</sup> Typically, TCD ultrasound has been the monitoring modality of choice, because it is noninvasive, relatively inexpensive, and portable. There are variable reports on its sensitivity and specificity for detecting vasospasm in general, but it reliably detects severe spasm, and the American Academy of Neurology Expert Committee concluded that the literature provides evidence that establishes TCD as useful for diagnosis of vasospasm.<sup>134–137</sup> In addition to TCD and traditional angiography, there are newer imaging modalities that can also detect vasospasm, such as perfusion imaging and angiography with MR or CT. Because of the continual changes in technology, we recommend monitoring the use of any of these modalities.

The intent of this metric is to track the number of studies performed for quality improvement purposes. We do not intend to imply more studies are necessarily better. We recognize that the available evidence does not permit the establishment of a specific benchmark for the minimum frequency of studies needed. Indeed, TCD may only have a limited ability to predict development of delayed cerebral ischemia, although this may be a result of therapies initiated because of the results of TCD.<sup>44</sup> Because there is a wide range of opinion about the optimum frequency of surveillance for vasospasm, we have not recommended this as a core metric. CSCs that choose not to track this metric should consider developing their own alternative metrics based on the protocols that they use to detect and treat vasospasm. In this regard, it is worth noting that The Joint Commission (for the Accreditation of Hospitals) has allowed hospitals to use “nonstandardized” measures of their own choosing for some

aspects of care in the early stages of developing criteria for disease-specific centers that treat diseases other than stroke.<sup>138</sup>

#### *Additional Data Elements*

In addition to recording the frequency of studies that were performed for detection of vasospasm, CSCs should consider tracking the types of studies performed and the days on which they were performed, as well as the types of therapy that were used for treatment of vasospasm and whether vasospasm was detected and treated before development of symptoms of delayed cerebral ischemia.

#### **Metric 18**

##### **Complication rates for aneurysm coiling and clipping.**

**Numerator:** Patients undergoing coiling or clipping of a ruptured or a nonruptured cerebral aneurysm who have complications as detailed below.

The complications to be monitored for endovascular or surgical treatment of ruptured intracranial aneurysms are ischemic stroke or death within 24 hours of the procedure or any rebleeding or second treatment for residual aneurysm within 30 days of the procedure. The complications to be monitored for endovascular or surgical treatment of unruptured intracranial aneurysms are any ischemic stroke, death, subarachnoid bleeding, or second treatment for residual aneurysm within 30 days of the procedure.

**Denominator:** Patients undergoing coiling or clipping of a ruptured or a nonruptured cerebral aneurysm.

The metric should be calculated separately for the following groups of patients: (1) Unruptured aneurysms undergoing coiling; (2) unruptured aneurysms undergoing clipping; (3) ruptured aneurysms undergoing coiling; and (4) ruptured aneurysms undergoing clipping. Death and stroke should be recorded separately. Stroke is defined as in Metric 10, and patients for whom 30-day outcome data are not available must be documented as noted for Metric 10.

#### *Justification*

The end points were chosen on the basis of both direct relevance to the procedure and reproducible ascertainment across studies.<sup>84,96,97,139–145</sup>

Bleeding is classified into 3 broad categories, and all of these should be included in calculating the metric: (1) Preprocedural if it occurred after admission but before the first attempt at aneurysm obliteration; (2) procedural if it occurred during the first (or subsequent) procedures; and (3) postprocedural if it occurred in the first 30 days after the procedure. CSCs should also track each of the 3 types of rebleeding separately.

Preprocedural rebleeding is included because the measure may be related to time interval between onset and treatment. In this regard, in ISAT, there was a small but significant difference for those patients allocated to endovascular treatment (mean interval 1.1 day) and those allocated to neurosurgery (mean interval 1.7 day), and the rate of rebleeding before the procedure was higher among those randomized to surgery than among those randomized to endovascular treatment (1.6% versus 0.7%).<sup>84,141</sup>

Postprocedural rebleeding is included because it reflects the adequacy of obliteration. In ISAT, incomplete obliteration of aneurysms, whether by coiling or by clipping, was associated with an increased risk of rebleeding.<sup>84,141</sup>

The requirement for a second procedure within 30 days for the target aneurysm is included because it is a measure of incomplete obliteration of the target aneurysm in the initial procedure. Subtotal occlusion of aneurysms (including neck remnants, incomplete occlusions, and failed occlusions) was another end point that has been reported in previous studies but was not recommended because of the lack of a clinically meaningful and reproducible definition.

