American College of Surgeons Guidelines Program: A Process for Using Existing Guidelines to Generate Best Practice Recommendations for Central Venous Access

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BACKGROUND: Many professional organizations help their members identify and use quality guidelines. Some of these efforts involve developing new guidelines, and others assess existing guidelines for their clinical usefulness. The American College of Surgeons Guidelines Program attempts to recognize useful surgical guidelines and develop research questions to help clarify existing clinical guidelines.

We used existing guidelines about central venous access to develop a set of summary recommendations that could be used by practitioners to establish local best practices.

STUDY DESIGN: A comprehensive literature search identified existing clinical guidelines for short-term central venous access. Two reviewers independently rated the guidelines using the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument. Highly scored guidelines were analyzed for content, and their recommendations were compiled into a summary table. The summary table was reviewed by an independent panel of experts for clinical utility.

RESULTS: Thirty-two guidelines were identified, and 23 met inclusion criteria. The AGREE rating resulted in four guidelines that were strongly recommended and five that were recommended with alterations. Three comprehensive tables of recommendations were produced: procedural, maintenance, and infectious assessment. A panel of experts came to consensus agreement on the final format of the best practice recommendations, which included 30 summary recommendations.

CONCLUSIONS: Our process combined assessing existing guidelines methodology with expert opinion to produce a best practice list of guidelines that could be fashioned into local care routines by practicing physicians. The American College of Surgeons guidelines program believes this process will help validate the clinical utility of existing guidelines and identify areas needing further investigation to determine practical validity. (J Am Coll Surg 2008;207:676–682. © 2008 by the American College of Surgeons)

Central venous access is one of the most common procedures performed in the care of hospitalized patients. Each year, hospitals and other health-care centers purchase millions of intravascular catheters, and some studies estimate that nearly 5 million central venous catheters (CVC) are inserted.1 A recent metaanalysis calculated the rate of bloodstream infections caused by short-term, noncuffed, nontunneled catheters as 2.7 for every 1,000 days of catheter use.2 Intensive care units report nearly 80,000 infections each year, making central venous access 1 of the most common sources of procedure-related nosocomial infec-

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infection is estimated to be $45,000.4

The high complication rate and resultant costs associated with central venous access have resulted in many guidelines being developed by many organizations. These attempts have been aimed at reducing the complication rates. Guidelines are defined by the Institute of Medicine as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.”5 A plethora of guidelines based on evidence exists, but it is often difficult to identify which represent the best use of the evidence. Additionally, a clinician may be overwhelmed by the volume of guidelines (often more than 50 pages) or may have difficulty locating key recommendations.

The American College of Surgeons (ACS) has recently developed a guidelines program to provide its physician membership with reliable, high-quality sources of information from the published guidelines on surgical topics. Increased use of guidelines has the potential to improve patient care by reducing variability in medical treatment. Central venous access was the first topic chosen for analysis under the new guidelines program. The project goal was to accumulate all guidelines on central venous access and consolidate them into one concise document for physician use. It is the hope of this project that the product will allow a practitioner to use the recommendations as a best practice guide.

METHODS

Our process included the following steps:

1. Identification of guidelines for central venous access with high methodological quality.
2. Consolidating the methodologically sound guideline recommendations into a user-friendly summary format.
3. Assessing the clinical importance of the summary recommendations by a panel of medical experts hoping to develop a list of best practices. Best practices can be loosely defined as a set of actions that have been evaluated and have demonstrated success, have had an impact on outcomes, and can be replicated.6

Definitions

Guideline terminology may be confusing for the average clinician. Guideline refers to the Institute of Medicine definition5 stated in the introduction. Component is defined as an individual recommendation listed in a guideline. Summary recommendation refers to a statement compiled or reworded from individual published components by the authors of this article. The term set of summary recommendations is a list of summary recommendations organized by the authors into a table for use by a physician.

Guideline selection

A thorough literature review was performed to identify all published guidelines pertaining to the topic of central venous access. PubMed was searched using the following Medical Subject Headings (MeSH) terms: central venous catheter, venous access, indwelling catheter, venous reservoir, and vascular access. The search was limited to articles published in the English language and to publication types categorized as “practice guideline” or “guideline.” Articles published during the last 10 years (November 1, 1996, to November 1, 2006) that met these criteria were included. Guideline repositories, such as the National Guideline Clearinghouse, National Institute for Health and Clinical Excellence, Institute for Clinical Systems Improvement, and the National Electronic Library for Health (UK), were also investigated. In addition, Web sites of specialty medical societies and the search engine Google were used to identify a number of other guidelines.

