
Research Methods of Inquiry

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Abstract

Incidents of significant consequence that create surge may require special research methods to provide reliable, generalizable results. This report was constructed through a process of literature review, expert panel discussion at the journal's consensus conference, and iterative development. Traditional clinical research methods that are well accepted in medicine are exceptionally difficult to use for surge incidents because the incidents are very difficult to reliably predict, the consequences vary widely, human behaviors are heterogeneous in response to incidents, and temporal conditions prioritize limited resources to response, rather than data collection. Current literature on surge research methods has found some degree of reliability and generalizability in case-control, postincident survey methods, and ethnographical designs. Novel methods that show promise for studying surge include carefully validated simulation experiments and survey methods that produce validated results from representative populations. Methodologists and research scientists should consider quasi-experimental designs and case-control studies in areas with recurrent high-consequence incidents (e.g., earthquakes and hurricanes). Specialists that need to be well represented in areas of research include emergency physicians and critical care physicians, simulation engineers, cost economists, sociobehavioral methodologists, and others.

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Defined as the ability to expand routine and critical care capabilities in response to an overwhelming patient influx, surge capacity is critical to hospital and health system crisis preparedness. Pervasive surge capacity inadequacies limit the current capability of health care systems in the United States to respond adequately to high-consequence events, such as natural disasters, terrorism, or pandemic influenza. However, these inadequacies have recently gained national atten-

tion as focal areas for improvement.¹⁻¹⁰ For that reason, in part, the Society for Academic Emergency Medicine's peer-reviewed journal *Academic Emergency Medicine* sponsored a consensus conference to address the science of surge capacity on May 17, 2006, in San Francisco, California. Emergency physicians and experts in operations and disaster research convened to determine the capabilities necessary for hospitals to achieve and sustain adequate readiness for surge events. The authors of this report facilitated a breakout session during this conference to address the scientific methods available to investigate surge capacity effectiveness in preparation for high-consequence events. Breakout session outcomes and literature review findings are discussed in the following sections.

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METHODS

To prepare for our breakout session, we reviewed publications that addressed hospital surge capacity, disaster behavior, and disaster research methodology. Publications from the medical, health care, and social sciences research literature were identified by searching key terms and phrases using four Internet search engines: MEDLINE, Google, GoogleScholar, and HazLit (The Library of the Natural Hazards [HazLit] Center at the University of Colorado offers information about how society can prepare for, respond to, recover from, and mitigate damage and other losses from natural hazards and catastrophic events; <http://www.colorado.edu/hazards/>). Key

search terms and phrases are provided (Table 1). Publications were selected for review when abstracts showed a practicable orientation to the topic area. Additional literature was identified in reference listings from publications previously selected for review.

The medical and health care research literature showed limited findings specific to surge capacity research methods. The social sciences research literature offered substantial resources that specifically discussed sociobehavioral research methodology in relation to incidents of high consequence. Outcomes from the literature review guided development of the breakout session stimulus questions listed as follows.

1. What research methods are available to scientifically investigate topic areas related to surge capacity effectiveness?
2. What are the strengths and weaknesses of various research methods for conditions producing surge?
3. How do we validate computer simulations?
4. What are the methods of studying pertinent aspects of human behavior that impact surge capacity effectiveness?
5. What are the methods of studying cost-utility and system recovery relevant to surge capacity?
6. What “regulatory research” is available and necessary for improving surge capability (altered standards of care, Health Information and Portability Accountability Act [HIPAA], Emergency Medicine Treatment and Active Labor Act [EMTALA], others)?

