

CTSA Strategic Goal Committee Four:

Enhancing the Health of Our Communities and the Nation

Face-to-Face Meeting

October 7, 2009

Meeting Summary

I. Welcoming remarks (Dr. Barbara Alving)

Dr. Alving provided the opening remarks for the Strategic Goal Committee Four face-to-face meeting. Dr. Alving briefly referenced the CTSA's as investments in the respective states in which they exist, benefiting various stakeholders including the patients they seek to serve.

II. Welcoming remarks and introduction of activities (Dr. Selker)

Dr. Selker greeted the Committee and explained that the Committee was assembled for this face-to-face meeting to address the goal of translating research into better health for the nation. During the meeting, Dr. Selker cited that accomplishments around deliverables would be celebrated while specific planning would also be done to ensure development of connections between the Community Engaged Research (CEnR) Workgroup and the Comparative Effectiveness Research (CER) Workgroup.

III. Working Sessions

4A: Community Engaged Research (CEnR) Workgroup

Participants: Dr. Michael Hatcher, Agency for Toxic Substances and Disease Registry Centers for Disease Control and Prevention; Dr. Lucy Savitz, Intermountain Healthcare, University of Utah; Dr. Lori Carter-Edwards, Duke University; Dr. Rowena Dolor, Duke University; Dr. Mark Spofford, Kaiser Permanente, Oregon Health and Science University; Dr. Paul Targonski, Mayo Clinic; Dr. Donna Jo McCloskey, NCRR; Dr. Lloyd Michener, Duke University; Sharrice White-Cooper, Prevention Research Centers; Centers for Disease Control and Prevention; Rosemary Simpson, University of North Carolina-Chapel Hill

Dr. Michener led the working session which was convened to discuss accomplishments to date as well as future goals and deliverables. A brief overview of the status of the four deliverables associated with the Community Engaged Research (CEnR) Workgroup was provided. The Community-based Academic and Practice Partnership Workgroup which began in the Community Engagement Key Function Committee served as the predecessor to the Community Engaged Research (CEnR) Networking subgroup. The created timelines for each deliverable and subgroup served as reference documents for the working group.

Community Engaged Research (CEnR) Networking Subgroup: Creating a network of research networks

The most immediate goal is to establish common ground for linking various networks. In assembling network leaders at a national two day meeting in April of 2010 funded by an R13 grant, the goal is to facilitate a discussion about linking together research leaders. Workgroup members discussed how the CTSA network may serve as a prototype for the creation of a network of research networks. The principals involved with establishing the meeting include Dr. Phil Greenland, Dr. Lucy Savitz, Dr. Sergio Aguilar-Gaxiola, Dr. Lloyd Michener, Dr. Kathleen Stevens. The subgroup is also exploring opportunities to connect with the Informatics Key Function Committee to discuss how to execute the meeting. The networking group will provide use case examples in preparation for the meeting.

There are two core elements in creating a research network of networks. These elements are structure and the definition of priorities. One of the largest challenges is how to organize the enormous network structure and how to integrate the various networks. In creating the network of networks, a standard definition of network will need to be created. Additional concerns include how to correctly establish the ultimate network, how to balance competing interests and how to create opportunistic relationships, that all researchers can benefit from.

Resource Development

The Resource Development Workgroup was formed within the Community Engagement Key Function Committee. The Workgroup functions to identify opportunities for funding and capacity building, and has identified two unique opportunities to do so. The Workgroup was invited to present examples of accomplishing achievements in networking activities. The group has collaborated with at least 5 other CTSA's in successful ARRA applications for an NCCR supplement, a go grant and a challenge grant.

Best Practices in Community Engagement Subgroup

The compendium document was generated from the compilation of best practices gleaned from the various workshops that occurred nationally. The document is not

meant to be a scholarly publication, rather it was written as a meeting proceedings document for dissemination encapsulating 2007-2008 community engagement conferences and regional workshops. It has in fact been widely disseminated to various entities including Health Resources and Services Administration (HRSA), Centers for Disease Control and Prevention (CDC), Association for Preventive Teaching and Research (APTR), the American Association of Medical Colleges (AAMC) and Community-Campus Partnerships for Health (CCPH). The goal is to transform the meeting proceedings document into a science based scholarly article. The translational research spectrum will be included in the scholarly publication to be completed by 2010. A white paper about translational research will be developed and written by members of the Community Engagement Key Function Committee as a follow on to the scholarly article.

Another topic was discussed under best practices which addressed the need to develop a white paper on defining translation within the context of community engaged research. Lucy Savitz voiced interest in this effort.