Two reviewers independently evaluated the resulting guidelines on the following inclusion criteria: the guideline made specific recommendations for central venous catheters, had more than one author, and had references. Guidelines that were written specifically for pediatric care, or that required a payment to obtain the full guideline, were excluded. Any guideline that was a subset of a parent guideline was also excluded to avoid redundancy. Guidelines that were not included were agreed on by both reviewers as not meeting eligibility criteria.

Methodologic assessment

The remaining guidelines were then assessed for methodologic quality using the AGREE instrument (Appraisal of Guidelines for Research and Evaluation) developed by the AGREE Collaboration.7 The AGREE is a validated tool that evaluates guidelines’ methodologic quality of development using 23 questions scored on a 4-point Likert scale. The 23 questions are grouped into 6 domains: scope and purpose, stakeholder involvement, rigor of development, clarity and presentation, applicability, and editorial inde-
pends. The tool provides suggestions for giving an overall guideline assessment based on the six domain scores as follows: strongly recommended, recommended with provisos or alterations, not recommended, or unsure. AGREE does not categorically identify thresholds for the overall assessment using domain scores but provides the following suggestions for overall assessment ratings: A “strongly recommended” guideline scores above 60% on most domains. A “recommend with provisos or alterations” classification scores between 30% and 60% on most domains. A “would not recommend” assessment results when most domain scores are below 30%. A number of published studies have used the tool to assess guideline quality.8-12

The AGREE tool instructions recommend that each guideline preferably be reviewed by four appraisers to increase the reliability of the assessment, but a minimum of two reviewers is acceptable. The reviewers used the AGREE training manual to learn the system and discussed the tool with one of the developers through a teleconference. No other formal AGREE training took place. The two reviewers (ACF and MS) independently scored the guidelines using AGREE and gave each an overall assessment based on methodologic quality. In cases where the two reviewers disagreed on the guidelines’ overall assessment, they came to consensus agreement on this overall rating. There were only two instances in which the two reviewers disagreed on overall assessment. The guidelines that were either strongly recommended or recommended with proviso or alterations were used in the next step of the study. Guidelines that were assessed as either not recommended or unsure by the reviewers were excluded.

Creation of summary recommendations
All components from the included guidelines were listed in one document. Components were excluded from the list if the statement was for any device other than nontunneled catheters or was not relevant to one of three categories: placement, management, and infectious assessment. Components that dealt with pediatric patients were also excluded. Components that were similar or overlapped were grouped together and consolidated into a summary recommendation. Both reviewers examined the summary recommendations to ensure that they retained the meaning of the original components. A third reviewer (JAW) reviewed the summary recommendation statements to make sure they were consistent with the original statements and could be applied in the clinical setting. A preliminary set of summary recommendations in three categories was created from the collection of original guideline components and summary recommendations.

Clinical utility assessment and creation of final document
An expert panel was recruited to assess the clinical utility of the summary recommendations. Expert criteria included surgeons who had an active critical care practice, who had published on central venous access, and who were geographically separated in the US. The summary recommendations reviewed by the experts included the levels of evidence for each statement listed as described from the original guidelines. Different grading systems were used by the various guidelines, and we did not try to reconcile these different methods. Emphasis was always placed on level I evidence.

The experts independently scored each summary recommendation using a scale of 1 to 3, as follows:

1. A “must have” for a final recommendation set
2. Would be nice to have in a final recommendation set, but other factors negate its inclusion
3. Is not important

The summary recommendations were organized next by the frequency of “1” ratings. The summary recommendations with 4 or 5 “1” ratings were included in the final summary set of recommendations. Summary recommendations with 0, 1, 2, or 3 “1” ratings were omitted from the final summary set.

Statistical analysis
The AGREE tool instructions were used to calculate scores for each domain. Agreement between the reviewers was assessed using the kappa statistic. A p value less than 0.05 was considered statistically significant. All calculations were carried out using SPSS v.14 (SPSS, Inc).

