Evaluating Translational Science

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Presentation to the Cornell Evaluation Network

September 29, 2008
Overview

• What is the impetus for translational science?
• What is translational research?
• What are the Clinical and Translational Science Awards (CTSAs)?
• What is Weill Cornell’s Clinical and Translational Science Center (CTSC)?
• What is the Evaluation Key Function of the CTSC?
• What are some of the major evaluation challenges in the translational sciences?
What is the impetus for translational science?
Fundamental Claims of Translational Research

“It takes an estimated average of 17 years for only 14% of new scientific discoveries to enter day-to-day clinical practice.”


“Studies suggest that it takes an average of 17 years for research evidence to reach clinical practice.”

What is translational research?
The current National Institutes of Health (NIH) Roadmap for Medical Research includes 2 major research laboratories (bench and bedside) and 2 translational steps (T1 and T2). Historically, moving new medical discoveries into clinical practice (T2) has been haphazard, occurring largely through continuing medical education programs, pharmaceutical detailing, and guideline development. Proposed expansion of the NIH Roadmap (blue) includes an additional research laboratory (Practice-based Research) and translational step (T3) to improve incorporation of research discoveries into day-to-day clinical care. The research roadmap is a continuum, with overlap between sites of research and translational steps. The figure includes examples of the types of research common in each research laboratory and translational step. This map is not exhaustive; other important types of research that might be included are community-based participatory research, public health research, and health policy analysis.

### How Many “Ts” are in Translation?

<table>
<thead>
<tr>
<th>Basic Research</th>
<th>Clinical Research</th>
<th>Meta-Analyses, Syntheses, Guidelines</th>
<th>Practice-Based Research</th>
<th>Health Impacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1</td>
<td>Basic Biomedical Research</td>
<td>Clinical Science and Knowledge</td>
<td>Clinical Efficacy Knowledge</td>
<td>Clinical Effectiveness Knowledge</td>
</tr>
<tr>
<td>Sung et al, 2003</td>
<td>Bench</td>
<td>Bedside</td>
<td>Clinical Science and Knowledge</td>
<td>Improved Health</td>
</tr>
<tr>
<td>Westfall et al, 2007</td>
<td>T1</td>
<td>T2</td>
<td>Bedside</td>
<td>Practice-Based Research</td>
</tr>
<tr>
<td>Dougherty &amp; Conway, 2008</td>
<td>T1</td>
<td>T2</td>
<td>Clinical Efficacy Knowledge</td>
<td>Clinical Effectiveness Knowledge</td>
</tr>
<tr>
<td>Khoury et al, 2007</td>
<td>Gene Discovery</td>
<td>Health Application</td>
<td>Health Application</td>
<td>Evidence-based Guideline</td>
</tr>
<tr>
<td>T3</td>
<td>Practice-Based Research</td>
<td>Practice</td>
<td>T3</td>
<td>Clinical Effectiveness Knowledge</td>
</tr>
<tr>
<td>T4</td>
<td>Practice</td>
<td>Health Impact</td>
<td>T4</td>
<td>Practice</td>
</tr>
</tbody>
</table>

From Trochim, Kane, Graham and Pincus (2008, in preparation)
What are the Clinical and Translational Science Awards (CTSAs)?
Impetus for the CTSA Program

- Implementing biomedical discoveries made in the last 10 years demands an evolution of clinical science.

- New prevention strategies and treatments must be developed, tested, and brought into medical practice more rapidly.

- CTSA awards will lower barriers between disciplines, and encourage creative, innovative approaches to solve complex medical problems.