Discussants did not attempt to reach consensus on stimulus questions due to the broad scope of the subject

Table 1
Preconference and Postconference Key Search Terms and Phrases

Search terms
Behavior
Disaster
Health Systems
Hospital
Research Methods
Research Methodology
Surge Capacity
Systems Effectiveness
Search phrases
‘Disaster Behavior’
‘Disaster Behavior’ + ‘Surge Capacity’
‘Disaster Research Methods’
‘Disaster Research Methodology’
‘Disaster Research Methodology’ + ‘Health Systems’ + ‘Surge Capacity’
‘Disaster Research Methods’ + ‘Health Systems’ + ‘Surge Capacity’
‘Health System’ + ‘Surge Capacity’ + ‘Research Methods’
‘Health System’ + ‘Surge Capacity’ + ‘Research Methodology’
‘Hospital Surge Capacity’ + ‘Research Methods’
‘Hospital Surge Capacity’ + ‘Research Methodology’
‘Surge Capacity Research’
‘Systems Effectiveness Research’
‘Surge Capacity’ + ‘Research Methods’
‘Surge Capacity’ + ‘Research Methodology’
‘System Effectiveness’ + ‘Research Methods’
‘Systems Effectiveness’ + ‘Research Methodology’

matter and limited knowledge concerning methods of inquiry. Instead, participants discussed the stimulus questions and produced key recommendations concerning appropriate research methods, collaboration with additional scientific disciplines, important areas of study, and regulatory issues. Key recommendations are presented with corresponding stimulus questions in the results section.

A focused postconference literature review was conducted to identify additional resources in consideration of discussion outcomes. The postconference literature review identified useful material on systems analysis but offered few additional resources beneficial to breakout session outcomes and study designs. However, several publications offered commentary about important surge-related issues. These findings are restated as additional recommendations in the results section.

Integrated preconference and postconference literature review findings are presented in the discussion section. Various factors affecting surge capacity research are presented, as well as important areas of study to consider for future investigations.

RESULTS

Our breakout session was convened to address research methods appropriate for investigating surge capacity effectiveness in preparation for high-consequence events such as natural disasters, terrorism, or pandemic influenza. We developed stimulus questions based on key concepts identified during the preconference literature review to encourage discussion about surge capacity research methods. Stimulus questions and the corresponding recommendations from the discussants are listed in the following text.

1. What Research Methods Are Available to Scientifically Investigate Topic Areas Related to Surge Capacity Effectiveness?

Recommendation 1. Consider the following research strategies that are likely to be appropriate for surge capacity study design: prospective and retrospective case-control design, nested case-control design (prospective and retrospective), double-cohort design, cross-sectional design, and qualitative design. Systems analysis^{8,11–13} study designs are strongly encouraged for measuring effectiveness of health care systems.

Recommendation 2. Define differing levels of surge onset and identify relevant “metrics of surge” for outcomes measurement.¹⁴

Recommendation 3. Identify successful strategies for mass casualty triage and thresholds for key aspects of clinical decision making.

Recommendation 4. Explore the “surge capacity supply chain inventory” to identify resources that may enhance response capabilities (e.g., promulgating the use of taxis for patient transport).¹⁵

Recommendation 5. Explore “surge supply” for materials and personnel in relation to probable “surge demand.”

2. What Are the Strengths and Weaknesses of Various Research Methods for Conditions Producing Surge?

Recommendation 6. Create a table in the report summarizing the strengths and weaknesses of the research methods available for surge. Of note is the substantial lack of evidence as a result of limited surge capacity research.

3. How Do We Validate Computer Simulations?

Recommendation 7. Due to lacking computer simulation validity testing, identify methods that validate simulations beyond the current 20%–30% anticipated increase in surge. Systematic evaluation of hospital and community exercises, especially when the exercise is performed to the point of system failure, is a reasonable method of validation, even though available data are still truly simulated.

Recommendation 8. Identify and recruit simulation experts to participate in designing future simulation studies that will help improve decision making.

4. What Are the Methods of Studying Pertinent Aspects of Human Behavior That Impact Surge Capacity Effectiveness?

Recommendation 9. Recruit social scientists specializing in disaster research to provide investigational assistance concerning behavioral impacts on surge capacity effectiveness, specifically motivating factors that influence human behavior during disaster events (e.g., risk perception, attitudes regarding disaster preparedness activities and relief efforts, decision-making thresholds, and confounding factors) and behavioral conduct as affected by health systems infrastructure.

5. What Are the Methods of Studying Cost-utility and System Recovery Relevant to Surge Capacity?

Recommendation 10. Recruit research economists to investigate costs in relation to improving surge capabilities, conducting surge capacity research, and examining the cost-effectiveness of improved surge capacity effectiveness.