RESULTS
The literature search identified 32 guidelines. Twenty-three of these met the study inclusion criteria. The AGREE overall assessment resulted in 4 guidelines rated “strongly recommended,” 5 guidelines rated “recommend with provisos or alterations,” and 14 rated “would not recommend.” The nine recommended guidelines were used to create the summary recommendations. Table 1 lists each domain score from the AGREE tool for the individual guidelines. The highest scoring domains were clarity and presentation (average of 91.2%) and scope and purpose (average of 75.9%). The domains with the lowest averages were editorial independence (49.2%) and stakeholder involvement (52.8%). The kappa statistic between the 2 reviewers was 0.673 (p < 0.001) when the 4-point scale was grouped into 2 categories (1 and 2 versus 3 and 4). Before the categories were collapsed, the kappa statistic was 0.512.
There were 219 components extracted from the 9 guidelines. Forty-seven components were omitted because they did not meet inclusion criteria. The remaining 172 components (78.5%) were grouped into 3 categories relevant to central venous access: placement, management, and infectious assessment. Fifty summary recommendations were created from the included components. The initial set of summary recommendations consisted of 15 placement summary recommendations, 21 maintenance summary recommendations, and 14 infectious assessment summary recommendations.

The breakdown for the frequency of “must have” summary recommendations is as follows: 14 were rated “1” by all the reviewers, 16 were rated “1” by 4 of the reviewers, 8 were rated “1” by 3 of the reviewers, 4 were rated “1” by 2 of the reviewers, 5 were rated “1” by 1 of the reviewers, and 3 were rated “1” by none of the reviewers.

Table 2 lists the final set of summary recommendations with their respective rankings from the clinical expert panel. Thirty summary recommendations were included: 7 in the placement section, 14 in the management section, and 9 in the infectious assessment section.

DISCUSSION

American College of Surgeons Guidelines Program

Our process demonstrates the feasibility of using previously developed guidelines to create a brief, evidence-based set of summary recommendations that can benefit our patients. The process of creating a new guideline consumes a great deal of time and resources—an estimated $1 million and 1 to 2 years per guideline. For example, the American College of Radiology’s timeline for guideline publication is 15 months from the time the first draft is submitted to time of publication.13 Because a number of organizations have already invested the resources to create central venous access guidelines, we believed that repeating this process was unnecessary. Instead, the project sought to adapt high-quality guidelines into a clinically useful format.

Use of the AGREE instrument aided in focusing the project on guidelines that were well developed from a methodologic standpoint. Documents excluded through the AGREE evaluation might be clinically useful, but their methods lacked the scientific rigor necessary to promote unbiased evidence-based results. The ACS process also included a formal, consensus-based process to adapt high-quality guidelines to make them more useful for our members. The adaptation process incorporated a number of different guidelines, because the topic of central venous access encompasses a variety of clinical themes. Extracting recommendations from different guidelines resulted in coverage of a variety of clinical issues; endorsing a single guideline would likely leave out some valuable aspect of care, because most of the guidelines vary greatly on their particular focus. Ultimately, we grouped the summary table into three categories that we thought were the most useful to central venous access: placement, management, and infectious assessment. These groupings were chosen because they represent the clinical course of use of central venous lines.