- These clinical and translational science awards will catalyze change -- breaking silos, breaking barriers, and breaking conventions.
Each CTSA academic health center is a home for clinical and translational science.
## Building a National CTSA Consortium

### FY06 Grantees
- The Rockefeller University
- University of Texas Health Sciences Center at Houston
- University of California, Davis
- University of Pittsburgh
- University of California, San Francisco
- University of Rochester School of Medicine and Dentistry
- Duke University
- University of Pennsylvania
- Columbia University
- Mayo Clinic
- Oregon Health and Science University (partnering with Kaiser Permanente)
- Yale University

### FY07 Grantees
- Emory University (partnering with Morehouse College)
- Case Western University
- Washington University
- **Weill Cornell Medical College (partnering with Hunter College)**
- University Of Wisconsin Madison
- Johns Hopkins
- University Of Washington
- University Of Michigan At Ann Arbor
- University of Texas Southwestern Medical Center – Dallas
- University Of Chicago
- University Of Iowa
- Vanderbilt University (partnering with Meharry Medical College)

### FY08 Grantees
- Albert Einstein College of Medicine
- Boston University Medical Campus
- Harvard University
- Indiana University-Purdue University at Indianapolis
- Northwestern University
- Ohio State University
- Scripps Research Institute
- Stanford University
- Tufts University Boston
- University of Alabama at Birmingham
- University of Colorado Denver/HSC Aurora
- University of North Carolina Chapel Hill
- University of Texas Health Science Center San Antonio
- University of Utah
CTSA Funding

• Total dollars NIH spent on the CTSA initiative last project year (July, 2006 – June 2007) for the first 24 CTSAs
  – $243 million

• Total dollars NIH has budgeted for the current project year (38 CTSAs)
  – $370 million

• Total dollars NIH expects to spend annually once the initiative is fully funded (60 CTSAs)
  – $500 million
What is the Weill Cornell Clinical and Translational Science Center (CTSC)?
Our CTSC Funding History

• NIH Planning Grant
  – Submitted by WCMC with its partners and funded September 2006
  – 50 awards, $150K direct costs

• Clinical and Translational Science Award
  – Submitted by WCMC in January 2007 and funded in September 2007
  – Largest single grant in Cornell’s history - $50 million over five years
  – 38 out of 60 have been awarded
Our mission is the creation of a diverse trans-institutional, multi-disciplinary Clinical and Translational Science Center (CTSC), focused on moving translational research seamlessly from bench to bedside and to the community.
Partnering Institutions

Weill Cornell Medical College

Cornell University

Center for Study of Gene Structure and Function

Memorial Sloan-Kettering Cancer Center
Weill Cornell CTSC Partner Institutions

A unique biomedical complex of renowned public and private institutions on the East Side of Manhattan

1) Hospital for Special Surgery
2) Weill Cornell Medical College & Graduate School
3) Memorial Sloan-Kettering
4) Hunter College
5) Cornell Cooperative Extension
6) Hunter School of Nursing
CTSC Affiliated Hospitals in Underserved & Multi-Ethnic Areas

Concentrated Minority Group
- African-American
- Hispanic
- Asian
- Other
- No Concentrated Group

1. Lincoln Medical and Mental Health Center
2. CTSC Core Institutions
3. New York Downtown Hospital
4. New York Methodist Hospital
5. Brooklyn Hospital Center
6. Wyckoff Heights Medical Center
7. New York Hospital Medical Center of Queens
Multi-disciplinary Research is Required to Solve the "Puzzle" of Complex Diseases

Genes
Behavior
Diet/Nutrition
Infectious agents
Environment
Gender
Society
???
"I see by the current issue of 'Lab News,' Ridgeway, that you've been working for the last twenty years on the same problem I've been working on for the last twenty years."
Organization of the CTSC

Antonio M. Gotto Jr., M.D., D.Phil.
Dean, Weill Cornell
Provost for Medical Affairs, Stephen and Suzanne Weiss Dean of the Medical College, Cornell University

Operations Committee
- Director of CTSC
- Coordinating Program Directors
- Core Directors
- Administrative Director

External Advisory Board

Internal Advisory Board with Community Representative

Evaluation and Tracking

Development of Novel Clinical and Translational Methodologies
Design, Biostatistics, and Clinical Research Ethics
Regulatory Knowledge and Support
Biomedical Informatics
Pilot and Collaborative Translational and Clinical Studies
Clinical and Translational Resource Unit
Community Engagement and Research
Translational Technologies and Resources
Technology Transfer
Research Education and Training
“To the individual who devotes his or her life to science, nothing can give more happiness than when results immediately find practical application. There are not two sciences. There is science and the application of science and these two are linked as the fruit is to the tree.”

