

issues central to identifying appropriate clinical topics and quality indicators. The remaining criteria are relevant in establishing priorities among those clinical topics that meet the first four criteria (essentially, determining how you can best allocate limited resources to obtain the greatest improvement for the most beneficiaries). We are providing additional guidance regarding the use of criteria for identifying clinical topics as follows:

- **Prevalence, Incidence and Disease Impact**—The burden (morbidity, mortality) of the clinical condition or medical procedure under consideration is great for the population affected. The burden within a subpopulation (for example, minority, disabled, at-risk) may be another consideration that is taken into account.

- **Science**—There should be scientific consensus through multiple independent observations or clinical trials that changing a process or procedure of care will measurably improve patient outcomes. Note that we are adopting the operational definition of the term “scientific consensus” by the Office of Medical Applications of Research in the Office of the Director of the National Institutes of Health as follows:

* * * (T)he (consensus) statement reflects the unified view of a panel of thoughtful people who understand the issues before them and have carefully examined and discussed the scientific data available on these issues. The creative work of the panel is to synthesize this information, along with sometimes conflicting interpretations of the data, into clear and accurate answers to the questions posed to the panel.

- **Measurability**—The process(es) or outcome(s) of care for the topic can be stated in clearly defined, discrete, and quantifiable data elements from data sources which are valid and reliable; accessible in a timely manner; from appropriate care settings; and when necessary, span the continuum of care. In addition to the final measures of outcome, interim measures of progress toward achieving the quality improvement goal are desirable.

- **Opportunity to Improve Care**—Not only should the process or outcome be measurable, there should be a gap between current performance and what can reasonably be achieved. The wider the gap between the present situation and what is feasibly achievable, the greater the opportunity is for improvement. Additionally, there must be a feasible means of narrowing that gap. Merely measuring the problem is not sufficient; you must also be

reasonably certain your actions can improve the situation.

Clinical topics meeting the above criteria should be further prioritized. The following criteria should be helpful in that process. Although it is likely that no topic will consistently meet all of the criteria, proposed topics can be compared on the basis of the number and degree to which the criteria are met.

- **Previous Projects or Pilot Studies**—Demonstrate or provide a citation that demonstrate previous experience with the proposed project methodology or demonstrate that a project of similar design can reasonably be expected to improve healthcare outcomes. Potential priority topics may have been the subject of previous successful projects by QIOs or other organizations. Here, the focus is on selecting topics for which quality improvement has previously been demonstrated or on replicating successful project methodologies.

- **Adequate Program Resources**—Consider whether you have adequate resources (time, personnel, and funding) to implement the quality improvement project. Alternative potential projects with similar costs should be compared for their relative potential benefit. Whenever feasible, topics that make use of existing data sets should be selected.

- **Availability of Partnerships**—Select topics that allow you to collaborate with other providers and national, regional, and local organizations with similar goals. Collaboration with other organizations is encouraged for several reasons: planning, implementation, and analytic costs can be shared; planned, coordinated differences in project methods can be compared for efficacy and cost; local lessons learned can be shared and compared; and ideas for second and subsequent improvement cycles can be gathered.

- **Ability to Enable or Facilitate Ongoing Quality Improvement**—Select topics and interventions that are likely to foster or enhance the development of quality improvement efforts which extend to care processes and conditions beyond those targeted by the improvement project. Some topics may be selected, in part, because of the learning value to the intended user (for example, demonstrating principles and methods that can be applied by the user to other topics) and the ability to sustain the improvements that they trigger.

- **Likelihood of Success (Readiness)**—Identify topics that are of interest to the relevant stakeholders who will be asked to make improvements. This criterion recognizes the fact that significant improvement is not likely to occur if some pivotal individuals (for example,

chiefs of Medicine, department heads, and clinical leaders) do not welcome or are not capable of participating in the project.

Comment: Several commenters stated that the regulation should eliminate the requirement to use QIO data. Others suggested that hospitals, especially rural hospitals, should be required to only use QIO data that is relevant to its own QAPI programs.

Response: A hospital is not required to use QIO data. The QAPI program must incorporate quality indicator data that may include data, for example, QIO data or other relevant data.

Comment: Several commenters stated that the quality of care and patient outcomes should be the focus of the QAPI program, not the usage of specific data. Some commenters stated the proposed data requirement was too prescriptive and unclear. Others stated that many providers are unaware of what “QIO data” is, how to access it, and the associated costs, if any. Several commenters requested this provision be removed.

Response: As stated previously, there is no requirement to use QIO data. QIO data is generally relevant information submitted to (or received) from the hospital’s QIO. It can be a good source of quality indicator data to inform the hospital of areas where improvements are necessary. It is important that each quality improvement project have valid and representative baseline data; however, that baseline data may be from QIO data or from another source.

Comment: A commenter stated QIO cooperative projects, rules, and policies are already established and stated referring to them in regulatory text is unnecessary.

Response: As stated before, the QIOs are making great strides in national quality projects; however, hospitals are free to work on projects of their own design as long as the effort is comparable to QIO projects. Our intent is to allow hospitals the greatest flexibility, by offering options and examples.

F. Assessment of Compliance and Enforcement

Through our survey process, we intend to assess whether hospitals have all of the components of a QAPI program in place. The SAs will expect hospitals to demonstrate, with objective data, that improvements have taken place in actual care outcomes, processes of care, patient satisfaction levels, hospital operations, or other performance indicators.

Comment: Many commenters strongly supported our proposal to require,