Methodology
Care of the Critically Ill and Injured During Pandemics and Disasters: CHEST Consensus Statement

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BACKGROUND: Natural disasters, industrial accidents, terrorism attacks, and pandemics all have the capacity to result in large numbers of critically ill or injured patients. This supplement provides suggestions for all those involved in a disaster or pandemic with multiple critically ill patients, including front-line clinicians, hospital administrators, professional societies, and public health or government officials. The field of disaster medicine does not have the required body of evidence needed to undergo a traditional guideline development process. In result, consensus statement-development methodology was used to capture the highest-caliber expert opinion in a structured, scientific approach.

METHODS: Task Force Executive Committee members identified core topic areas regarding the provision of care to critically ill or injured patients from pandemics or disasters and subsequently assembled an international panel for each identified area. International disaster medicine experts were brought together to identify key questions (in a population, intervention, comparator, outcome [PICO]-based format) within each of the core topic areas. Comprehensive literature searches were then conducted to identify studies upon which evidence-based recommendations could be made. No studies of sufficient quality were identified. Therefore, the panel developed expert opinion-based suggestions that are presented in this supplement using a modified Delphi process.

RESULTS: A total of 315 suggestions were drafted across all topic groups. After two rounds of a Delphi consensus-development process, 267 suggestions were chosen by the panel to include in the document and published in a total of 12 manuscripts composing the core chapters of this supplement. Draft manuscripts were prepared by the topic editor and members of the working groups for each of the topics, producing a total of 11 papers. Once the preliminary drafts were received, the Executive Committee (Writing Committee) then met to review, edit, and promote alignment of all of the primary drafts of the manuscripts prepared by the topic editors and their groups. The topic editors then revised their manuscripts based on the Executive Committee's edits and comments. The Writing Committee subsequently reviewed the updated drafts and prepared the final manuscripts for submission to the Guidelines Oversight Committee (GOC). The manuscripts subsequently underwent review by the GOC, including external review as well as peer review for the journal publication. The Writing Committee received the feedback from the reviewers and modified the manuscripts as required.

CONCLUSIONS: Based on a robust and transparent process, this project used rigorous methodology to produce clinically relevant, trustworthy consensus statements, with the aim to provide needed guidance on treatment and procedures for practitioners, hospital administrators, and public health and government officials when addressing the care of critically ill or injured patients in disasters or pandemics.

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ABBREVIATIONS: CHEST = American College of Chest Physicians; COI = conflict of interest; GOC = Guidelines Oversight Committee; PICO = population, intervention, comparator, outcome
In 2011, the Institute of Medicine released new guideline standards\(^1\) that require a significant degree of scientific rigor and high-quality evidence for clinical practice guidelines to be considered trustworthy. The American College of Chest Physicians (CHEST), is committed to upholding those standards and has a proven history of developing guidelines.\(^2\) However, some recently emerging fields, or others by the very nature of their practice, may not have developed a significant body of high-grade research upon which an evidence-based guideline can be formulated. With these unique disciplines in mind, CHEST has created a consensus development process in which the highest-caliber expert opinion can be captured in a structured, scientific manner.\(^3\) This process brought international disaster medicine experts together to define the important questions, perform systematic reviews of the scientific literature, develop suggestions, and use a modified Delphi voting technique to achieve consensus. Care of the critically ill or injured in pandemics or disasters is vitally important for support of international emergency preparedness and was selected by CHEST to be the first consensus statement to undergo the new development process. The goal of this CHEST consensus statement project is to produce clinically relevant and useful suggestions on treatment and procedures that provide needed guidance on treatment and procedures for practitioners, hospital administrators, and public health and government officials when addressing the care of critically ill or injured patients in pandemics or disasters.

CHEST previously supported and published the results of the Task Force for Mass Critical Care Summit Meeting in 2008, which was extremely successful and sparked engagement of critical care disaster considerations by public health and hospital systems. Subsequently, leaders from CHEST’s Disaster Network submitted a proposal for an update in 2011, with projected publication in 2014.