Louis Pasteur
Support for the Conduct of Research

- Biostatisticians
- Bioinformatics specialists
- Translational Research Support Team (TREST)
- Regulatory Knowledge Coordinator
- Other team members as needed*

*e.g., nutritionist, epidemiologist, clinical pharmacologist
CTSC Research Support Pipeline

CTSC TREST

- Design and Biostatistics
- Biomedical Informatics
- Community Engagement

Researchers

Translational Research

CTRU

- Regulatory Knowledge
- Research Ethics

Special Technical Resources

Improved Health Outcomes

Novel Methodologies
“They’re harmless when they’re alone, but get a bunch of them together with a research grant and watch out.”
What is the Evaluation Key Function of the CTSC?
CTSC Evaluation Roles & Activities

ROLES

– Input and Feedback
– Program improvement and accountability
– Process and outcome

ACTIVITIES

– PART I. Milestones
– PART II. Evaluation Projects
– PART III. National CTSA Leadership
PART I. Milestones and Tracking

EVALUATION & TRACKING MILESTONES

SHORT-TERM MILESTONES
(WITHIN 1 YEAR - 9/17/07 – 5/31/08)
1. Hire key staff
2. Hire support staff
3. Engage external evaluation support consultants
4. Coordinate with Biomedical Informatics group
5. Develop and launch milestone tracking system
6. Collect milestone data from Key Functions
7. Collaborate with National CTSA Evaluation Committees
8. Launch publications pilot project
9. Conduct initial survey project with one key group
10. Analyze and report on pilot awards
11. Analyze and report on training awards (T32 and K12)
12. Develop and begin piloting the training and mentoring evaluation system
13. Annual Reporting

MEDIUM-TERM MILESTONES (WITHIN YEARS 2-3 )
14. Develop translational research pipeline evaluation
15. Develop and implement initial researcher survey
16. Develop and implement network analysis
17. Collect and report annually on milestones
18. Collaborate on National CTSA Evaluation Committees
19. Annual Evaluation reporting

LONG-TERM MILESTONES (BETWEEN YEARS - 4-5 )
20. Collaborate on National CTSA Evaluation Committees
21. Annual Evaluation reporting
22. CTSC Multi-Year Evaluation Progress Report
# PART II. Evaluation Projects

## Short Term Evaluation Questions

<table>
<thead>
<tr>
<th>Evaluation Question</th>
<th>Evaluation Approach</th>
</tr>
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</table>
| How effective is the *inter-institutional collaboration* between CTSC partners?     | • *Publication Analysis*: Thompson Scientific/ISI Web of Science  
• *Social Network Analysis*: Northwestern, Discovery Logic  
• *Interviews*: Cornell Survey Research Institute (SRI)  
• *Descriptive Statistics*: Cornell Statistical Consulting Group                       |
| How effective is CTSC *training and mentoring*?                                      | • *Interviews of Mentors and Trainees*: Cornell SRI  
• *Berk Mentorship Effectiveness Scale*: Developed at Johns Hopkins  
• *Structured Tracking via Electronic Survey*: Hunter Masters Intern                    |
| How effective and efficient is the *management infrastructure* of the CTSC?        | • *Milestones*: Dashboard Across All Key Functions  
• *Development of Internal Evaluation Policy*: AEA, NIH OPASI  
• *Institutional Infrastructure Checklist*: Adapted CTSA Resource                        |
## Part II. Evaluation Projects
### Intermediate Evaluation Questions

