Introduction: Conference on “Emergency Care Research Networks”

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Motivation

• IOM report on the Future of Emergency Care
• Increasing investment and diversity in clinical research networks with focus on emergency care
• Major shift in focus and structure of NCRR-supported clinical research infrastructure to align and support the NIH Roadmap
Selected Objectives

• Identify the unique features and infrastructure required for emergency care research
• Define the present state of emergency care research networks (ECRNs), including disease-based networks and the integration of emergency care research into CTSA programs
• Describe the optimal structure and components of ECRNs
• Develop an instrument or metric to evaluate the effectiveness of research networks
Examples of Existing ECRNs

- Emergency Medicine Network (EMNet)
- Neurological Emergencies Treatment Trials (NETT)
- Pediatric Emergency Care Applied Research Network (PECARN)
- Resuscitation Outcomes Consortium (ROC)
- Emergency Infectious Diseases Network (EMERGEency ID NET)
- Single trial networks (e.g., ProCESS)
**Mission:** To advance public health objectives through multicenter, emergency department-based research.

EMNet involves 198 medical centers and focuses on three areas:

1. Respiratory/allergy emergencies -- Multicenter Airway Research Collaboration (MARC),
2. Health policy -- e.g., National ED Inventories (NEDI), National ED Safety Study (NEDSS), and
3. Other public health projects -- e.g., ED 24-hour Research Network (ED24), surveys, analysis of federal datasets.

23-May-2008  EMNet Newsletter
14-May-2008  National Emergency Department Inventories
26-Mar-2008  MARC-33: Multicenter Cohort Study of Tobacco Users Treated in the ED
09-Jan-2008  MARC-30: Prospective Multicenter Study of Bronchiolitis Admissions
Emergency Medicine Network

- Began as the Multicenter Airway Research Collaboration (MARC)
- Group is presenting 13 abstracts at SAEM
The NIH has created a **Neurological Emergencies Treatment Trials (NETT) Network** to conduct large simple trials to reduce the burden of very acute injuries and illnesses affecting the brain, spinal cord, and peripheral nervous system. The network recognizes and seeks to explore the special narrow window of opportunity that seems to exist in treating neurologic damage from a variety of pathologies ranging from stroke to traumatic brain injury to seizures to meningitis. The study of very rapid interventions will have to be implemented by paramedics in the field, or by physicians in the Emergency Department. This network provides the basis for conducting efficient studies in these environments.

This is an exciting opportunity to improve emergency care. We appreciate your interest and participation. Welcome to the NETT.

**Bill Barsan**  
Principal Investigator  
Clinical Coordinating Center
Mission

The mission of the Neurologic Emergencies Treatment Trials (NETT) Network is to improve outcomes of patients with acute neurologic problems through innovative research focused on the emergent phase of patient care.

Vision

NETT will engage clinicians and providers at the front lines of emergency care to conduct large, simple multicenter clinical trials to answer research questions of clinical importance. The NETT structure will be utilized to achieve economies of scale enabling cost effective, high quality research.
PECARN, the Pediatric Emergency Care Applied Research Network, is the first federally-funded pediatric emergency medicine research network in the United States. PECARN conducts high-priority, multi-institutional research on the prevention and management of acute illnesses and injuries in children and youth of all ages.

PECARN is supported by cooperative agreements between four academic medical centers and the Health Resources Services Administration / Maternal and Child Health Bureau / Emergency Medical Services for Children Program (HRSA / MCHB / EMSC).
Resuscitation Outcomes Consortium

Mission Statement

The mission of the Resuscitation Consortium is to provide infrastructure and project support for clinical trials and other outcome-oriented research in the areas of cardiopulmonary arrest and severe traumatic injury that will rapidly lead to evidence-based change in clinical practice. The focus on pre-hospital and early hospitalization interventions recognizes the critical importance of this time frame and early congruence between the emergency cardiac and trauma populations. ROC Investigators will conduct collaborative trials of variable size and duration (equally directed towards the cardiac and trauma populations), leveraging the combined power of the member institutions and promoting the rapid translation of promising scientific and clinical advances for the public good.