For ruptured aneurysms, we recommend considering only ischemic strokes and death within 24 hours of the procedure. Later strokes may be a result of vasospasm and therefore may be an effect of the initial hemorrhage. Similarly, although deaths shortly after a procedure should be presumed to be a result of the procedure, deaths at longer intervals are increasingly likely to be related to the severity of the underlying hemorrhage or other causes. In this regard, the consensus among radiologists is that deaths should be considered related to diagnostic angiograms only if the cause of death was present within 24 hours of the procedure.<sup>95</sup> To avoid the difficulty of determining when the cause of death developed, we propose to simply include all deaths within 24 hours.

Factors such as the patient's age, clinical grade and location of aneurysm, and the need for stenting should be taken into account before interpretation of the observed rate of these end points.<sup>84,141,142,146</sup>

#### *Additional Data Elements*

CSCs should consider tracking other variables involving aneurysm patients, including the location and size of their aneurysms, development of vasospasm, delayed cerebral ischemia, presence of residual aneurysm after treatment, and for coiling, major nonneurological angiographic complications.<sup>95</sup> They should also record whether aneurysm patients were seen in consultation by a vascular neurologist before and/or after coiling or clipping.

### **Intracerebral Hemorrhage**

#### **Metric 19**

**Median time from arrival to start of treatment to reverse the international normalized ratio (INR) with a procoagulant preparation (eg, fresh frozen plasma, recombinant factor VIIa, prothrombin complex concentrates) for patients with warfarin-associated ICH and an elevated INR (INR >1.4). (Core metric)**

Patients with an elevated INR should be excluded from this metric if a reason is documented for not treating them, for example, if there is a decision to treat the patient with comfort measures only or if the risks of reversing anticoagulation are judged to outweigh the benefits. Times for this metric should be recorded in minutes.

#### *Justification*

Hemorrhage expansion appears to occur primarily in the first hours after a hemorrhage, so treatment should be initiated as quickly as possible, with a goal of rapid correction of the INR. Warfarin use is a significant risk factor for hemorrhage

expansion, with an odds ratio of 6.2.<sup>144,147</sup> It is therefore imperative to correct the INR rapidly to prevent hemorrhage expansion.<sup>148,149</sup> The AHA/ASA “Guidelines for the Management of Spontaneous Intracerebral Hemorrhage”<sup>114</sup> recommend treatment with intravenous vitamin K and with replacement of clotting factors (*Class I; Level of Evidence B*), although clinical trials have not established the superiority of any specific treatment strategy.<sup>150</sup> Given the strength of the evidence in favor of prompt correction of the INR, we propose that time to initiation of treatment to correct the INR should be a core metric. There are no definitive trials establishing the best treatment; however, procoagulant preparations such as fresh frozen plasma and newer options including recombinant factor VIIa and prothrombin complex concentrate work faster than vitamin K, so the time to start of treatment with a procoagulant preparation should be recorded for this metric rather than the time of treatment with vitamin K.<sup>151–158</sup>

#### *Additional Data Element*

CSCs should also consider tracking the time from arrival to achievement of an INR <1.4 for patients who present with ICH and an INR of  $\geq 1.4$ .

#### **Metric 20**

**Percentage of patients undergoing surgical or endovascular treatment of an AVM with stroke or death within 30 days of the procedure.**

**Numerator:** Patients undergoing surgical or endovascular treatment of an AVM with new intracranial hemorrhage or ischemic stroke or death within 30 days of the procedure.

**Denominator:** All patients undergoing surgical or endovascular treatment of an AVM.

The metric should be calculated for AVMs treated after hemorrhage separately for embolization and for surgical resection and for AVMs treated with no history of hemorrhage separately for each type of procedure, with the 30-day assessment periods depending on the date of the given procedure. Stroke is defined as in Metric 10, and patients for whom 30-day outcome data are not available must be documented as noted for Metric 10.