Clinical utility

Previous studies have endorsed or selected guidelines for local use based solely on results of the methodologic quality of development using the AGREE instrument. We sought to increase the value of our efforts by having a panel of physician experts review the guideline recommendations for their clinical utility. Some guidelines, although well developed methodologically, may not be clinically useful to the target audience.14 Twenty of the 50 summary statements (40%) were excluded after the expert review for clinical usefulness. Although this number seems high if all
<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Ranking*</th>
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<tbody>
<tr>
<td><strong>Placement recommendations</strong></td>
<td></td>
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<tr>
<td>Designate experienced personnel to perform catheter insertion and supervise trainees.</td>
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<tr>
<td>Consider risks and benefits of specific site selection prior to insertion.</td>
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<tr>
<td>Use full barrier precautions (including cap, sterile gown, mask, sterile gloves, and large sterile sheet) for all CVC insertions or guidewire exchanges.</td>
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<tr>
<td>Prepare skin with chlorhexidine gluconate (2% in alcohol or aqueous solution) before catheter insertion. It is also acceptable to use iodine, iodophor, or 70% alcohol as needed; do not use organic solvents.</td>
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<tr>
<td>Minimize the number of lumens necessary for care when choosing a CVC.</td>
<td>4</td>
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<tr>
<td>Allow the antiseptic to air dry before catheter insertion.</td>
<td>4</td>
</tr>
<tr>
<td>Exchange a new catheter over a guidewire to replace a malfunctioning nontunneled catheter if no evidence of infection is present.</td>
<td>4</td>
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<tr>
<td><strong>Maintenance recommendations</strong></td>
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<tr>
<td>Do not routinely replace central venous access devices to prevent catheter-related infections.</td>
<td>5</td>
</tr>
<tr>
<td>Use chlorhexidine gluconate solution (either alcohol or aqueous) to clean catheter site during dressing change. Allow to air dry. May also use iodine, an iodophor, or 70% alcohol if needed. Do not use organic solvents.</td>
<td>5</td>
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<tr>
<td>Maintain asepsis with chlorhexidine or other appropriate antiseptic when accessing or using injection port.</td>
<td>5</td>
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<tr>
<td>Do not routinely use anticoagulants for clot or infection prevention, unless indicated in specific patients.</td>
<td>5</td>
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<tr>
<td>Do not routinely use systemic or local antibiotic prophylaxis.</td>
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<tr>
<td>Must wash hands with soap and water or alcohol handrub (even when using gloves) before contact with patient or devices.</td>
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<tr>
<td>Sterile technique should be used for catheter site care and accessing the system.</td>
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<tr>
<td>Clean gloves and a no-touch technique may also be used for dressing changes.</td>
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<tr>
<td>Use a sterile, transparent dressing to cover catheter site.</td>
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<tr>
<td>Change transparent dressing every 7 days or sooner if it becomes loose.</td>
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</tr>
<tr>
<td>Use sterile gauze if the insertion site is not dry (ie, from blood, perspiration, etc).</td>
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</tr>
<tr>
<td>Assess and change gauze dressing as needed. Change to transparent dressing as soon as possible.</td>
<td>4</td>
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<tr>
<td>Use sterile NaCl injection (or heparin if indicated) to flush and lock in order to maintain catheter patency.</td>
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<tr>
<td>Use needle-free connectors when possible to avoid needle stick injuries. Follow manufacturer’s recommendations for changing device. Use appropriate antiseptic technique.</td>
<td>4</td>
</tr>
<tr>
<td><strong>Infectious assessment recommendations</strong></td>
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<tr>
<td>Do not remove device based on fever only. Use clinical judgment to assess infection, then follow necessary steps for infection management.</td>
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<tr>
<td>Culture of catheters should be done only when CRBSI is suspected.</td>
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<tr>
<td>When culturing a CVC segment, either the catheter tip or a subcutaneous segment should be submitted for culture.</td>
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<tr>
<td>For complicated infections, the CVC or the ID should be removed.</td>
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<td>CVC should be removed and cultured if the patient has erythema or purulence overlying the catheter exit site, or clinical signs of sepsis; if blood culture results are positive or if the CVC is exchanged over the guidewire and has significant colonization according to results of quantitative or semiquantitative cultures, the catheter should be removed and placed into a new site.</td>
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<tr>
<td>After removal of a colonized catheter associated with BSI, if there is persistent bacteremia or fungemia, or a lack of clinical improvement (especially if it is &gt;3 days after catheter withdrawal and initiation of appropriate antimicrobial therapy), aggressive evaluation for septic thrombosis, infective endocarditis, and other metastatic infections should ensue.</td>
<td>5</td>
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<tr>
<td>Hospital should have systems in place to monitor outcomes, including infection rate and complication rate. Preventative measures should be implemented when complications exceed predetermined benchmarks.</td>
<td>4</td>
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<tr>
<td>Two sets of blood samples for culture, with at least 1 drawn percutaneously, should be obtained from all patients with a new episode of suspected CRBSI.</td>
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<tr>
<td>After catheters have been removed from patients with CRBSI, nontunneled catheters may be reinserted after appropriate systemic antimicrobial therapy is begun.</td>
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*Ranking definition: The number of expert reviewers (out of 5) who graded the summary recommendation as a “1-must have” recommendation.