6. What “Regulatory Research” Is Available and Necessary for Improving Surge Capability (Altered Standards of Care, HIPAA, EMTALA, others)?

Recommendation 11. Inform regulatory decision makers about issues associated with practical surge capacity efforts and surge capacity research.

Recommendation 12. Recruit regulatory research personnel and agencies (e.g., Congressional Research Service) to develop a better understanding of the implications for surge as impacted by regulatory reforms.

Supplemental Recommendations from the Literature

Following the conference, we conducted a focused literature review meant to address the recommendations listed previously, but instead found further recommendations for consideration.

Certain recommendations listed in the following text were previously published in outcome reports following expert meetings and consensus conferences also convened to address weaknesses in surge preparedness. Because little evidence exists about progress achieved in many of these areas, previously published recommendations concerning surge capacity research are restated in the following text. We are hopeful that repeated efforts to increase awareness about ongoing research needs will inspire future investigations. Other recommendations were implicitly derived from relevant publications. Source documents are cited for all recommendations.

Recommendation 13. Consider evidence-based drills and exercise evaluations to measure surge preparedness (see recommendation 19), geographic information systems as a highly useful instrument for inclusion in study design,¹⁶ and latent growth modeling to examine trends in social characteristics that may impact surge capacity effectiveness.

Recommendation 14. Consider an all-hazards approach for study designs to measure surge capabilities in response to man-made or natural disasters, as well as large-scale public health emergencies.^{11,17}

Recommendation 15. Develop and support a research agenda specific to health and medical care standards for mass casualty events.¹⁸

Recommendation 16. Investigate disaster preparedness planning assumptions relevant to surge capacity effectiveness.¹⁹

Recommendation 17. Establish a national clearinghouse for disaster health and medical research that can collect, collate, analyze, and disseminate relevant research findings from across the United States.^{16,19}

Recommendation 18. Report future research findings in peer-reviewed scientific journals and thoroughly describe advantages and limitations of methodologies used.^{16,19}

Recommendation 19. Establish categorical domains of inquiry (i.e., single health care entity vs. community-wide health systems vs. regional health systems vs. national health systems) and related study metrics of scale.²⁰

Recommendation 20. Standardize investigative tools and resources (e.g., standardized questionnaires) and study designs that are easily replicated.^{16,19}

Recommendation 21. Examine trends in social characteristics that affect emergency department overcrowding and diversion.^{6,7,16}

Recommendation 22. Explore cost-effective methods for establishing regional hospital planning and response groups in anticipation of federal monies that may soon become available to support surge improvements specific to pandemic influenza.⁷