PRIMER

The PRIMER project was funded by an administrative supplement. The goal of the supplement was to determine what resources researchers are presently in need of through a survey, and then to develop a resource guide of these specific tools. There were six main categories of tools. The categories include: building collaboration; developing proposals; starting up a study; conducting and managing products; disseminating and closing research and resources for studies. The PRIMER team is presently working on two publications which include the online survey results and the toolkit.

The Community Engagement Consultative Service

The main deliverable of the Consultative Service, which is funded by an administrative supplement is a website for CTSA's to use as a resource to identify community engagement consultants. To date, 27 of 38 consultative visits have been completed and five additional visits are presently scheduled. One of the findings that the Consultative Team documented, was that prior to the consultative visit, members at the various institutions categorized outcomes that matter as a high priority. However, after the visit, relationship building was communicated as the highest priority. Consultative visits were deemed to be very productive with plans developed.

Principles of Community Engagement Committee

The Principles of Community Engagement Committee is working on a revision of the 1997 Centers for Disease Control and Prevention booklet entitled: *Principles of Community Engagement*. Previously developed chapters include a review of the literature, articulation of principles of community engagement and examples of how community engagement works at the national, state and local level in communities and utilization of the

principles. New sections have been added and include social networking, challenges to improving community engagement, organization and change management. The booklet has a target completion date of July, 2010.

Upon completion of the working session, Dr. Michener summarized that there are several moving pieces of the Community Engaged Research (CEnR) Workgroup. In evaluating next steps and opportunities, the Workgroup will seek to complete tasks that facilitate dissemination. Websites, speaker's bureaus and consultants may be some venues for dissemination. Federal partners can also be facilitators of dissemination. The Workgroup will also explore work that SGC 4A and SGC 4B can pursue together. The Workgroups will identify opportunities for reciprocity. Translational research will likely be a unique opportunity to explore the reciprocity between all the T's of translational research.

B: Comparative Effectiveness Research Workgroup

Deliverable Workgroups 4B-1, 4B-3 and 4B-5

Attendees: Dan Ford, Johns Hopkins; Mark Helfand, Oregon Health and Science University; Robert Dittus, Vanderbilt, Harold Pincus, Columbia, Harry Selker, Tufts, Pamela Mitchell, University of Washington

The Institute of Medicine (IOM) has defined over 100 priorities for CER, and the main concern is where to start. There are main characteristics of the research, and there is a need to identify what the barriers are, i.e. infrastructure issues, not enough experience on staff, methods issues, etc. Another concern was what methodologic problems are encountered.

The effort was developed to define characteristics for a study that has comparative effectiveness:

- 1) methods to involve patients,
- 2) methods to involve decision makers in designing research (meaningful comparisons) and avoid bias (evaluating both benefits and harm)
- 3) methods to recruit and include patients that were not being represented in other research
- 4) methods for conducting comparative effectiveness research (CER) and to link the findings of CER
- 5) methods to make it easier and faster to conduct clinical trials
- 6) methods to apply results of studies to individuals (how to do that in trials/observation studies, statistical approaches)
- 7) statistical and logistical methods for pragmatic trials
- 8) methods to measure value or utility
- 9) methods to keep comparative effectiveness research up-to-date in a credible way
- 10) determining how we survey the research cycle and linkages (a way to connect T1-T2-T3-T4 in a coherent way)

11) consideration of the role of different types of studies (evidence synthesis, practice-based trials, registries, studies using existing databases, etc.)—and where these different studies fit in.

A great test for research, is to identify a population that has a problem, and then to evaluate how you are affecting that population. The aim of the breakout group was not to try to distinguish between good research and bad research. The Deliverable Working groups are attempting to demonstrate that the point of CER is to examine the effectiveness of meaningful comparators in the population of the 80%, where you really don't know the benefits and the harms. CER uses a series of tools to study a population. But, this may not be useable by the rest of the scientific population. Methods and tools that ensure that data that is analyzed for one study is actually applicable to other populations must be developed. Ex: for genetic studies, when you do a study now, you have to publish everything online on a gene database for others to use. The CTSA's that are focused on clinical research do not always have the expertise in-house to use these strategies. One reason may be because of their focus, or another reason is that it may be difficult to say that a cooperative study is being executed in an institution, and that all of the resources are necessary for this.