BSI, bloodstream infection; CRBSI, catheter-related bloodstream infection; CVC, central venous catheter; ID, intravascular device.
guidelines were originally thought to be important, the results of the clinical evaluation emphasize the problem with accepting all guidelines at face value. Without a step that assesses clinical validity, guidelines have an opportunity to bring recommendations to the clinical community that may not necessarily be useful to the practitioner. We believe this additional consensus-building process brings the summary recommendations closer to a best practice goal. This step may be especially influential in the surgical community, where recommendations based on level I evidence are not plentiful.

In addition, this summary set has the potential to improve quality of care for central lines if implemented by surgeons and hospitals. In a cohort of ICUs in Michigan, a number of evidence-based recommendations developed by the Centers for Disease Control and Prevention were implemented in a program designed to reduce the incidence of catheter-related bloodstream infections. The intervention resulted in a significant reduction in the rate of infections after implementation of the program, and infection rates continued to decline during the 18-month followup period.\(^\text{15}\) The summary set created here includes the recommendations implemented in the Michigan program, but it also adds additional statements addressing the safe insertion and maintenance of catheters and treating infections if they arise. The summary set is useful to hospitals with high rates of surgical site infections, because it greatly reduces the effort needed to adapt existing guidelines to meet individual hospital needs.

All of our summary recommendations will not be useful to every clinician. Our hope is that this summary set can serve as a starting point for clinicians who wish to incorporate guidelines dealing with central venous access into their practice. By reviewing the summary set, a group of clinicians can decide which are most appropriate for their practice and patient population.

Potential limitations in our methodology could include the numbers of reviewers applying the AGREE tool and the number of clinical experts reviewing the final list of guidelines. Although there is no argument that four reviewers is the optimal number for AGREE evaluation, in trying to find a balance between timely evaluation of the guidelines and reliability of the evaluation, we chose to minimize the human resources required for this project. In an analysis conducted by MacDermid and associates,\(^\text{16}\) the authors evaluated intraclass correlation for each AGREE domain as a function of the number of raters. The intraclass correlation for 2 raters ranged from 0.54 to 0.89. For 3 raters, intraclass correlation ranged from 0.64 to 0.9. The authors concluded that reliability did increase somewhat from two to three raters, but it did not increase beyond three raters.

In addition, several other published studies used two raters on the AGREE instrument with good results. Coomarasamy and colleagues\(^\text{17}\) used 2 reviewers and found kappa levels between 0.74 and 1, with disagreements resolved by consensus or by a third reviewer. An evaluation of clinical depression guidelines also used 2 raters; the resulting kappa was 0.57.\(^\text{18}\) Two other guideline evaluation articles using AGREE and one using the Shaneyfelt instrument with two reviewers have been published in the peer-reviewed literature.\(^\text{19-21}\) As the guideline project at the ACS continues, we may consider adding additional reviewers in future assessments.

The number of expert reviewers for the clinical utility assessment was set at five, again as a convenience sample. They were chosen with wide geographic distribution and with different training backgrounds. More experts would give us more data, but we are unaware that an optimal number has been defined.

Another potential limitation is omission of clinically important issues not addressed in the guidelines. We believed our selection criteria and process were adequate to select the guidelines without repetition or exclusion of important published guidelines. Only time will tell whether additional clinically relevant issues need to be addressed.

In summary, we have taken a wide variety of guidelines on central venous access from the medical literature, assessed them for sound methodologic development, and organized the recommendations into a concise, expertly validated set of summary recommendations. Using this procedure, the ACS guidelines program will continue to create summary sets of guidelines to help aid in patient safety and quality improvement.

**Author Contributions**

Study conception and design: Freel, Shiloach, Weigelt, Ko
Acquisition of data: Freel, Shiloach, Weigelt
Analysis and interpretation of data: Freel, Shiloach, Beilman, Mayberry, Nirula, Stafford, Tominaga
Drafting of manuscript: Freel, Shiloach
Critical revision: Shiloach, Weigelt, Beilman, Mayberry, Nirula, Stafford, Tominaga, Ko

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**REFERENCES**


