THE NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

ENGAGING COMMUNITY PERSPECTIVES IN ALL PHASES OF RESEARCH: THE CTSA PROGRAM

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NATIONAL CONFERENCE ON ENGAGING PATIENTS, FAMILIES, AND COMMUNITIES IN ALL PHASES OF TRANSLATIONAL RESEARCH TO IMPROVE HEALTH

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Community Engagement in Translational Research – Shared Goals

• To translate basic and clinical discoveries into better health for individual patients and communities

• Accelerate and streamline the process

• Broaden the impact
  – Rare and neglected diseases
  – Special populations
  – Access
How can we get there?

• Engaging individuals and communities not only as consumers of healthcare, but as active partners
• Including a broad range of communities
• Seeking community engagement throughout all phases of research
My experience

• Caring for people with chronic diseases
• Facilitating research access for people with rare diseases
• Including patients and families in concept and protocol development
• Engaging patients in risk/benefit assessments
Implementation of IOM Report Recommendations

Overview of the Process

IOM Report Recommendations June 2013

WG Report Recommendations May 2014

NCATS develops implementation strategy and programmatic metrics

NCATS measures results
IOM Report on the CTSA Program

Recommendations

• IOM CTSA Report released June 2013
• Report includes 7 recommendations

1. Strengthen leadership of the CTSA program by NCATS
2. Reconfigure and streamline CTSA consortium
3. Build on the strengths of the individual CTSAs across the spectrum of research
4. Formalize and standardize clear, consistent, and novel metrics
5. Advance innovative education and training models with a focus on team science, leadership, and entrepreneurship
6. Ensure community engagement in all phases of research
7. Strengthen translational research relevant to child health
NCATS Advisory Council WG on the IOM CTSA Report

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• Recommendations presented to NCATS Council May 16, 2014
• Find report at
• http://www.ncats.nih.gov/about/ncats-council/wgs/ctsa-iom/ctsa-iom.html
 Strategic Goals

Working Group Recommendations

• Workforce Development
  – The translational science workforce has the skills and knowledge necessary to advance translation of discoveries.

• Collaboration/Engagement
  – Stakeholders are engaged in collaborations to advance translation.

• Integration
  – Translational science is integrated across its multiple phases and disciplines within complex populations and across the individual lifespan.

• Methods and Processes
  – The scientific study of the process of conducting translational science itself enables significant advances in translation.
CTSA Community Engagement
in all Phases of Research

- **Observation to POC intervention (T1)**
  - Identify most important research questions
  - Recruit best people
  - Build partnerships
  - Complementary funding for research studies
  - Bridge gap between fundamental science researchers and patients

- **Clinical and translational research (T2-T3)**
  - Help develop relevant and feasible research protocols
  - Foster community participation and recruiting research participants for clinical trials
  - Increase collaboration and communication among key stakeholders (e.g., academia, biopharma, patients)
  - Make sure that we have outcomes that matter

- **Community health and population research (T4)**
  - Adoption of demonstrably useful interventions
  - Implementation
  - Dissemination
  - Adherence
Bi-directional interaction between communities and researchers

- Defining community broadly to include but not to be limited to
  - Disease advocacy groups
  - Clinicians
  - Community-based organizations
  - Culturally-defined groups
  - Non-profit or industry entities engaged in research
  - Physical or virtual communities
  - National or local communities
Clinical and Translational Science Awards
Current evolution based on CTSA WG Report

Strategic Goal: Collaboration/Engagement

Engage stakeholder communities across the translational spectrum

- Include patients in
  - Concept development early on to assure we answer questions that matter to them.
  - Protocol development to assure the plan is feasible in terms of participant burden.
  - Considering risk/benefit relationships and in developing consent language.
  - Considering endpoints to assure what is measured matters
  - Developing communication plans to assure messages reach relevant communities.

- Include all relevant stakeholders in the health care delivery system (e.g. hospitals, office-based clinicians).
- Promote partnerships with industry and non-profit organizations.
- Identify and disseminate successful collaboration models.
- Coordinate with other initiatives such as the PCORNet, AHRQ, the Collaboratory etc.
CTSA as a catalyst
Matching scope and resources

CTSA program
= 2% of NIH budget
= 0.5% of total R&D investment  (Shekhar 2014)

- CTSA program innovates
- Finds generalizable solutions

CTSA program does NOT
- Support unspecified pieces of all research
- Favor disease areas over others
- Support study-specific research services

Clinical Research Enterprise
(public and private funders)

CTSAs $472M
What we need:

- Integrate community engagement with translational research goals
- Apply rigorous research methodology to community-engaged research
- Reach out to investigators working in your space to offer assistance, ideas, study advocacy
- Reach out to health care providers to engage them
- Partner with researchers to ensure community engagement in protocol development:
  - Study design
  - Consent Review
  - Recruitment & retention material and literature design, review, editing
- Data and Safety Monitoring Boards
NCATS support for Community Engagement Task Force

• In response to IOM report, NCATS has streamlined governance and committee structure
• Next steps include establishing task forces in high priority areas
• The number of task forces will be limited
• Each task force includes a larger group of volunteer experts from CTSA hubs
• Experts elect lead team
  • Lead team is liaison to NCATS and SC
• Include NCATS staff and NIH staff if applicable
• Work on defined goals and priorities, in synergy with NCATS and SC
• Progress and outcomes will be tracked
Enhancing the CTSA program so that it can better support the path from discovery to health

- Building on the existing strength at the CTSA hubs
  - Strengthening CTSA network capacity
  - Fostering innovative collaboration

- Where are we going:
  - To supporting science through targeted, innovative research resources
  - To investments that lead to tangible results towards better health

- We will do what gets us there
- We will not do what does not get us there
Take-home messages

• The guiding principle is to engage communities around specific projects and translational research goals not to create community engagement infrastructure for the sake of it being there
• Rigorous research methodology is the foundation to high quality data that can make a difference
• Building on the existing strength, the CTSA program will
  – Promote innovative approaches to solve scientific problems
    • Discover, demonstrate, disseminate
    • Evaluate the method, generalize if successful
  – Streamline methods and processes, especially for multi-site research
• The CTSA program will tackle big, systemic translational problems to improve human health
• A key to the success of the CTSA program is engaging community stakeholders across the entire translational spectrum