<table>
<thead>
<tr>
<th>Evaluation Question</th>
<th>Evaluation Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>How productive are CTSC participants with respect to <em>presentations and publications</em>?</td>
<td>• Publication Analysis: ResearcherID, ISI, and Discovery Logic</td>
</tr>
<tr>
<td></td>
<td>• Social Network Analysis: CiteSpace and BiomedExperts</td>
</tr>
<tr>
<td></td>
<td>• Structured Tracking via Electronic Survey</td>
</tr>
<tr>
<td>Does the CTSC work help us to understand the <em>translational research process</em>?</td>
<td>• CTSA National Evaluation Steering Committee</td>
</tr>
<tr>
<td></td>
<td>• Systems Evaluation: Mixed methods on Translational Pathway</td>
</tr>
<tr>
<td>How effective is the <em>community engagement</em> component of the CTSC?</td>
<td>• Concept Mapping: Barriers to Participation in Clinical Trials</td>
</tr>
<tr>
<td></td>
<td>• Connection to Research: Integrate evidence-based dissemination systems in community contexts (e.g., P.L.A.N.E.T)</td>
</tr>
</tbody>
</table>
Network for person: Bajorin, Dean F
Co-Authorship Network for Year One Pilots
PART III: National CTSA

- Key Roles in Evaluation Steering Committees:
  - Standardization and Operationalization
  - Social Network Analysis
  - Shared Resources

- Collaboration with CTSA Evaluation Colleagues:
  - Northwestern, Pittsburgh, Johns Hopkins, Columbia, Rockefeller

- Professional Leadership and Key Presentations at AEA:
  - Panels, Presentations, Papers
What are some of the major evaluation challenges in the translational sciences?
Evaluation Challenges

• Stakeholders
• Definitions
  – Translational Research
  – Disciplinarity
  – Collaboration
  – Community Engagement
• Operationalization and Measurement
• Evaluation Questions
• Evaluation Approaches and Methods
• Developing a “culture” of evaluation
• Focusing on the ends → Health Impacts
"It takes an estimated average of 17 years for only 14% of new scientific discoveries to enter day-to-day clinical practice."


"Studies suggest that it takes an average of 17 years for research evidence to reach clinical practice."

Redrawn from
### Balas & Boren, 2000, Table II

<table>
<thead>
<tr>
<th>Clinical Procedure</th>
<th>Landmark Trial</th>
<th>Current Rate of Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flu Vaccination</td>
<td>1968 (7)</td>
<td>55% (8)</td>
</tr>
<tr>
<td>Thrombolytic therapy</td>
<td>1971 (9)</td>
<td>20% (10)</td>
</tr>
<tr>
<td>Pneumococcal vaccination</td>
<td>1977 (11)</td>
<td>35.6% (8)</td>
</tr>
<tr>
<td>Diabetic eye exam</td>
<td>1981 (4)</td>
<td>38.4% (6)</td>
</tr>
<tr>
<td>Beta blockers after MI</td>
<td>1982 (12)</td>
<td>61.9% (6)</td>
</tr>
<tr>
<td>Mammography</td>
<td>1982 (13)</td>
<td>70.4% (6)</td>
</tr>
<tr>
<td>Cholesterol screening</td>
<td>1984 (14)</td>
<td>65% (15)</td>
</tr>
<tr>
<td>Fecal occult blood test</td>
<td>1986 (16)</td>
<td>17% (17)</td>
</tr>
<tr>
<td>Diabetic foot care</td>
<td>1983 (18)</td>
<td>20% (19)</td>
</tr>
</tbody>
</table>