By assembling Deliverable Workgroups 4B1, 4B3, and 4B5 together during this breakout session, the task is to connect up the survey, the list of research priority areas (from printout titled "Introduction" that is in DRAFT form) and the CER Workforce Development Paper. There was a group consensus on taking all three reports and strengthening them. There is a great need to develop methods. A menu can be put together of what the different focus areas are, and determine the competencies necessary. Then, the group can argue to develop some type of training around this field. Where are the practical issues of doing research in a timely manner? Also, there has to be some acknowledgment (from NIH, etc.) that support is needed to advance method/methodologic issues. In clinical research, it has to have a clinical application. For this, there is a basic science that has to be developed to be able to do what is needed. With NCRR not being disease-focused, it would be the perfect place to house that effort.

What should be established-- a portfolio as core opportunities/courses for individuals to be able to make that link? Not every institution will have the resources to do each one of these, but there can be a centralized place for this. What would be a plan to develop what the "how" is? Perhaps hosting conference calls, or bringing in other people to the groups, etc. What should be done over the next 6 months to 1 year?

Action: Dr. Bob Dittus could propose a plan—a set of consultants at CTSA sites to help pull together a list that could be brought to this group. Propose another member or two to the existing group. He could outline a plan, and come up with an execution plan for this.

Key Decision: There was a group consensus to merge the 4B1, 4B3, and 4B5 groups.

Deliverable Workgroups 4B-2 and 4B-4

SGC 4B -2, 4B-4, Working Session Summary

Attendees: Matthew Thompson, Gene Rich, AAMC; Steve Pauker, Tufts University; Harry Selker, Tufts University; Joel Tsevat, University of Cincinnati; Tom Concannon, Tufts University; June Wasser, Tufts University; Jody Sachs, NCCR; Anthony Hayward, NCCR; Dan Ford, Johns Hopkins University; Rosemarie Filart, NCCR

Overall Aim: The group sought to provide a brief, but comprehensive list of accomplishments and output to report to the CTSA Consortium Steering Committee (CCSC).

SGC Subgoal 4B 2 & 4 White Paper

The group briefly discussed the 6 Recommendations of the White Paper:

1. The CTSA Consortium should organize and support clinical trial infrastructure capacities to be responsive to the needs of CER, including especially the ability to link these capacities across institutions to support multi-site CER clinical trials.
2. The CTSA Consortium should support education, training, and career development in CER by funding T, K, and other appropriate awards sufficiently to contribute substantially to the needed CER workforce
3. The CTSA Consortium should develop capacities using CTSA Community Engagement components to incorporate input from the public and the clinical practice communities into generating, prioritizing, and developing CER questions and research protocols; interpreting CER results; and implementing CER results into practice
4. The CTSA Consortium should develop the capacity to generate new research methods for evidence generation (studies and trials), evidence synthesis (systematic reviews and modeling studies), and evidence translation of CER to enhance current research and to provide approaches for the new opportunities and needs of CER.
5. The CTSA Consortium should participate in the implementation of electronic health records (EHR) and health information technology (HIT) to ensure the resulting data can be used for the conduct of CER and to study which types of EHR-based interventions are successful in changing practice and which are not
6. The CTSA Consortium should organize a CTSA Network for CER that links to agencies and entities outside CTSA's.

Dr. Tom Concannon outlined the list of next steps for the coming year:

- CER Point of Contact
- Oct. 28 – Informatics/Research Networking meeting
- Oct. 18-21 – Society for Medical Decision Making (SMDM) meeting

- Winter 2009-2010 – stakeholder meeting
- 2010-2012 – CTSA Meetings using R13 funding

CER Point of Contact discussion:

The group initially discussed the value of providing and discovering a single point of contact for all Comparative Effectiveness Research (CER) – related matters at each of the 46 CTSA institutions. While discussing the breadth of expertise and communications that would be required for such a network of contacts, it was suggested that it would be more appropriate to create another Key Function Committee (KFC) for this task. A CER KFC could establish an important connection with Informatics KFC and Strategic Goal Committee (SGC) 3 to establish a best approach to connecting researchers and establishing points of contact. It was noted that the point of contact at each CTSA should not only be knowledgeable about individuals and work occurring at his or her CTSA, but also have a good sense of the entire institution.

Action item: Propose the idea of creating a CER point-of-contact and develop a work plan with the rest of SGC4.

October 28 Meeting Discussion – Virtual networking, in-person networking, data sharing tools On October 28th a Research Networking face-to-face meeting will occur at the Natcher Conference Center on the Main Campus of NIH. The Research Networking group has invited members of the CER subgoal group to discuss utilizing systems to connect researchers and also act as needs-assessment session for Comparative Effectiveness researchers. The group determined that their primary needs included assistance with building or using a pre-existing virtual networking tool and data-sharing tools.

Dr. Matthew Thompson summarized the group’s needs by stating that CER research networking would need an informatics tool that auto-updates profile information and aggregates information from multiple databases that take into consideration efforts already in and outside of CTSA.