#### *Justification*

The recommended end points to monitor for endovascular or surgical treatment of an AVM are new intracranial hemorrhage or ischemic stroke or death within 30 days of the procedure. The end point is derived from the ARUBA trial (A Randomized Multicenter Clinical Trial of Unruptured Brain AVMs).<sup>159</sup> This trial, which is currently in progress and is the first major randomized trial of AVM treatment, compares medical management of unruptured AVMs to interventional treatment with any combination of endovascular, surgical, and radiosurgical approaches. Its primary end point is stroke or death. To examine procedure-related complications, we propose examining these end points within 30 days. Because of the variations in morphological features, clinical presentations, and the multitude of modalities used for treatment, adjustment for known predictors is strongly recommended before the complication rates of the procedure are interpreted.<sup>160</sup> It is particularly important to track the complications of treating

unruptured AVMs, because the benefit of treating such lesions is unproven.

#### *Additional Data Elements*

In addition to recording whether or not there was any complication, centers should consider tracking the rates of each of the complications and should analyze them for quality improvement purposes. CSCs should also consider tracking details of AVM location and vascular characteristics, as well as features of the clinical presentation, including the presence of seizures, progressive deficit, headaches, and hemorrhage, and the use of stereotactic radiosurgery.

CSCs should also consider tracking other major complications of AVM treatment that are being monitored in the ARUBA trial and have been recorded in other studies of AVM treatment.<sup>159,161</sup> These include neurological events such as new seizures, focal neurological deficits (unrelated to stroke), and new-onset headache, as well as nonneurological complications including acute renal failure, procedure-related nephropathy, contrast reaction, infection related to invasive therapy, periprocedural bleeding (other than intracranial), systemic (nonbrain) embolization, vascular injury related to invasive therapy, and catheter adherence to embolization material.

#### **Stroke Systems of Care**

##### *Metric 21*

**Percentage of patients with ischemic or hemorrhagic stroke or TIA transferred from another hospital to the CSC with documentation of the time from the first call from the transferring hospital to the CSC (to a member of a stroke program or to a centralized transfer center) to arrival time at the CSC.**

**Numerator:** Patients with ischemic or hemorrhagic stroke or TIA transferred from another hospital for whom time from initial call to arrival is documented.

**Denominator:** All patients with ischemic or hemorrhagic stroke or TIA transferred from another hospital to the CSC.

Times should be recorded in hours and minutes. The percentage of transferred patients for whom the time of the initial contact cannot be identified should also be tracked.

#### *Justification*

CSCs need to demonstrate the existence of a functioning network and effective transfer protocols for timely transfer to the CSC from regional referring hospitals. Within a region, CSCs serve as the foundation of stroke care. Although most patients will initially present to either PSC or nonstroke centers, many patients may require more advanced interventions and management, including endovascular or neurosurgical procedures, specialized ICU care, and specialized diagnostic procedures. Data clearly demonstrate the important association of time to initiation of both intravenous and endovascular treatment of ischemic stroke. Good clinical outcome and rapid treatment are also important for patients with SAH and ICH. Thus, a CSC must document and monitor the details of transfers to ensure timely and efficient transport. The time of the call from the originating hospital and the time of arrival at the CSC should be collected and reviewed to eliminate systematic delays.<sup>5</sup>

Given variability in local conditions, the lack of data about what is a reasonable expectation, and the varying urgency of transfer for different types of patients, we do not think that it is appropriate to set a benchmark time or to compare centers on the basis of their average transfer times, and therefore, the metric is simply whether the time is recorded, so that it can be used for quality improvement and to look for improvements as the CSC and its surrounding hospitals gain more experience. We recognize that it may be difficult to identify the time of the initial contact from the referring hospital, but because of the importance of an efficient transfer process, we encourage CSCs to develop procedures to make it possible to track the time that the transfer process takes.

#### *Additional Data Elements*

Centers should also consider tracking additional data points for purposes of quality improvement (eg, time from onset to initial call, transfer ambulance dispatch time, departure time, source of ambulance, reason for transfer, transport delay for administration of intravenous thrombolysis, or transport during intravenous thrombolysis) depending on local procedures, availability of air transportation, and weather conditions.<sup>5</sup> Analysis of the times for patients for whom the initial call is within 6 hours of stroke onset should be a priority, because these are the patients for whom rapid transfer is generally most important. We anticipate that the actual transfer times for such patients may eventually become a metric for stroke systems of care that include both CSCs and PSCs.