Balas & Boren, 2000, assumed calculations

<table>
<thead>
<tr>
<th>Clinical Procedure</th>
<th>Year of Landmark Trial</th>
<th>Year of Rate of Use Study</th>
<th>Difference RoU - Landmark</th>
<th>Rate of Use</th>
<th>Annual Increase In Rate of Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flu Vaccination</td>
<td>1968 (7)</td>
<td>1997</td>
<td>29</td>
<td>55</td>
<td>1.896551724</td>
</tr>
<tr>
<td>Thrombolytic therapy</td>
<td>1971 (9)</td>
<td>1989</td>
<td>18</td>
<td>20</td>
<td>1.111111111</td>
</tr>
<tr>
<td>Pneumococcal vaccination</td>
<td>1977 (11)</td>
<td>1997</td>
<td>20</td>
<td>35.6</td>
<td>1.78</td>
</tr>
<tr>
<td>Diabetic eye exam</td>
<td>1981 (4)</td>
<td>1997</td>
<td>16</td>
<td>38.4</td>
<td>2.4</td>
</tr>
<tr>
<td>Beta blockers after MI</td>
<td>1982 (12)</td>
<td>1997</td>
<td>15</td>
<td>61.9</td>
<td>4.126666667</td>
</tr>
<tr>
<td>Mammography</td>
<td>1982 (13)</td>
<td>1997</td>
<td>15</td>
<td>70.4</td>
<td>4.693333333</td>
</tr>
<tr>
<td>Cholesterol screening</td>
<td>1984 (14)</td>
<td>1995</td>
<td>11</td>
<td>65</td>
<td>5.909090909</td>
</tr>
<tr>
<td>Fecal occult blood test</td>
<td>1986 (16)</td>
<td>1993</td>
<td>7</td>
<td>17</td>
<td>2.428571429</td>
</tr>
<tr>
<td>Diabetic foot care</td>
<td>1983 (18)</td>
<td>1998</td>
<td>5</td>
<td>20</td>
<td>4.0</td>
</tr>
</tbody>
</table>

Average Annual Rate of Increase:  3.149480575

Balas & Boren Annual Rate of Increase:  3.2
An average annual increase of 3.2 percent was calculated using all nine clinical procedures. Correspondingly, it would take 15.6 years to reach a rate of use of 50 percent from a rate of zero assumed at the time of publication of a landmark study. It takes a minimum of 6.3 years for evidence to reach reviews, papers and textbooks [24][26]. By subtracting 6.3 years from 15.6 years, an estimated 9.3 years transition period is needed to implement evidence from reviews, papers and textbooks (Figure 1).

Balas and Boren (2000), p. 66
Balas & Boren, 2000, calculations dissected

An average annual increase of 3.2 percent was calculated using all nine clinical procedures.

Based on averaging from Table II

Correspondingly, it would take 15.6 years to reach a rate of use of 50 percent from a rate of zero assumed at the time of publication of a landmark study.

Because 50% divided by 3.2% annual rate = 15.6 years

It takes a minimum of 6.3 years for evidence to reach reviews, papers and textbooks [24][26].

From references cited

By subtracting 6.3 years from 15.6 years, an estimated 9.3 years transition period is needed to implement evidence from reviews, papers and textbooks (Figure I).

Balas and Boren (2000), p. 66
Balas & Boren, 2000 17 years claim

Original Research

Submission

Acceptance

Publication

Bibliographic Databases

Review, Paper, Textbook

Implementation

Cumulative Total

- Original Research: 0.5 year
- Submission: 0.6 year
- Acceptance: 0.5 year
- Publication: 1.1 years
- Bibliographic Databases: 1.4 years
- Review, Paper, Textbook: 7.4 years
- Implementation: 16.7 years
- Total: ~17 years
Westfall et al, 2007, the 14% figure

Approximately 14% of original research studies survive to implementation.
But it’s worse than that…

“It takes an estimated average of 17 years for only 14% of new scientific discoveries to enter day-to-day clinical practice.”


“Studies suggest that it takes an average of 17 years for research evidence to reach clinical practice.“


Should be (at best) something like:

It takes an estimated average of 17 years for only 14% of new scientific discoveries to enter day-to-day clinical practice at a rate of 50% use.
Conclusions

• Evaluation plays a critical role in translational research
• Need to address conceptualization, operationalization and validity
• Need to develop estimates of
  – Time to Use
  – Rates of Use
• Need ongoing surveillance mechanisms
• Need a “translational research laboratory”
• Need a “Science of Science Management”
“Oh, if only it were so simple.”