Action items:

Dr. Thompson will synthesize his comments regarding CER Research Networking needs and email the members of SGC Subgoal 4B(2,4) prior to their next call.

Discuss and develop 3 use cases to bring to the Research Networking group that will ensure that CER use cases are incorporated into a pre-existing or future research networking tool.

Dan Ford volunteered to bring a few ideas for use cases to the group’s next conference call.

October 18-21 – Society for Medical Decision Making Meeting

The Society for Medical Decision Making (SMDM) recently put out a white paper on CER. It was noted that a potential next step for the CTSA CER Workgroup would be participate in a symposium or abstract session at future SMDM meetings. The group also clarified

that CTSA presence at SMDM should not be confused with any specific endorsement of SMDM as CTSA remains open and oriented to all stakeholders.

The group discussed the value of creating a presentation package “to be taken on the road” that can be presented at other organizations’ meetings that answers the question: “What does CTSA offer to CER?”

Stakeholder Meeting Winter 2009-2010

The purpose of a stakeholder meeting to be held in the winter of 2009 or 2010 is to identify people within industry, research organizations, agencies representing Federal Council and the Institute of Medicine and possibly present the SGC4B white paper goals, establish buy-in and support for the direction of CER within CTSA. The stakeholder meeting would also provide a valuable networking opportunity as a large portion of ARRA funds were awarded to CTSA institutions.

2010-2012 CTSA meeting (R13 grant)

There is a letter of intent that has been submitted to NCRR for support through R13 conference support programs to conduct 3 annual meetings from 2010-2012. The final proposal is due December 12th. The purpose of the conferences will be to identify the right people within CTAs to address the 6 recommendations of the CTSA-CER white paper. Target audiences for these annual meetings would include clinical researchers, IT professionals and methods innovators. The purpose of the R13 conference funds would be to disseminate information regarding the white paper and the ensuing meetings. The group hopes to evolve the recommendations of the white paper into implementable projects with tangible results.

IV. Status Reports: SGC 4A: Community Engaged Research (CEnR) Workgroup

Overview: The Workgroup has worked to identify best practices in community engagement, disseminate these findings and employ rigor and method in conducting community engagement.

4A-1: Community Engaged Research (CEnR) Networking Subgroup

The subgroup is exploring the creation of a network of research networks. In creating this expansive network, the subgroup is attempting to determine how to catalog and link networks together. A national meeting will be convened in 2010 to facilitate this goal. The CTSA infrastructure will be a key asset in establishing the network of research networks.

4A-2: Best Practices in Community Engagement Subgroup (Dr. Lloyd Michener)

The subgroup created a meeting proceedings document which was informed by several regional workshops that were convened across the country. The document sought to address what it takes to engage with communities in practice. The document will be amended and transformed into a scholarly article to be submitted for publication.

4A-3: Administrative Supplements Subgroup

Partnership-driven Resources to Improve and Enhance Research (PRIMER) (Dr. Rowena Dolor)

This project funded by an administrative supplement was developed to address the resource needs of researchers. A survey was initially conducted to establish the resource needs of practice based research network researchers. The survey which was sent to 95 individuals explored a variety of topics including barriers and benefits to collaboration. Upon receipt of the results, the PRIMER team created a resource guide divided into six areas with 120 resources listed. Presently, the PRIMER team is accepting feedback from researchers via the questionnaire on the website.

Community Engagement Consultative Service (CECS) (Dr. Lori Carter-Edwards)

The Consultative Service, also funded by an administrative supplement was developed to provide a list of best practices and experts in community engagement via a website. The service provides guidance on how sites can more effectively work with communities. The Committee is presently working on developing a publication of the results and these results will be provided to the Consortium for review.

4A-4: Principles of Community Engagement Subgroup (Dr. Michael Hatcher)

The revision that is currently underway, will produce a second version of the Centers for Disease Control and Prevention Principles of Community Engagement booklet. The second version will incorporate new chapters and several writing groups have been assembled to tackle the revision effort. The first iteration of the draft will be completed by November 2009.

V. Status Reports: SGC 4B: Comparative Effectiveness Research Workgroup

The CER Workgroup has four deliverable workgroups which were initiated in January with a fifth deliverable workgroup developed in July of 2009. To date, the Workgroup has developed some key deliverables in a very short period of time. In looking ahead, the Workgroup will build upon already developed deliverables and will deliver work products currently being developed. Key decisions and outcomes from today's working session include merging Deliverable Workgroups 4B-1, 4B-3 and 4B-5. The deliverable papers from Deliverable Workgroup 4B-1 and 4B-4 will be re-visited and strengthened to more accurately reflect the scope of CER. A CER point of contact will be identified at each institution, and the final key decision is the exploration of the creation of a CER Key Function Committee. An additional focus will be on addressing how to fund and conduct methods research.