March 24, 2006 NIH Press Release regarding ROC

ROC Brochure | ROC Professional Brochure
Resuscitation Outcomes Consortium

- Created to conduct clinical research in CPR and traumatic injury
- 10 Regional Clinical Centers (RCCs) and a Data and Coordinating Center (DCC)
- Trials may evaluate existing or new therapies as well as clinical management strategies
- Sponsors: NHLBI and other NIH Institutes, the Canadian Institutes of Health Research, Canadian Defense Research and Development, the Heart and Stroke Foundation of Canada, the American Heart Association
- Sponsors’ support is approximately $10 million/year
IOM Recommendation

• … development of multi-center research networks, funding of General Clinical Research Centers (GCRCs) that specifically include an emergency and trauma care component …
Clinical and Translational Science Awards

ON THIS PAGE: General Information • CTSA Questions and Answers • Publications • Events • Small Business Opportunities • Support for Conferences and Scientific Meetings • Contact Information

SEE ALSO: CTSA Funding Guidelines

A national consortium, funded through Clinical and Translational Science Awards (CTSAs), is transforming how clinical and translational research is conducted, ultimately enabling researchers to provide new treatments more efficiently and quickly to patients.

Now comprising 24 academic health centers in 18 states (including 12 centers added in September 2007), the consortium ultimately will link about 60 institutions together to energize the discipline of clinical and translational science.

The consortium’s Web site, CTSAweb.org, ensures broad access to CTSA resources, enhances communication, and encourages information sharing.
Key Elements of the CTSA

- Development of Novel Clinical and Translational Methodologies
- Pilot and Collaborative Translational and Clinical Studies
- Biomedical Informatics
- Design, Biostatistics, and Clinical Research Ethics
- Regulatory Knowledge and Support
- Translational Technologies and Resources
- Participant and Clinical Interactions Resources
- Community Engagement
- Research, Education, Training, and Career Development
Key Opportunities

- Training programs
  - Bring K30, K12, T32 and other research training programs into one structure
  - Intended to establish translational and clinical research as an academic discipline
- Collaborative opportunities
  - Access to patients, key populations
- Seed grants
  - Support to design, initiate, and gather preliminary data
CTSA Funding

- Original plan: ~12 new sites per cycle and final group of 60 institutions
- Current cycle $14 million for 6 awards
Funded CTSA Sites

• Columbia University
• Duke University
• Mayo Clinic
• Oregon Health & Sciences University
• Rockefeller University
• University of California, Davis
• University of California, San Francisco
• University of Pennsylvania
• University of Pittsburgh
• University of Rochester
• University of Texas, Houston
• Yale University

• Emory University
• Case Western University
• Weill Cornell Medical College
• Johns Hopkins University
• University Of Michigan At Ann Arbor
• University of Texas Southwestern Medical Center
• University Of Wisconsin Madison
• University Of Chicago
• University Of Iowa
• University Of Washington
• Vanderbilt University
• Washington University
CTSAs and Emergency Care

- Sections of applications for 11 of first 12 funded CTSA sites posted
- Observations from searching those applications for the word “emergency”:
  - Most occurrences of “emergency” are related to volume of patient visits, not research questions, scientific areas of focus, or even locations of subject recruitment
CTSAs and Emergency Care

• Finding the word “emergency”:
  • Incorporation of emergency and trauma care research is highly variable across CTSAs
  • Rockefeller: no emergency care site
  • OHSU: high level of integration of emergency care activities and investigators
Finished searching for:

Emergency

Total instances found:

0

New Search
Case Study 5: Emergent intervention for treatment of self ...

