Community-Based Models of Research: Views from the Health Center
Presented at: NACHC CHI 2007

Jonathan N. Tobin, Ph.D.

PRESIDENT/CEO
CLINICAL DIRECTORS NETWORK (CDN)

DIRECTOR OF EDUCATION & TRAINING
INSTITUTE FOR PUBLIC HEALTH SCIENCES
YESHIVA UNIVERSITY
ALBERT EINSTEIN COLLEGE OF MEDICINE

Tel 212-382-0699 Ext 234
Fax 212-382-0669

JNTobin@CDNetwork.org
www.CDNetwork.org
www.eClinician.org
Clinical Directors Network
A Practice-based Research Network (PBRN)

www.CDNetwork.org
CDN: Past, Present & Future

• An informal network of clinical leaders who practice as primary care clinicians in low-income and minority communities

• A research and educational organization

• A means to translate clinical research into clinical practice

www.CDNetwork.org
CDN’s Strategic Objectives

• A Means to Translate Clinical Research into Clinical Practice
  – Collaborative Investigation & Learning
  – Clinical Practice Guidelines
  – Best Practices

• Diffuse Knowledge Through Collaboration

• Build Enduring Partnerships Among Clinicians, Researchers, Policy-makers, Communities
  – Multi-disciplinary

• Ensure Adequate Representation of Neglected Subgroups
  – Providers
  – Patients

• CBPR = Include Relevant Stake-Holders in
  – Design
  – Conduct
  – Analysis
  – Implementation
  – Sustainability

www.CDNetwork.org
CDN’s Primary Activities

• Practice-based Research

• Education and Training

• Professional Development

www.CDNetwork.org
CDN’s Primary Activities

CDN

PBRN

CBPR

www.CDNetwork.org
Models of Practice-Based Research

- **Top-Down**
  - Researcher-focused
  - Funder-focused

- **Bottom-up**
  - Clinician-focused (PBRN)
  - Patient-focused (CBPR)

- **Mixed (Bi-directional)**
  Clinician  
  Researcher
“…nearly all [PBRNs] have attempted to balance bottom-up research (studies important to clinicians) with top-down research (studies important to researchers and/or funders)…”

MIXED MODEL

• Meets the NIH and AHRQ vision by creating “…bi-directional venues for translating research into practice and practice into research …”

• In a recent national survey of PBRNs representing
  – N=111 PBRNs → n=86 (80% response rate)
  – 1871 practices
  – 12,957 MDs
  – 14.7 million patients

• % Ever Receiving Federal Funding:
  – Bottom-up 27%
  – Top-down/Mixed model 84% (p=0.006)

CDN has successfully employed the “Mixed Model” PBRN in a variety of experimental and observational studies conducted in primary care practices serving low-income and minority communities, such as:

- Community/Migrant Health Centers (CHCs)
- Diagnostic and Treatment Centers (DTCs)
- Health Department Clinics (DOH)
- Public/Voluntary Hospitals (HOSP)
- Primary Care Residency Programs
- Managed Care Organizations (MCOs)
Employing the Mixed Model, Significant Improvements Have Been Achieved In:

- Clinical Preventive Services
- Disease Management
- Health Behavior Change
- Quality of Life
Community-Based Participatory Research (CBPR) & Mixed Model

**CHC/Site Recruitment Process**

CDN + Acad Partner(s) → CMO/Clinical Director → CEO/Executive Director → Community Board
Community-Based Participatory Research (CBPR) & Mixed Model

CHC/Site Implementation Process

CDN + Acad Partner(s) → Clinical Staff → Admin & Support Staff → Patient Informants
Community-Based Participatory Research (CBPR) & Mixed Model Participant Recruitment Process