**Composition and Selection of Panelists and Content Experts**

For this consensus statement project, the Guidelines Oversight Committee (GOC) of CHEST appointed two co-chairs (A. D., J. R. D.). The co-chairs nominated three more experts (M. D. C., N. K., and Lewis Rubinson, MD, PhD) to form the project’s Executive Committee. The Executive Committee, with other Disaster Network leaders, held an organizational meeting at the 2011 CHEST Annual Meeting to develop a task force and topic objectives. Task Force Executive Committee members subsequently identified core topic areas regarding the provision of care to critically ill or injured patients from pandemics or disasters. Eleven topic areas were chosen originally, which eventually resulted in 12 main articles for the final document:

1. Business and Continuity of Operations
2. Education
3. Engagement
4. Ethics/Culture
5. Mobilization and Evacuation
6. Systems Planning, Coordination, and Communication
7. Policy/Legal
8. Triage
9. Resource-Poor Settings
10. Special Populations
11. Surge Capacity

Executive committee members, in conjunction with the Disaster Network leadership, nominated task force members. Nominees were all experts in their assigned topics and included physicians, nurses, respiratory therapists, and other related health-care professionals. All nominees, including the Executive Committee, were

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**COI grids reflecting the conflicts of interest that were current as of the date of the conference and voting are posted in the online supplementary materials.**

**DISCLAIMER:** American College of Chest Physicians guidelines and consensus statements are intended for general information only, are not medical advice, and do not replace professional care and physician advice, which always should be sought for any medical condition. The complete disclaimer for this consensus statement can be accessed at http://dx.doi.org/10.1378/chest.1464S1.

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required to complete a conflict of interest (COI) disclosure process managed by the GOC. Based on their review, members without noted conflicts were then appointed to the task force as panelists. If a conflict was noted, the GOC recommended an appropriate management plan for the nominee or recommended that the nominee not be appointed.

Topic editors were chosen by the Executive Committee from the panelist group and the Executive Committee itself to be leaders for the 11 topics (at least two topic editors per group). Most were chosen before the scheduled June 2012 task force meeting (see later); some were added afterward as the needs of the task force evolved. Each Executive Committee member served as the topic editor for one or two groups. Topic editors were responsible for the following: coordinating the development of initial questions in the population, intervention, comparator, outcome (PICO) format, preparing the data table and graded with a quality assessment tool. Additionally, each panelist had the support of an experienced librarian, could work with their own librarian resources, or performed literature searches themselves.

Task force members completed a training session to orient them to the process for PICO question development, literature search strategies, and the COI policy. This was done in person at an organizational meeting at the annual meeting of the Society of Critical Care Medicine in February 2012 or online thereafter. The work of the task force formally began in March 2012 and commenced with biweekly conference calls.

The task force also invited content experts to participate in the process. Content experts were professionals who attended a task force meeting in June 2012, during which they participated in formulating key questions and provided expert testimony. They were not required to pass a COI review and did not participate in the consensus process again after this meeting. Ultimately, 100 members (18 topic editors, 68 panelists, and 14 content experts) participated on the task force, drawing participants from the United States, Canada, Hong Kong, Mexico, Israel, Switzerland, South Africa, United Kingdom, and Belgium.

The task force met in June 2012 in the Chicago, Illinois, area to formulate the key questions (in a PICO-based format) within each of the core topic areas. The meeting was structured over 4 days, with the Executive Committee and topic editors meeting on day 1 to finalize meeting plans and again on day 4 to debrief. Days 2 and 3 were dedicated to topic groups’ developing key questions in the morning, with presentation to the entire task force in the afternoons. The 2-day format facilitated all Task Force members being engaged with two different topic groups.

Identifying and Reviewing the Evidence and Formulating Suggestions

Over the following 9 months, the 11 groups formally searched the scientific literature in an attempt to find evidence to answer the key questions formulated at the task force meeting. The topic groups all performed thorough literature searches using MEDLINE via PubMed. All articles identified by literature searches were reviewed (title and abstract) by two panelists and then included or excluded; included articles were then obtained and reviewed in depth. If articles were found with sufficient quality data, they were to be included in a data table and graded with a quality assessment tool.4

Disaster medicine data are primarily of observational-level quality or less, and the limited data gathered across all topics were determined insufficient to enable evidence-based recommendations to be developed.3 Therefore, the groups proceeded to develop suggestions based on the limited published observational evidence found, content expert testimony, and expert opinion within their group.

Formulating and Finalizing the Suggestions

Each topic group drafted suggestions that were informed by expert opinion as well as published evidence, where available, based on what was believed to be most relevant to end-user clinicians, hospital administrators, and government/public health officials. The suggestions were formally vetted and discussed during weekly conference calls the month prior to initiation of the Delphi voting process,3 with all task force members invited to participate.