The study will assess an emergent intervention for self inflicted injuries. The intervention will use a hypothetical new antidepressant that has a rapid...

www.ctsaweb.org/uploadedfiles/CTSA_Peds_IRB_Slides_20070911_CASE51.ppt - Similar pages

NCRR Fact Sheet

Oregon stroke center, organic chemistry, and emergent services, will monitor two groups of... diabetics at risk of hyper- or hypoglycemic emergences...

www.ctsaweb.org/docs/CTSA%202006%20Grantees%20fact%20sheet%20final.pdf - Similar pages

Meeting Summary CTSA Ethics Steering Committee

... Other priorities/action items. o Conflicts of Interest, o Emergency Waivers, o Emerging Issues [Biorepositories]...

www.ctsaweb.org/uploadedfiles/CTSA%20Meeting%20Summary%202006%20Feb%202007%20final1.pdf - Similar pages

PENN REP

... studies of vulnerable populations, research in emergent settings, conflict of interest, data safety and monitoring, and other ethical issues. Penn REP...

www.ctsaweb.org/uploadedfiles/Karlawish1.ppt - Similar pages

Mars Database System at UPMC

This is a **<AGE in 20> old male patient presenting to the emergent department for evaluation of his multiple complaints. ...

(Media-Newswire.com) - The University of Rochester Medical Center is leading a new network of hospital emergency departments across upstate New York, to strengthen and expand clinical and biomedical research.

"The strength of this network lies in the diversity of the institutions, which serve a mix of urban, suburban and rural patients, and in the personnel and leadership," said Thomas Richardson, M.B.A., Ph.D., director of Emergency Medicine research at the University of Rochester. Richardson is also principal investigator and director of the upstate network. "The network team also possesses a significant diversity in terms of their skills, education, training, areas of expertise, and current research portfolio."

"The fact that we are joining forces to perform research, in spite of the competitive nature of medicine, is a tremendous statement about our commitment to attract the best researchers and funding to upstate New York," Richardson added.

The network recently received $56,000 in startup funding from the University of Rochester CTSI and the Foundation for Healthy Living. Emergency department chairs and research directors plan to meet in Rochester on October 30 to begin work. The network is part of the Upstate New York Consortium for Healthcare Research and Quality (UNYCHRQ) and the Upstate New York Translational Research Network (UNYTRN). Partners on this grant include: Albany Medical College; State University of New York, University at Buffalo; State University of New York, Upstate Medical University; Bassett HealthCare; Guthrie Health; and the University of Rochester Medical Center.
A Unique Partnership: Using Technology to Better Detect and Treat Common Diseases

Researchers at the Oregon Clinical and Translational Research Institute (OCTRI) are partnering with Intel to explore and fund a novel research method. Dr. Robert Lowe, an associate professor at the university, was awarded funding to support health applications of Intel's technology. Lowe’s interdisciplinary investigative team, comprised of researchers from neurology, emergency medicine, the Oregon stroke center, organic chemistry, and emergency services, will monitor two groups of patients outside of the hospital setting: 1) patients at high risk of atherosclerotic disease (e.g., stroke and myocardial ischemia) and 2) diabetics at risk of hyper- or hypoglycemic emergencies. The proposed sensing devices couple state-of-the-art wireless and mobile technology with sensors to enable earlier detection and treatment of these common and life-threatening diseases.
Engaging Communities in Research and Dissemination

CTSA funding at the University of Pittsburgh has established the Community PARTners (Partnering to Assist Research and Translation) Program to coordinate community engagement activities. It facilitates community involvement by providing researchers with training to work with communities and encouraging community health care providers to participate in research.

CTSA researchers at Mayo Clinic are moving clinical research outside of its traditional setting to the bedsides of acutely ill patients, as well as operating and emergency rooms, and into the community. Currently, the Mobile Clinical Research Unit’s trained research nurses and technicians are collecting specimens, administering study drugs, and gathering data for more than 20 research studies. To meet the increased demand for the mobile unit, six additional staff members were hired, and soon the unit will offer 24 hour coverage.