4B-1: Capacity and Needs Assessment (Drs. Harold Pincus and Dan Ford)

An executive summary of the CER capacity and needs assessment was developed based upon responses from 34/39 CTSA institutions. In the summary results of the capacity and needs assessment, the strengths of the various institutions were captured. The capacity

and needs assessment will likely be repeated to include new CTSA institutions, qualitative interviews and more specific questions relating to comparative effectiveness research.

4B-2: White Paper (Dr. Harry Selker)

The CER White Paper which is currently in final form was developed and mapped to the IOM Report and the Federal Coordinating Council report as well as various CTSA components and the CER capacity and needs assessment. The paper will be submitted for publication to a scholarly journal.

4B-3: CER Methods (Dr. Mark Helfand)

The CER Methods Deliverable Workgroup has begun work on and will continue to pursue the prioritization of methods areas. Additionally, they will develop a CER Methods White Paper and continue the work began today regarding the prioritization of attributes of CER at the face-to-face meeting.

4B-4: Networking Activities (Drs. Tom Concannon and Steve Pauker)

The Networking Activities Deliverable Workgroup has worked with other CTSA Committees such as the Informatics Key Function Committee to share work products and identify shareable resources. The Workgroup has recently submitted a letter of interest and permission letter for an R13 grant to develop a national networking meeting. Next steps include identifying a CER point of contact within each CTSA, creating a CTSA interest group for participation in the SMDM meetings, identifying in person network meeting opportunities and coordinating with the Strategic Goal Three Committee on virtual networking tools. Lastly, the Workgroup will seek to hold three meetings over three years which will include a diverse list of invitees including clinical researchers, IT professionals, methods innovators and people working on health care strategies.

4B-5: CER Training Needs for Workforce and Curriculum (Dr. Mark Helfand)

Synergies: Community Engagement, Community Engaged Research (CEnR) and Comparative Effectiveness Research

The Deliverable Workgroup referenced the yet unpublished IOM report on workforce needs. Their main focus will be evaluating mechanisms to support CER training. The white paper developed shortly before the face-to-face meeting will be re-evaluated and likely revised to reflect the larger scope of CER.

Next steps: Discussion regarding future deliverables (Drs. Selker and Michener)

Wrap Up and Adjournment

In looking ahead, the Strategic Goal Four Committee which is tasked with enhancing the health of communities and the nation, will focus on capitalizing upon pivotal synergies between the Community Engaged Research (CEnR) Workgroup and the Comparative Effectiveness Research Workgroup. The Committee will seek to utilize the Community

Engaged Research (CEnR) expertise in the SGC 4A Workgroup and the CER expertise in the SGC 4B Workgroup.

The Committee will:

- 1.) Determine how to collaborate with stakeholders and develop a report on issues, challenges and best practices guidelines within the next year.
- 2.) Explore employment of a Community Engagement Consultative Service like model, to equip researchers with tools to enlist in community engagement in the next two years.
- 3.) Determine venues for SGC 4A and SGC 4B to meet together, such as the Informatics Key Function Committee October Research Networking meeting.
- 4.) Address implementation and dissemination to improve the public's health and reduce health disparities.

Key Decisions:

1. Explore the creation of a CER Key Function Committee.
2. Explore opportunities for the SGC 4A Community Engaged Research (CEnR) Workgroup and the SGC 4B CER Workgroup to join together on future opportunities and create a joint networking workgroup.
3. Deliverable Workgroups 4B-1, 4B-3 and 4B-5 will join into one Deliverable Workgroup.

Action Items:

1. Solicit individuals to serve as the CER point-of-contact at their CTSA institutions, and develop a work plan with the rest of SGC4.
2. Articulate charge to Community Engagement Key Function Committee regarding the development of a white paper on the spectrum of translational research.
3. Dr. Bob Dittus could propose a plan to the group—a set of consultants at CTSA sites to help pull together a list that could be brought to this group. Propose another member or two to the existing group. He could outline a plan, and come up with an execution plan for this.
4. Dr. Thompson will synthesize his comments regarding CER Research Networking needs and email the members of SGC Subgoal 4B(2,4) prior to their next call.

5. Discuss and develop 3 use cases to bring to the Research Networking group that will ensure that CER and CEnR use cases are incorporated into a pre-existing or future research networking tool.

6. Dan Ford volunteered to bring a few ideas for use cases to the group's next conference call.