Table 2
Research Methods Appropriate for Investigating Surge Preparedness

Methodology and Overview	Advantages	Disadvantages
<p>Randomized experimental designs²²</p> <p>Includes randomized clinical trials</p> <p>Causal relationship between two variables</p> <p>Power lies with causal conclusion (unavailable using other methods)</p> <p>Dependent variable differences due to independent variable differences</p> <p>Random condition placement critical to reduce differences as consequence of condition placement</p>	<p>Strong internal validity control</p> <p>Study cause-effect relationships</p>	<p>Difficult to control random assignment</p> <p>Surge research: nonrandom placement may reduce study scope</p>
<p>Quasi-experimental designs²³</p> <p>Study cause-effect when random assignment not possible</p> <p>Requires nonequivalent group comparison and additional pretreatment/posttreatment measures</p> <p>Types: before-after, regression-discontinuity, interrupted time series, nonequivalent group designs</p> <p>Maintaining validity is key factor</p> <p>Validity types: internal, external, construct of cause, construct of effect, statistical conclusion validity</p>	<p>Approximate experimental design</p> <p>Study cause-effect when random placement not feasible</p> <p>Surge research: greater applicability and feasibility for surge vs. randomized experimental designs</p>	<p>Potential comparison group bias via inaccurate estimates</p>
<p>Survey designs²⁴</p> <p>Sample respondents selected from population respond to structured questionnaire</p> <p>Questionnaire completed via in-person interview, self-administered, telephone, mail, Internet, fax</p> <p>Qualitative and quantitative data collected</p> <p>Options to implement: cross-sectional, one-time, longitudinal</p> <p>Experimental conditions may be incorporated</p> <p>Generalizability of results: respondents selected via probability methods (simple random, systematic, stratified, cluster, multistage)</p> <p>Nonprobability sampling (convenience, most similar/dissimilar, typical cases, critical cases, snowball, quota): results not generalizable but informative of respondent group</p>	<p>Great amount of data collected from large population (not available by other means)</p> <p>Random selection: generalizable results</p> <p>Multiple structured methods for data collection</p> <p>Surge research: common tool because data collected various sources on various topics</p>	<p>Self-reporting: recall biases and potential for missing data</p> <p>Social norms effects (e.g., self-presentation and social desirability)</p> <p>Low response rates</p>
<p>Simulation designs^{8,11-13}</p> <p>Models anticipated event(s) to examine needs, response, and efficiency</p> <p>Conducted using real people or computer (likely application for surge research)</p> <p>Attempt to identify strength vs. weakness via replicating actions/responses of true events before actual occurrence</p>	<p>Safe for subjects and scientists</p> <p>System-wide application: identify gaps in role knowledge, communication, transportation, and triage</p>	<p>Difficult/impossible to implement</p> <p>CPU-based: limited by accuracy of available data for model input</p> <p>People-based: limited by lack of "realness"</p> <p>Requires validation</p>
<p>Qualitative study designs²⁵⁻²⁷</p> <p>Produce descriptive data (not quantitative data)</p> <p>Types: focus groups, observational studies, case studies</p>	<p>Surge research: useful for planning or further research (i.e., surveys or simulations)</p> <p>Understand meaning, context, and processes (i.e., how people make sense of events and influence on behavior)</p> <p>Identify unanticipated phenomena and influences</p> <p>Assist in developing causal explanations</p>	<p>Lacks generalizability</p> <p>Nonstatistical</p>

Table 2
Continued

Methodology and Overview	Advantages	Disadvantages
Need analysis designs²⁸ Includes need identification and need assessment Identifies users and uses Describes target population, service and communication environment	Identify areas needing greater resources Identify needs of victims, health care providers, other stakeholders	Reflect bias of survey sources
Ethnographical designs²⁹ People interviews, records review, weigh opinion credibility, identify ties between people and organizations for detailed reporting Includes field work, participant observation, interviewing, lists or forms, life histories for rich description about situations or people of interest	Depth of detail used to gain understanding of complex phenomena Surge research: detailing processes and systems involved in surge events	Significant resources required (i.e., time, labor, materials)
Epidemiological designs³⁰ Study "occurrence and distribution of diseases" Study population-based health-related conditions Case cohort: affected cohort-cases studied, control via random sample from same cohort Prospective cohort: data collected at study time, identify new cases then on (e.g., incidence or mortality) Retrospective cohort: identify exposure status via data obtained in past, past to present incidence determined Nested case-control: condition cases vs. sample cases without condition matched on specific variables Cross-sectional: one-time or short period study of population prevalence condition Panel: sample population data gathered across time Ecological: geographic or time period population studied (not individuals)	Depending on design selected: Study social or cultural processes Statistical efficiency Generalizability Short data collection period Longitudinal data collection Compare same control group on many conditions Flexibility time scale for analysis Repeated use of control groups for future study Surge research: Understand population disease and therapy efficacy	Depending on design selected: Lack cause and effect Difficult results interpretation Easier to identify long-duration cases vs. short-term cases High dropout rate Conditioning effects (learning, fatigue)
Cost-benefit analysis designs³¹ Study services cost vs. benefit to improve services May include budget constraint impacts May include minimal accepted outcomes on service provision May include impact of economies of scale and diminishing returns on investment Must study both cost and benefit to prevent misleading results	Identify resource allocation site yielding greatest benefit Surge research: Identify best resource site location for maximized dispensing and treatment	Difficult identifying value defined by specific cost benefit

