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Evidence-based Guidelines Pertaining to Select Thoracentesis- and Paracentesis- related Conditions

**Excerpted from “Evidence-based Guidelines for
Selected and Previously Considered Hospital-
Acquired Conditions Final Draft Report v 1/6/2015”
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UPDATED FINAL DRAFT REPORT EXCERPT

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CONTENTS

SECTION 1 INTRODUCTION	1
1.1 Brief Background.....	1
1.2 Organization of the Report.....	1
SECTION 2 METHODS	2
2.1 Approach Used to Identify the Appropriate Guidelines	2
2.2 Definition of Evidence-Based Guidelines Applied.....	3
SECTION 3 RESULTS	5
3.1 Candidate Conditions.....	5
SECTION 4 SUMMARY	11

List of Tables

Table 1 Identified guidelines for thoracentesis- and paracentesis-related conditions	6
Table 2 Summary of the number and ratings of available guidelines for each condition	11

SECTION 1 INTRODUCTION

1.1 Brief Background

This memo represents an updated excerpt from the Evidence-based Guidelines for Selected and Previously Considered Hospital-Acquired Conditions Final Draft Report v 1/6/2015, as presented to the Centers for Medicare and Medicaid services in January 2015. This excerpt was updated in April 2015. It provides a summary of evidence-based guidelines that can be used as a basis for hospital care that will reasonably be expected to prevent two specific conditions of interest: iatrogenic pneumothorax with thoracentesis, and accidental puncture/bleeding with abdominal paracentesis.

1.2 Organization of the Report

In the following sections of this report, we present our methodological approach to identifying the HAC-related evidence-based guidelines (Section 2), the results of our review of those guidelines (Section 3 and Table 1) and a summary of the findings (Section 4 and Table 2).

SECTION 2 METHODS

2.1 Approach Used to Identify the Appropriate Guidelines

Our search for evidence-based guidelines was based on specific inclusion and exclusion criteria. In order to be included in this report, guidelines must:

- focus on clinical recommendations for primary or secondary prevention of the specific condition of interest
- have been developed in the United States. International guidelines were accepted if no appropriate guidelines developed in the United States were located.

Guidelines were excluded if they had been withdrawn by guideline developers or were developed outside the United States, except in the case listed above. In this report, guidelines archived by the NGC but still listed as current on the developer's website have been included if no other US guideline with updated information could be identified. Relevant systematic reviews that meet the above criteria are included only when evidence based guidelines cannot be identified. Documents that have a primary purpose other than provision of clinical guidance for HAC prevention (e.g. training manuals or presentations) are not considered guidelines. Please refer to Section 2.2 for further definition of "evidence-based guideline" as used in this report.

2.1.1 Search of Guidelines.gov (<http://www.guidelines.gov/>)

We began our systematic approach by searching the National Guideline Clearinghouse (NGC) website for guidelines representing each of the conditions. Alternative terms were used if we did not find the appropriate guidelines after searching for the condition as it is listed in the Federal Register. For example, for iatrogenic pneumothorax with thoracentesis, we also used the terms "pleural tap" or "thoracocentesis" to identify relevant guidelines. We chose these broad search terms in order to capture all guidelines related to thoracentesis; specifying "ultrasound-guided" as an additional search term would constitute a narrower search, with the possible ramification that relevant guidelines might not have been identified.

For accidental bleeding with paracentesis, we also searched for "ascites." As we reviewed one guideline and it referred to another, we would investigate that guideline as well.

2.1.2 Search of CDC.gov

We also searched the CDC website for guidelines representing each condition. The CDC did not have guidelines for iatrogenic pneumothorax with thoracentesis, or accidental puncture/bleeding with abdominal paracentesis.

2.1.3 Search of Other Sources

In addition to the key sources listed above, we also searched the US Department of Veterans Affairs (VA/DOD) website, Medscape.com, and the Agency for Healthcare Research and Quality (AHRQ) website to locate conditions not found in the NGC. We also searched the Federal Register and used PubMed and employed a popular internet search engine to identify

other guidelines as well as government and professional clinical associations that may have relevant publications. In addition, links attached to the guidelines for additional information were used to clarify processes for evidence evaluation and as a means to identify other relevant guidelines.

2.1.4 Limitations of the Methods Used

The method of identifying primary and secondary sources of guidelines relies on the NGC and the CDC as primary sources of guidelines relevant to the conditions of interest. RTI recognizes that most, but not all, evidence-based guidelines are contained in the NGC. We assumed that all U.S. guidelines have been developed by professional societies or governmental agencies and employed a secondary search strategy to identify these sources that may not have provided their guidelines to the NGC. It is possible that there are other ad hoc groups that have developed guidelines that may be missed by these techniques. For conditions for which U.S. guidelines were not identified, we did search for potentially applicable international guidelines. Because international guidelines may not be perceived to be applicable to U.S. providers, we did not perform a more extensive search and thus may have missed non-U.S. guidelines for those conditions.