Building a Matrix for Clinical and Translational Science

NIH recognizes the need to develop multidisciplinary teams to conduct research that can be translated from the laboratory into clinical trials and further translated into the community through practicing physicians interacting directly with patients. These multidisciplinary teams need to conduct their research in integrated homes at their academic health centers, while also working together as a consortium across the country. The homes also need to provide the training ground for the next generation of clinical and translational researchers, including physicians, basic scientists, and nurses.
Emergency Care Research Sub-network

- Multiple disease-specific and discipline-specific research networks duplicate key infrastructure → Cost effective?
- CTSAs constitute a formal consortium
- Potential to form an emergency care research “sub-network” within CTSAs raised at NIH, which would
  - build on existing investment in infrastructure at each CTSA
  - leverage existing expertise and personnel
Breakout Number 1

- Focus Topic: Define emergency care research and delineate its unique features, addressing the scientific and clinical questions addressed, infrastructure requirements, and the populations served.

- Related Pre-conference Questions:
  - How would you define emergency care research?
  - What makes emergency care research unique?
  - What patient populations are primarily served by research performed in the emergency care setting?

- Related Specific Aims of Conference included in printed materials
Pre-conference Survey
Question 2: Define ECR

• … the systematic investigation of the prevention, access, delivery, diagnosis and management of the acute phase of care of many different illnesses and injuries within a system in which such care is organized …

• … unscheduled, acute, sudden, unexpected, rapid assessment, time-sensitive, time-dependent, life-threatening, optimal interventions, acute decompensation, exacerbation of chronic disease, dynamic, chaotic, severe, direct or long term effect on care, outcome oriented, collaborative, defined by time and place, improves access, drives policy

• The definition of ECR frequently incorporates the setting(s) in which it takes place (e.g. prehospital or ED) or describes a system or a chain of health care settings (prehospital, triage, ED, inpatient post ED care, rehabilitation)
Pre-conference Survey
Question 3: What makes ECR unique?

• … unscheduled and unpredictable nature, challenge of obtaining informed consent, cross-cutting or multidisciplinary nature, ability or inability to perform follow-up procedures, interface with the community, involvement of vulnerable populations including those in life-threatening situations, lack of disease or organ system focus, undifferentiated nature and diversity of potential patients (e.g. age, socioeconomic status, ethnicity)…

• The most commonly cited unique aspect of ECR is it’s time-dependent, time-limited, time-pressured, or time-constrained nature
Pre-conference Survey
Question 4: Patient populations

• …ECR serves a very broad spectrum of patients and their illnesses and injuries; it is particularly inclusive and sensitive to the acutely or unexpectedly ill and injured, underserved populations, underrepresented minorities, those without other access to care, and those at greatest risk for sudden deterioration
Breakout Number 2

• Focus Topic: What are the strengths, weaknesses, and potential pitfalls of research networks focused on a particular disease or patent population for facilitating emergency care research?

• Related Pre-conference Questions:
  • What are the strengths, weaknesses, and potential pitfalls of research networks focused on a particular disease or patent population?
  • How do research networks facilitate emergency care research?

• Related Specific Aims of Conference included in printed materials
Pre-conference Survey
Question 6: Focused networks

• Strengths include enhanced external validity, increased fundability, greater patient enrollment, specific investigator expertise and interest, experience with disease specific outcomes, ease of collaboration, centralized reading or evaluation of outcomes, ease of studying rare diseases or outcomes, synergy of thought, economies of scale, coordination of activities, efficient development of infrastructure

• Weaknesses include regulatory hassles, narrow focus, inability to “think outside the box,” inadvertent exclusion of patients, less generalizability of findings, lack of sustainability, air of exclusivity, limited to those inside network, limits innovation
Pre-conference Survey
Question 7: How do networks facilitate ECR?

• Accelerating protocol development, amassing a critical number or community of researchers, elimination of redundancies, standardization of data collection, optimizing funding opportunities

• Improvement of research design, enhancement of external validity, acceleration of the translation process, decrease in individual work, reduction in regional and population specific biases, provision of experts, foreseeing problems

• Helping sites that have less resources, fostering teamwork, mentorship, improving dissemination of results, shortening the duration of studies, creating an environment of enthusiasm and excitement
Breakout Number 3

• Focus Topic: What are the advantages, disadvantages, and barriers related to utilization of the CTSA infrastructure to conduct emergency care research and to construct an emergency care research network?