Recommendation 23. Explore study designs that would accurately measure the hospital's perception of its linkages and that of emergency preparedness experts, and consider identifying benchmarks to measure linkage effectiveness.^{8,9}

Recommendation 24. Utilize evidence-based tools and resources developed with funding provided by the U.S. Agency for Healthcare Research and Quality Bioterrorism Planning and Response program for guidance in data collection methods and in selecting metrics for study.²

Recommendation 25. Identify information needs of clinicians during surge events, beneficial information technology and decision support systems, and criteria by which information technology and decision support systems should be evaluated with respect to usefulness.²¹

DISCUSSION

The following discussion addresses important themes identified in the literature and during the breakout session. Researchers are encouraged to review referenced

publications to expand their knowledge concerning surge capacity research methods and related topics of importance.

Methods of Inquiry

The concept of surge capacity is generalizable to single health care organizations and health systems of various scales, including community-wide, regional, statewide, or interstate health systems. Operational components of surge (staffing and response roles, surveillance, supplies and equipment, areas of accommodation, bed availability, mutual aid agreements, and so on) have been identified at each system level, and the only apparent difference is that of scalability. To organize the science of surge, researchers should consider establishing standard metrics of study for scalable components of surge.

When deciding on a method of inquiry and study design, investigators should define the research focus (understand the problem or issue, develop a conceptual framework, identify research questions, clarify study questions, negotiate the study scope) to properly address the topic and select the most appropriate research design. Next, researchers should develop their research design (maximize validity; identify key concepts and variables; outline comparisons; identify level of analysis; identify population, geographic, and time boundaries; select level of precision; choose a design) to match their research focus. Next, researchers need to identify sources of data (self-report, database, observation, documents) and begin resource planning (time, personnel, money, facilities) for conducting the research. In addition, investigators need to recognize that different methods and study designs have tradeoffs affecting generalizability, conclusiveness, precision, comprehensiveness, feasibility, reliability, validity, and ethics.²²

Several sources of data are available to researchers. These include self-reports, databases, records, after-action reports, observations, and documents. Studies can use one or more of these sources, but a combination of sources adds strength to any conclusions. Each source has benefits and limitations that may affect their usefulness for a particular study or to reach a specific conclusion. For example, self-reports can provide a wide range of data that are not available from records or observation but may have biases resulting from recall errors or social desirability. In addition, databases, records, and documents may have greater accuracy but may not contain important information needed for study or may not be accessible.

An overview of research methodology and study designs appropriate for investigating surge capabilities is provided (Table 2). Known methodological advantages and disadvantages are included.²³⁻³¹

Additional Scientific Disciplines for Participation

Additional scientific domains of study related to surge capacity are broad and traverse several research disciplines, including emergency and trauma medicine, the sociobehavioral sciences, and simulation engineering and modeling. Other valued disciplines include ethics, economics, and politics. It is incumbent on emergency medicine researchers to recruit these scientists for participation in collaborative study and cross-learning. Collaborative areas of study may include markets and market

Table 3
Important Areas of Study Identified During Methods of Inquiry Breakout Session

<p>Areas of study specific to medical or health care surge capacity effectiveness</p> <ol style="list-style-type: none"> 1. Implications for surge as impacted by regulatory issues^{18,32-35} 2. Surge capacity supply chain inventory⁴⁰ 3. "Surge supply" for materials and personnel in relation to probable "surge demand"^{3,20,41,42} 4. Thresholds of surge onset and response scope²⁰ 5. Thresholds for key aspects of clinical decision making and information technology and decision support systems²¹ <p>Areas of study specific to sociobehavioral aspects of surge capacity effectiveness</p> <ol style="list-style-type: none"> 1. Personal attitudes and beliefs and confounding factors influencing decisions⁴³ 2. Personal perception of risk/danger and confounding factors influencing decisions⁴³ 3. Impacts surrounding individual's or group's behavior, attitudes, beliefs, and perception of risk/danger on surge experience⁴³

imperfections; race, gender, and political economy factors; political participation, stability, and democracy; policy information, implementation, and enforcement; interest groups and their formation; public planning and decision making; conflict and its mitigation; interorganizational networks and coordination; financing and assessment of risk; and the structure of ecological networks and systems.¹⁶

Regulatory Issues for Consideration

Researchers must also consider important regulatory issues impacting surge capacity research. Regulatory issues of primary concern include altered standards of care, institutional review board (IRB) policies, EMTALA, and HIPAA.