2.2 Definition of Evidence-Based Guidelines Applied

Guideline-development processes have been evolving from expert panel recommendations supported by a selective literature search or based on a consensus of the panel members, to the more recent adoption of systematic processes. A comprehensive systematic review entails the a priori development of critical questions as well as study inclusion and exclusion criteria (I/E criteria), the use of standardized key words to search multiple databases, and step-by-step independent comparison of articles against the I/E criteria by two or more reviewers. The methods of each included study are assessed for scientific rigor using a standardized quality assessment tool. After results from included articles are compiled to form the evidence base, an explicit evidence-grading and strength-of-evidence designation is employed by subject matter experts (SMEs) based on the quality of the studies and the consistency of findings across studies. Results from high quality, well-designed clinical trials provide the strongest (most convincing, lowest risk of bias) evidence, followed by observational studies and clinical trials with poorer methodology, both of which have greater risk of biased results due to lower internal study validity. A “best evidence” approach refers to the exclusion of information from studies deemed to be of lower internal validity, which limits the confidence that can be drawn that a reported association of a treatment or other activity is causally related to the observed results. Included studies are only those studies that are most likely to demonstrate that the intervention caused the observed change in outcome and the exclusion of information from studies deemed to be of lower internal validity. The result of this process is that guideline recommendations rely only on the most scientifically sound evidence base. (Owens DK, Lohr KN, Atkins D, et. Al. *Journal of Clinical Epidemiology*. 2009. 63(5):513-523)

Despite increasing movement toward systematic evidence-based processes in guideline development, there continue to be important clinical areas for which there is no definitive clinical trial or other relevant high-quality evidence base. SMEs typically address this issue by either making no recommendation when there is clinical uncertainty, or by making recommendations, clearly specified as being expert opinion, that are typically based on SME

clinical experience and reasoning from underlying scientific principles. To account for this evolution in “evidence-based guidelines,” we developed a tiered set of criteria to categorize the type of evidence base used for each guideline.

We set Level I as the highest level of evidence-based guideline. To account for current guideline-development processes, we have subdivided this level into Level Ia: guidelines that used a systematic literature search, rated the quality of each individual study considered, and graded the overall strength of evidence, or demonstrated that they used a “best evidence” approach through exclusion of information from studies deemed to be of lower internal validity; and Level Ib: guidelines that rated the quality of each individual study considered, graded the overall strength of evidence, or demonstrated the use of a “best evidence” approach, but did not employ a systematic methodology for the review of the literature.

For those guidelines or recommendations within guidelines that did not describe a systematic methodology and only provided citations for the recommendation, we called these “evidence-cited” and designated them as Level II. Our lowest level, Level III, represented those guidelines or recommendations within guidelines, that were based only on expert opinion, or that provided no specific information to describe the basis of the recommendation. Guidelines typically present various levels of recommendation depending on the quality of evidence, and most employ expert opinion for some of the recommendations that are made when there is not sufficient evidence in the literature. The use of expert opinion may occur with Level Ia, Ib, or Level II guidelines and thus, guidelines may be rated as either Level Ia, Ib, or Level II and, in addition, Level III. For guidelines with recommendations arising from a more mixed evidence base (e.g. “Ib and II”), we assigned the level pertaining to the predominate methodology used in that guideline.

Level of Evidence

- Level Ia: Good evidence-base (e.g. highest quality, most consistent evidence). Guideline recommendations are based on a comprehensive, systematic literature search and review, AND either a) description of the quality assessment of the studies or the overall body of literature or b) a “best evidence” approach.
- Level Ib: Fair evidence base. Guideline recommendations are based on a non-systematic literature review, or literature review using unspecified methods, AND either a) review of the quality of the studies or the overall body of literature or b) description of a “best evidence” approach.
- Level II: Poor evidence base or evidence base not well characterized. Evidence is cited, but guideline authors do not describe quality or strength of evidence
- Level III: No evidence base. Specific guideline recommendations are based only on expert opinion, or guideline authors provide no information on how recommendations were developed.

SECTION 3 RESULTS

In this section, we describe the evidence based guidelines found for iatrogenic pneumothorax with thoracentesis and accidental puncture/bleeding with paracentesis.

3.1 Candidate Conditions

In Table 1, we present the current guidelines identified through our searches that provide recommendations to prevent the conditions under consideration:

- Iatrogenic pneumothorax with thoracentesis
- Accidental puncture/bleeding with abdominal paracentesis

The paragraphs immediately below the table discuss each condition and provide a description of the guidelines that includes the developer of the guidelines, commentary on the evidence level, and whether the guideline includes identification of appropriate actions to be taken to prevent the condition.