• Related Pre-conference Questions:
  • What do you believe are the advantages and disadvantages of utilizing the CTSA infrastructure to construct an emergency care research network?
  • What are the barriers, if any, to integrating emergency care research into the CTSA program?

• Related Specific Aims of Conference included in printed materials
Pre-conference Survey
Question 10: Using the CTSA

• An opportunity to engage institutional leaders in the discussion about the role of EM research, to span all disease and patient populations, and to offer research training

• Advantages: linkage of ECR to the continuum of care, the potential for data to be easily transferred between studies, conducting studies without constructing a network from scratch, use of existing resources (e.g. core labs, data systems, biostatistical support)

• An ECRN within the CTSA would allow departments of EM to have a "seat at the research table", establish educational programs (i.e. Masters, etc), and build relationships

• Disadvantages: an inability to focus network resources on specific needs or clinical questions, inheritance of the GCRC programs emphasis on in-hospital and non-acute studies, lack of active EM researchers at all CTSA institutions
Pre-conference Survey

Question 11: Barriers to CTSA

- CTSA leaders may not see the ED as having value and may expect the ED to only perform screening of patients.
- The CTSA is mandated to "translate" basic science findings but there is a paucity of basic sciences researchers in EM.
- Other barriers include: need for CTSA leadership to recognize how EM can contribute, lack of familiarity between key CTSA personnel and EM investigators, general belief that EM research is messy and unlikely to lead to new insights, convincing the primary investigators of the CTSA application that there is value in integrating the ED, lack of original involvement in the planning of CTSA programs, difficulty in adding new components after funds have already been allocated, narrow focus on certain diseases and types of research.
Breakout Number 4

• Focus Topic: Define metrics that can be used to measure the performance and effectiveness of emergency care research networks, applicable to both disease- or population-specific and general research networks.

• Related Pre-conference Question:
  • How should the efficacy and effectiveness of research networks be evaluated and measured?

• Related Specific Aims of Conference included in printed materials
Pre-conference Survey
Question 13: How to measure performance

- Number and dollar amount of grants secured, projects completed, number and quality of papers published, and global and specific impact on practice change and the number of new researchers
- The number of studies performed, number of enrolled patients, time to completion of trials, cost per patient enrolled, percentage enrollment of eligible patients, meeting projected enrollment targets, responsiveness to questions, number of protocol violations
- Some type of third party external evaluation
Errata and Corrections

• Noon Panel
  • Shavon L. Arline, MPH, representing NAACP and the Black Women’s Health Imperative

• 3:15 Panel Membership
  • Charles B. Cairns, MD
  • Craig D. Newgard, MD, MPH
  • Nathan Kupperman, MD, MPH
  • Glen N. Gaulton, PhD

• Truncation of Survey Responses for questions 4, 6A, 6B, and 13
1. Briefly describe your experience in emergency care research.
2. How would you define emergency care research?
3. What makes emergency care research unique?
4. What patient populations are primarily served by research performed in the emergency care setting?
5. Briefly describe your experience with clinical research networks.
6. What are the strengths, weaknesses, and potential pitfalls of research networks focused on a particular disease or patient population?
7. How do research networks facilitate emergency care research?
8. Does your institution have a Clinical and Translational Science Award (CTSA)? If yes, what is the role of emergency care researchers in CTSA activities at your institution?
9. Is your institution in the process of applying for or reapplying for a Clinical and Translational Science Award (CTSA)? If yes, what is your role or the role of emergency care researchers in this process?
10. What do you believe are the advantages and disadvantages of utilizing the CTSA infrastructure to construct an emergency care research network?
11. What are the barriers, if any, to integrating emergency care research into the CTSA program?
12. What are the essential features required for a research network to be successful?
13. How should the efficacy and effectiveness of research networks be evaluated and measured?
14. Which governmental, professional, patient advocacy, or political groups do you believe are the most significant stakeholders in improving emergency care through research?
15. What are the best ways to disseminate the findings of this conference?