In August 2004, the Agency for Healthcare Research and Quality convened a number of experts from bioethics, emergency medicine, health law and policy, and other fields to examine how current standards of care might be altered in response to a mass casualty event. Recommendations were produced concerning a collaborative approach for further input. Researchers are encouraged to review these next steps and identify relevant methods for contribution.¹⁸

Research of emergency department or emergency medical services system responses to surge must consider the federal regulations governing human research.³² Human research, with very few exceptions, must be approved by an appropriate IRB. Department of Health and Human Services regulations³² state that research involving "...survey procedures, interview procedures, or observation of public behavior, unless ... subjects can be identified directly, or through identifiers linked to the subjects..." is approvable but exempt from further IRB oversight. "Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that *the subjects cannot be identified, directly or through identifiers linked to the*

Table 4
Important Areas of Study Identified During Preconference and Postconference Literature Reviews

Areas of study specific to medical or health care surge capacity effectiveness

1. Hospital preparedness assessments^{20,43,44,64}
2. Hospital staffing^{20,43,44}
3. Bed availability^{12,20,43}
4. Personal protective equipment^{20,43,46}
5. Decontamination^{20,43,46}
6. Isolation and quarantine^{20,43,46}
7. Laboratory capacity^{20,43,46}
8. Risk communication^{20,47}
9. Specials needs populations²⁰
10. Altered standards of care¹⁸
11. Credentialing of nonemployees²⁰
12. Untraditional patient care providers²⁰
13. Adaptation of existing in-hospital capacity²⁰
14. Surge capacity in rural areas^{48,49}
15. Robust communications^{3,6,50}
16. Evacuation protocols and expedited discharge^{20,51}
17. Strategies for mass casualty triage including necessary security needs^{20,38,46,51,52}
18. Effective drilling and exercising^{54,55}
19. Community, regional, and statewide planning^{7-9,20,37,38,40,42,55-57}
20. Systems effectiveness and coordinated interaction between all area hospitals^{8,11,13,38}
21. Hospital's perception of preparedness linkages vs. that of emergency preparedness experts²⁰
22. Level of understanding of roles and responsibilities for each stakeholder group²⁰
23. Facilities of opportunity for surge hospitals^{20,49,58}
24. Simulation technologies^{8,11-13}
25. Patterns of injury³⁸
26. Static and dynamic events across variable timelines²⁰
27. Differing levels for resource requirements for static and dynamic events²⁰
28. Field studies of operational emergency health and medical care responses in disasters⁴³
29. Facilitators or barriers to surge effectiveness: individual, organizational, or structural factors⁴³
30. Factors in the external environment influencing decisions⁴³
31. Risk factors associated with injury or death and protective factors associated with surviving or not⁴³
32. Standard metrics of study for scalable components of surge relative to differing health care system levels²⁰

Areas of study specific to sociobehavioral aspects of surge capacity effectiveness

1. Convergence behavior³⁹
2. Convergence volunteerism⁵⁹
3. Victim transport^{19,39,42}
4. Triage and decontamination^{19,39,42}
5. Antisocial behavior³⁶
6. Behaviors that increase human loss^{42,60}
7. Mental health concerns⁶¹⁻⁶⁴
8. Patterns of citizen response^{36,37,42}
9. Socially integrative responses³⁶
10. Extrapolating citizen responses to terrorism³⁶
11. Challenges posed by weapons of mass destruction incident characteristics³⁶

subjects" (emphasis added) is also exempt. Retrospective research of surge should qualify as exempt when investigators avoid use of subject identifiers.

On some occasions, research may not precisely meet the criteria to be exempt, yet the research need not require review by the entire IRB membership. An IRB may use the expedited review to approve research that involves "...no more than minimal risk."³² Retrospective research generally involves little risk to research subjects. Each local IRB has significant latitude in determining exactly what is meant by "minimal risk." Nonetheless, for expedited approvals, "...the IRB membership must be informed of research proposals approved under this classification."