Table 1
Identified guidelines for thoracentesis- and paracentesis-related conditions

Evidence-based guideline and publishing organization	Location	Evidence level	Comments	Prevention recommendations
Iatrogenic pneumothorax with thoracentesis Havelock T, Teoh R, Laws D, Gleeson F, BTS Pleural Disease Guideline Group. Pleural procedures and thoracic ultrasound: British Thoracic Society pleural disease guideline 2010. Thorax. 2010 Aug;65(Suppl 2):ii61-76.	NGC: http://www.guideline.gov/content.aspx?id=37615 (accessed 4/29/15) Full guidelines available here: https://www.brit-thoracic.org.uk/document-library/clinical-information/pleural-disease/pleural-disease-guidelines-2010/pleural-disease-guideline/ (accessed 4/29/15)(redirects to PDF)	Levels Ia and III: Systematic review, evidence rating and expert opinion	British guideline. The methodology followed the criteria as set out by the Appraisal of Guidelines Research and Evaluation (AGREE).	Contains recommendations for thoracic ultrasound safety, including training, pre-procedure preparation, use of triangle of safety, aseptic technique, proper needle size, and stopping aspiration.
Hooper C, Lee YC, Maskell N, BTS Pleural Guideline Group. Investigation of a unilateral pleural effusion in adults: British Thoracic Society pleural disease guideline 2010. Thorax. 2010 Aug;65(Suppl 2):ii4-17.	NGC: http://www.guideline.gov/content.aspx?id=37289 (accessed 4/29/15) Full guidelines available here: https://www.brit-thoracic.org.uk/document-library/clinical-information/pleural-disease/pleural-disease-guidelines-2010/pleural-disease-guideline/ (accessed 4/29/15) (redirects to PDF)	Levels Ia and III: Systematic review, evidence rating and expert opinion	British guideline. The methodology followed the criteria as set out by the Appraisal of Guidelines Research and Evaluation (AGREE).	Recommendation for ultrasound-guided thoracentesis is brief: “Bedside ultrasound guidance significantly increases the likelihood of successful pleural fluid aspiration and reduces the risk of organ puncture. (B)”

Table 1 (continued)
 Identified guidelines for thoracentesis- and paracentesis-related conditions

Evidence-based guideline and publishing organization	Location	Evidence level	Comments	Prevention recommendations
Accidental puncture/bleeding with abdominal paracentesis				
Runyon BA. Management of adult patients with ascites due to cirrhosis: update 2012. Alexandria (VA): American Association for the Study of Liver Diseases; 2013 Feb.	http://www.guideline.gov/content.aspx?id=45103 (accessed 4/29/15)	Levels Ib and III: Literature review and expert opinion.	Only briefly mentions paracentesis. In this guideline, Level C evidence is derived from consensus opinion of experts, case studies, or standard-of-care.	“Since bleeding is sufficiently uncommon, the routine prophylactic use of fresh frozen plasma or platelets before paracentesis [for evaluation and diagnosis of ascites caused by cirrhosis] is not recommended (Class III, Level C).”
Patel, I.J., Davidson, J.C., et al. (2012). "Consensus guidelines for periprocedural management of coagulation status and hemostasis risk in percutaneous image-guided interventions." <i>J Vasc Interv Radiol</i> . 23:727-736	NGC summary: http://www.guideline.gov/content.aspx?id=48773 (accessed 4/29/15) http://www.sirweb.org/clinical/cpg/4E8CA01.pdf (accessed 4/29/15)	Levels Ib and III: Literature review and expert opinion.	Published by the Society for Interventional Radiology (SIR). Specific to patients with abnormal coagulation parameters undergoing percutaneous image-guided intervention. Although the guideline is based on a literature review, the recommendations pertaining to paracentesis are based on expert consensus.	Contains brief recommendations for periprocedure laboratory testing and bleeding management. See Table 2.

A. Iatrogenic Pneumothorax with Thoracentesis

1. Guidelines identified

We found no guidelines developed in the United States that addressed iatrogenic pneumothorax with thoracentesis. Two international guidelines were identified that included recommendations for ultrasound-guided thoracentesis

- Pleural procedures and thoracic ultrasound: British Thoracic Society pleural disease guideline 2010. BTS Pleural Disease Guideline Group, 2010.
- Investigation of a unilateral pleural effusion in adults: British Thoracic Society pleural disease guideline 2010. BTS Pleural Disease Guideline Group, 2010.