Each drafted suggestion was presented to the entire panel for consensus development process based on a modified Delphi technique that was created and run by members of the executive committee (J. R. D., M. D. C.), with support from a methodologist (J. O.) and technical assistance from CHEST staff. Using an online survey (www.surveymonkey.com), panelists were required to vote representing their level of agreement with each presented suggestion statement based on a five-point Likert scale derived from the Grading of Recommendations Assessment, Development and Evaluation (GRADE) grid (Fig 1).3,5 Additionally, each panelist had the option to provide open-ended feedback on each suggestion regarding suggested edits or general remarks.
A survey response rate of ≥ 75% was required for each presented suggestion for the result to be counted as valid. Reminder e-mails and follow-up phone calls from the Executive Committee to panelists were used to maximize the response rate. This technique enabled achievement of formal consensus on each suggestion while accounting for group interaction bias and maintaining anonymity among respondents (Fig 2). A suggestion needed to achieve panel consensus to be included in the final manuscript. Consensus was defined as a suggestion receiving positive endorsement (either "strongly agree" or "weakly agree") from ≥ 80% of the total votes. The Executive Committee, topic editors, and key panelists met in April 2013 at CHEST headquarters in Northbrook, Illinois, to discuss the results of the first round of the Delphi voting. The purpose of this meeting was to review each group's suggestions, resolve any confusion or controversy, and address any other key issues to guide modification of the suggestions prior to the second round of voting.

Of the 315 suggestions presented in the first round, seven did not achieve consensus. Based on the anonymous open-ended feedback from the respondents in the survey combined with the discussion at the face-to-face meeting, the topic editors revised any suggestions that did not achieve consensus in the first round or that the Executive Committee and topic editors believed required revision to improve the clarity of the suggestion. If the suggestion was revised, it was then resubmitted to the next Delphi round of the survey for voting again by the entire panel. Minor revisions to the suggestion to correct grammar or to improve adherence to the standard structure for the suggestions did not require revoting in the second round of the Delphi as long as the substantive meaning of the suggestion was in no way modified.

In total, 57 suggestions were submitted to a second round of Delphi voting. Three suggestions that did pass the first Delphi round were not included after discussion at the April meeting (see “Business and Continuity of Operations” article by Tosh et al in this consensus statement). All of the 57 suggestions in the second round achieved consensus. Both rounds received an adequate response rate for all suggestions submitted. If panelists did not vote on the first round, they were not invited to vote on subsequent rounds. A total of 62 panelists voted in both Delphi rounds and remained active throughout the project.

Each set of topic editors, with support and input from their groups, prepared a first-draft manuscript based
on suggestions that passed the Delphi process. Once the preliminary drafts were received, the Executive Committee (Writing Committee) then met to review, edit, and promote alignment of all of the primary drafts of the manuscripts prepared by the Topic Editors and their groups. The Topic Editors then revised their manuscripts based on the Executive Committee’s edits and comments. The Writing Committee subsequently reviewed the updated drafts and prepared the final manuscripts for submission to the GOC.

Review by CHEST and External Reviewers
The CHEST GOC provided an extensive peer review to consider content, methods, and adherence to the CHEST consensus development process (Table 1). Reviewers were self-nominated and vetted through the same COI disclosure and management process as the task force panelists. Reviewers are members of the CHEST Critical Care Network, the CHEST Disaster Network, the CHEST GOC, and the CHEST Board of Regents. None of the GOC reviewers had participated in the development of the suggestions or manuscripts. The CHEST journal also conducted a separate peer review. Additionally, the CHEST Board of Regents primary reviewer and the Editor in Chief of the CHEST journal reviewed the entire document.

Final Manuscript Preparation
The GOC review process generated detailed comments and feedback regarding the manuscripts. All deficiencies and areas of concern identified by the GOC were reviewed by the Executive Writing Committee and revisions made as seemed necessary. A detailed response was prepared for the GOC outlining how each issue was addressed. Subsequently, two members of the Writing Committee (M. D. C., N. K.) undertook a final detailed edit of the manuscripts to ensure consistency of the discussion content and style across all manuscripts. The manuscripts were then resubmitted to the GOC for a final review, approval, and submission to the CHEST journal. Minor copy-editing was conducted where required to comply with the journal style guide by the CHEST journal staff and approved by the Executive Writing Committee for publication.