Ideally, a study design is prospective, randomized, and blinded. Prospective research protocols must be de-

signed and refined well in advance of data collection. Weeks or even months to design a study and obtain IRB approval generally precede prospective study data collection.

Also, human prospective research generally requires informed consent on the part of the patient (with emergency exceptions, narrowly designed for use with resuscitation protocols,³³ as defined by the "Final Rule" of the Food and Drug Administration). Consent documents are designed to facilitate research subjects' understanding of the purpose of the research and the risks and benefits of that research.³²

Prospective studies of surge topics, approvable by an IRB, can probably be designed for selected surge topics when surge is due to recurrent events, such as ambulance diversion from other nearby hospitals, daily variation in

patient census, or means to improve turnover of emergency department beds and emergency department throughput.

However, several roadblocks to the performance of prospective randomized trials in the evaluation of surge due to large-scale disasters exist that occur infrequently and relatively unpredictably. These include the following:

1. The time requirement for the conception of an appropriate research project, the definition of a specific research question and proposal, and the subsequent development of an informed consent statement.
2. The IRB review process, which involves a deadline for protocol submission, followed by a period for committee members to review the protocol and consent statement, and then the need for the IRB membership to meet as a group to approve or disapprove the research.
3. The probable need, in the face of large-scale disasters, to collect data on very short notice.

The roadblocks to performing prospective randomized research trials to study rare sources of large-scale surge are perhaps more daunting than those that faced the resuscitation research community in the early 1990s.³³

In summary, it is probably impossible to meet regulatory requirements currently codified by the Department of Health and Human Services and the Food and Drug Administration for the execution of prospective randomized research on large-scale, rare sources of surge, except possibly under the exception to informed consent rules when these stringent criteria can be met. Study of such events is likely to utilize retrospective research designs. Prospective, blinded, randomized studies of frequently recurrent surge events, however, can probably be designed and executed.

Researchers should become familiar with the implications for hospital-based research as impacted by recent EMTALA regulations. A current checklist for compliance is provided,³⁴ as are guidelines to help researchers navigate through the HIPAA Privacy Rule requirements when designing research.³⁵

Important Areas of Study

While our topic is specific to research methods, we consider this an opportunity to present an approximate foundation of baseline literature on surge-related topics. Becoming familiar with this body of literature will increase awareness about key study areas and stimulate thought on research design. Study areas are critical components of surge and relevant aspects of human behavior. Clearly it is impossible to know the specific surge capacity deficiencies within each community. Thus, we have identified critical components of surge and relevant aspects of human behavior (Tables 3 and 4) for researchers to consider for study within their specific environments. Although previous studies have directly addressed human behavior impacts on surge effectiveness,^{16,19,36-39} we have identified additional significantly relevant sociobehavioral topics⁴⁰⁻⁶⁴ (Tables 3 and 4) that are significantly meaningful to surge effectiveness and should be considered for future investigation.

CONCLUSIONS

This report provides recommendations for developing research on the topic of surge capacity; identifies research methods appropriate for investigating the capabilities of hospitals and health systems to rapidly meet patient influx resulting from natural disasters, terrorism, and other public health emergencies; and recommends research collaborations involving multiple scientific disciplines, including emergency and trauma medicine, simulation engineering, cost economics, and the sociobehavioral sciences. Researchers are encouraged to review cited publications, because this body of literature will increase awareness about important study topics and stimulate thought on study design. Priority study areas emphasized in the literature and during the breakout session include altered standards of care, "surge supply" versus "surge demand," mass casualty triage and decision making, aspects of behavior impacting surge effectiveness, and systems effectiveness. Investigators are also encouraged to utilize computer simulation methods with the intent of validating data input, qualitative methods seeking perceptual and attitudinal data from the public, and systems effectiveness designs. Initial research efforts should attempt to establish standard metrics of study, document lessons learned concerning regulatory obstacles, and thoroughly identify study design strengths, weaknesses, and limitations. Finally, researchers are strongly encouraged to publish findings in peer-reviewed sources.

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