2. Guidelines considered “evidence-based”

Both of these guidelines are published as chapters of the British Thoracic Society pleural Disease Guideline 2010. All of the guidelines in this document are based on an extensive, systematic literature review with evidence grading based on both type and quality of included studies. Methods were adapted to meet the rigors of the AGREE instrument, a tool developed by the Appraisal of Guidelines Research and Evaluation (AGREE) Collaboration for the purposes of assessing the quality of clinical guidelines. More information about the tool is available here: http://www.agreetrust.org/wp-content/uploads/2013/06/AGREE_Collaboration_2003.pdf (accessed 4/29/15).

3. Identification of the appropriate actions to be taken to prevent the condition

The BTS Guideline for Pleural Procedures and thoracic ultrasound considered iatrogenic pneumothorax as one of the primary outcomes of interest, and contains a number of recommendations for thoracic ultrasound guidance and procedural safety, including use of triangle of safety, aseptic technique, proper needle size, and stopping aspiration. The accompanying guideline for Investigation of a unilateral pleural effusion in adults contains only one recommendation applicable to thoracentesis: “Bedside ultrasound guidance significantly increases the likelihood of successful pleural fluid aspiration and reduces the risk of organ puncture. (B).”

B. Bleeding with Abdominal Paracentesis

1. Guidelines identified

We found two guidelines developed in the United States that addressed bleeding with abdominal paracentesis. One guideline was found that contained a brief discussion regarding this condition but no formal guidelines for its prevention; according to our methods, we are not including it in our list of guidelines for prevention of this condition.

- Management of adult patients with ascites due to cirrhosis: update 2012. Alexandria (VA): American Association for the Study of Liver Diseases (AASLD), 2012.
- Consensus guidelines for periprocedural management of coagulation status and hemostasis risk in percutaneous image-guided interventions. Society for Interventional Radiology, 2012.

2. Guidelines considered “evidence-based”

These two guidelines -- the AASLD guideline and the SIR guideline -- are based on a literature search with evidence grading. The SIR guideline is based on a literature search of and critical review of peer-reviewed literature; it also employs a modified Delphi consensus process when the evidence in the literature is weak or contradictory; for the purposes of these studies, consensus is defined as 80% of Delphi participant agreement on a value or parameter. All recommendations related to prevention of abnormal bleeding with paracentesis were supported via modified Delphi consensus due to weak support in the literature. The strength of recommendations provided by the AASLD guidelines is classified on three levels, with two additional sublevels (IIa and IIb) to better categorize Level II. Quality of evidence is ranked A-C depending on the types of studies on which the recommendations are based.

We did identify one international guideline that contained a brief discussion of recommendations for prevention of accidental bleeding with paracentesis, Guidelines on the management of ascites in cirrhosis. British Society of Gastroenterology (BSG), 2006. This guideline is likewise based on a literature search; authors noted that, “where possible,” efforts had been made to grade the quality of evidence as well. However, suggestions for prevention of accidental bleeding with paracentesis were not presented as formal recommendations and therefore were not graded. For this reason, and because there are two domestic evidence-based guidelines that do contain formal recommendations for prevention of this condition, we did not include this guideline in the final table above. It can be found here: <http://www.bsg.org.uk/clinical-guidelines/liver/guidelines-on-the-management-of-ascites-in-cirrhosis.html> (accessed 4/29/15).

3. Identification of the appropriate actions to be taken to prevent the conditions

Recommendations pertaining to paracentesis are brief in both evidence-based guidelines, and relevant recommendations in both guidelines are based on expert opinion, case studies, or standard of practice. The SIR guidelines (Malloy et al., 2012) categorizes paracentesis as a procedure with low risk of bleeding, and contains recommendations for periprocedure laboratory testing and bleeding management. Guideline authors recommend that aspirin should not be withheld, and that platelet counts and hematocrit are not routinely recommended prior to the procedure. The AASLD guidelines contain one recommendation for prevention of abnormal bleeding with paracentesis: “Since bleeding is sufficiently uncommon, the routine prophylactic use of fresh frozen plasma or platelets before paracentesis [for evaluation and diagnosis of ascites caused by cirrhosis] is not recommended (Class III, Level C).”

SECTION 4
SUMMARY

Summaries of the numbers of guidelines found for each condition are provided in Table 2. The number of guidelines with Level Ia: Systematic Reviews; Level Ib: Evidence-grading system Level II: Evidence Cited; Level III: Expert Opinion are also summarized by condition. Note that guidelines may employ Level III: Expert Opinion in addition to Level Ia, Level Ib or Level II.

Table 2
Summary of the number and ratings of available guidelines for each condition

Condition	Guidelines with recommendations for prevention of the condition	Guidelines with Level Ia: systematic review and evidence grading,	Guidelines with Level Ib: evidence grading	Guidelines with Level II: evidence cited only	Guidelines with Level III: expert opinion
Iatrogenic pneumothorax with thoracentesis	2	2	0	0	2
Accidental puncture/bleeding with abdominal paracentesis	2	0	2	0	2