Table 1 | Questions Considered In Guideline Oversight Committee Review Process

<table>
<thead>
<tr>
<th>Question Domain</th>
<th>Question</th>
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<tbody>
<tr>
<td>Methodology</td>
<td>Are the inclusion and exclusion criteria clearly described?</td>
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<tr>
<td></td>
<td>Was the methodology used, as described, to develop the practice guideline?</td>
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<td></td>
<td>Was a systematic review of the literature conducted?</td>
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<td></td>
<td>Was the evidence graded using a formal system?</td>
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<tr>
<td>Usability</td>
<td>Are the objectives of the guideline and specific clinical questions clearly stated in the practice guideline?</td>
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<td></td>
<td>Are the intended users of the guideline appropriately stated?</td>
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<td></td>
<td>Are recommendations specific and easy to comprehend?</td>
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<tr>
<td></td>
<td>Is the patient population specifically described?</td>
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<td></td>
<td>Are the key recommendations clearly identifiable in the practice guideline?</td>
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<td></td>
<td>Is a summary of recommendations provided?</td>
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<td>Are clinical algorithms included, where appropriate?</td>
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<td></td>
<td>Does the practice guideline provide strategies for implementing the recommendations?</td>
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<td></td>
<td>Is the guideline readable?</td>
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<tr>
<td>Validity</td>
<td>Is the guideline clinically feasible?</td>
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<tr>
<td></td>
<td>Is the guideline clinically relevant?</td>
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<td></td>
<td>Does the guideline make sense?</td>
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<td></td>
<td>Does the discussion flow from the evidence (where evidence exists)?</td>
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<tr>
<td></td>
<td>Do the recommendations flow from the discussion?</td>
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<tr>
<td>Bias</td>
<td>Were funding bodies identified in the practice guideline?</td>
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<tr>
<td></td>
<td>Did all members of the guideline development entity disclose potential conflict of interest, and was this explicitly stated?</td>
</tr>
<tr>
<td>Summative</td>
<td>Would this document receive approval to represent the organization (CHEST)?</td>
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Online Appendixes

Online appendixes are included for each topic group with their list of key questions, search terms used to find articles, the databases that were searched, the dates searches (if available), and the number of articles obtained, and data tables composed of original scientific data, if any were found.

Limitations and Challenges

The primary limitation of this process was the inability to provide evidence-based recommendations because of the lack of high-quality studies within the field of disaster medicine. Providing evidence-based statements should remain the ultimate goal of future guideline updates but will require significant advances to be made in the field of disaster medicine research to do so. Given the inability to develop evidence-based recommendations, we strived to strengthen the process and methodologic rigor used to develop expert opinion-based suggestions.

Although unlikely to have negatively affected the validity of the process, several additional challenges were faced that may represent potential opportunities for improving future disaster guideline development. First, the use of the PICO format for key question development presented significant challenges for some topic groups, particularly those such as the Legal and Policy group, which (1) are not specifically clinical subject areas, and (2) use significantly different forms of research and data from that of traditional clinical trials. Additionally, embarking on this project as the first consensus statement group applying the new methodology essentially made this a pilot study, given that much of the process was still being finalized by the GOC as the task force was performing its work. Finally, the use of a modified Delphi process with such large topic areas presents many obstacles. The first round of the Delphi process included 315 suggestions that equaled to 150 pages (if printed) and required several hours to complete. We noted significant response rate fade (from 89% down to 75%) over the length of the survey, likely due to respondent fatigue. Consideration was given to randomly varying the presentation of questions to the participants, but doing so would have significantly increased the complexity of conducting the survey, given that many suggestions were related to others or required the context provided by each other.

Conclusions

Methods for development of consensus statements have evolved as the field of evidence-based medicine has advanced. This project used the latest consensus methodology to provide trustworthy guidance in this clinically important area, where evidence is lacking or weak. As new interventions, changes in practice, or advances in the body of disaster medicine evidence become available, a reassessment of appropriate clinical guidance in this field will again be required.

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Endorsements: This consensus statement is endorsed by the American Association of Critical-Care Nurses, American Association for Respiratory Care, American College of Surgeons Committee on Trauma, International Society of Nephrology, Society for Academic Emergency Medicine, Society of Critical Care Medicine, Society of Hospital Medicine, World Federation of Pediatric Intensive and Critical Care Societies, World Federation of Societies of Intensive and Critical Care Medicine.

Role of sponsors: The American College of Chest Physicians was solely responsible for the development of these guidelines. The remaining supporters played no role in the development process. External supporting organizations cannot recommend panelists or topics, nor are they allowed prepublication access to the manuscripts and recommendations. Further details on the Conflict of Interest Policy are available online at http://chestnet.org.

Other contributions: The opinions expressed within this manuscript are solely those of the author (M. D. C.) and do not represent the official position or policy of the Royal Canadian Medical Service, Canadian Armed Forces, or the Department of National Defence.

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