CSCs should consider documenting all requests for patient transfers and should document reasons for accepting or not accepting the transfer to ensure the CSC provides necessary services as appropriate. Hospitals that make the commitment to serve as a CSC must be available to the regional hospitals without exception. Overcrowding issues often cause hospitals to divert patients during these times. Because most CSCs will be geographically distant from other CSCs, every CSC must make the necessary accommodations to accept appropriate patients who require the unique services of the CSC.

### **ICU and Stroke Unit**

#### *Metric 22*

**Percentage of patients admitted to each type of unit to which patients with ischemic or hemorrhagic stroke or TIA are initially admitted (eg, neurological/neurosurgical ICU, medical ICU, surgical ICU, general ICU, coronary care unit, burn ICU, stroke unit, other intermediate-level-of-care unit, neurology floor, or other floor). A separate percentage should be calculated for each type of unit.**

**Numerator:** Patients admitted to each type of unit to which all patients with ischemic or hemorrhagic stroke or TIA could be admitted initially.

**Denominator:** All patients with ischemic or hemorrhagic stroke or TIA.

Patients with inpatient strokes are excluded from this measure.

#### *Justification*

The BAC PSC report emphasizes that all PSCs must have a stroke unit (*Class I; Level of Evidence A*), and the BAC CSC report reaffirms this for CSCs.<sup>2,3</sup> The BAC CSC report<sup>3</sup> adds

that a CSC must have a full ICU and that a dedicated neurosciences ICU is desirable but not required for a CSC. There is good evidence that clinical outcomes are better and resource utilization is lower for neurocritically ill patients treated in a neurosciences ICU,<sup>162–167</sup> so documenting the location of treatment is warranted. The primary argument against requiring a specialized neurosciences ICU is resource availability: The number of specialty ICUs in any hospital may be limited, and the number of neurointensivists may be equally limited. In this setting, we believe that it is essential to track the unit to which patients are admitted so that quality improvement efforts can identify and, if necessary, correct variations in care between different units in a hospital or improve triage of patients to the most appropriate unit.

#### *Additional Data Element*

We recognize that patients move from one unit to another during an admission and that tracking these transfers may be important to understanding variations in care, but because collecting the necessary data may be time consuming, we have not included it in Metric 22. We do recommend, for quality improvement purposes, that CSCs should consider tracking the units to which a patient is transferred after admission. In addition, if and when the CSC guidelines are modified and a neurosciences ICU is required, we would favor consideration of a metric that examines whether or not each stroke patient who requires ICU admission is admitted to the neurosciences ICU and whether or not each stroke patient not admitted to an ICU is admitted to a stroke unit or to another intermediate-care unit or regular floor bed.

### **Outcomes and Complications**

#### *Metric 23*

**Percentage of patients with stroke or death within 24 hours of diagnostic neuroangiography. (Core metric)**

**Numerator:** Patients with death or stroke after diagnostic neuroangiography within 24 hours of the procedure or before discharge, whichever comes first.

**Denominator:** All patients who undergo a diagnostic neuroangiographic procedure.

Patients should be excluded if they undergo a therapeutic angiographic intervention as part of the same procedure or within the first 24 hours after the diagnostic procedure unless the complication is identified before the therapeutic intervention begins. Stroke is defined as in Metric 10, and patients for whom 24-hour outcome data are not available must be documented as noted for Metric 10.

#### *Justification*

The Joint Standards of Practice Task Force of the Society of Interventional Radiology, the American Society of Interventional and Therapeutic Neuroradiology, and the American Society of Neuroradiology<sup>95</sup> reviewed the complications of diagnostic neuroangiography. The Task Force stated that neurological complications that occurred within 24 hours of the angiogram should be attributed to the angiogram, as should all deaths for which the onset of the cause is within 24 hours of the angiogram. The Task Force suggested that the rate of reversible neurological deficits (including TIA and stroke) should be <2.5% and that of permanent neurological