CDN + CHC Staff + Community Partners \[\downarrow\] Patients & Families
<table>
<thead>
<tr>
<th>Condition</th>
<th>Agencies/Entities</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV/AIDS</td>
<td>NIAID, NIMH, HRSA, AmFAR, BMS, DMP, Roche</td>
</tr>
<tr>
<td>CANCER CONTROL</td>
<td>NCI AHCPR</td>
</tr>
<tr>
<td>DEPRESSION</td>
<td>NIDA, SAMHSA, NIMH</td>
</tr>
<tr>
<td>STRESS MANAGEMENT</td>
<td>NIMH</td>
</tr>
<tr>
<td>HYPERTENSION</td>
<td>NHLBI</td>
</tr>
<tr>
<td>DIABETES</td>
<td>HRSA</td>
</tr>
<tr>
<td>IMMUNIZATIONS</td>
<td>CDC, HRSA, Pharma</td>
</tr>
<tr>
<td>MIGRAINE/HEADACHE</td>
<td>Merck</td>
</tr>
<tr>
<td>ANEMIA</td>
<td>Ortho Biotech</td>
</tr>
<tr>
<td>ASTHMA</td>
<td>EPA, DEP, HRSA</td>
</tr>
<tr>
<td>PALLIATIVE CARE</td>
<td>NCI</td>
</tr>
<tr>
<td>NUTRITION/PHYS. ACTIV.</td>
<td>RWJ, NYS Atty Gen</td>
</tr>
<tr>
<td>PERIODONTAL DISEASE</td>
<td>NIDCR</td>
</tr>
<tr>
<td>GENETICS</td>
<td>March of Dimes</td>
</tr>
<tr>
<td>PREGNANCY/PRENATAL</td>
<td>NIMH</td>
</tr>
</tbody>
</table>
NIH Road Map for Clinical Research: Inventory and Evaluation of Clinical Research Networks (IECRN)

The NIH Roadmap Initiative Inventory and Evaluation of Clinical Research Networks

Acknowledges participation of:

Clinical Directors Network

in the Best Practices Study

Stephen Katz, M.D., Ph.D.
Director of the National Institute of Arthritis
and Musculoskeletal and Skin Diseases

Awarded May 31, 2006

www.clinicalresearchnetworks.org

www.CDNetwork.org
ACADEMIC PARTNERS & PROJECTS

- **YALE SCHOOL OF PUBLIC HEALTH**
  - Centering Pregnancy (NIMH)

- **DARTMOUTH MEDICAL SCHOOL**
  - Cancer Control (NCI)

- **COLUMBIA UNIVERSITY**
  - College of Physicians and Surgeons (P&S)
  - Mailman School Of Public Health (MSPH)
  - Hypertension in African Americans; BP Adherence (NHLBI)
  - Cancer Caregiver Support (NCI)
  - A Web-based Rx Support Tool for HIV (HRSA)

- **RAND CORP & UCLA**
  - PTSD Among Refugees (NIMH)

- **UNIVERSITY OF MICHIGAN**
  - School of Dental & Oral Surgery
  - School of Public Health
  - Periodontal/Diabetes (NIDCR)

- **UNIVERSITY OF MIAMI**
  - Miller School Of Medicine
  - Stress Management/HIV (NIMH)

www.CDNetwork.org
CDN RECRUITMENT EXPERIENCE
1992-Present

52,465 Patients enrolled

69 % Female

49 % African-American

34 % Latino/a

www.CDNetwork.org
CDN RESEARCH
KEY RESULTS (1992-Present)

Cancer Early Detection (NCI)
• Medical Director turnover predicts lower adoption of innovations
• Telephone Care Management significantly increases Pap, Mammography and Colorectal Cancer Early Detection Rates
• An abbreviated Telephone Prevention Care Management delivered by a Managed Care Organization staff significantly increases screening for colorectal cancers in women

HIV/AIDS & Behavior (NIMH)
• Group-based Stress Management and Relaxation Training for HIV+ women significantly
  – Improved ARV Rx adherence
  – Decreased HIV Viral Load
  – Decreased depression in moderately depressed women
  – Enhanced emotional well-being and quality of life
  – Significant improvements for Nutrition, Alcohol, Safer Sex

Hypertension Control (NHLBI)
• Home Blood Pressure Monitoring with & without Telephone Case Management significantly increases Blood Pressure Control Rates

Pediatric Immunization Levels (HRSA & CDC)
• Immunization QI Project significantly improves Pediatric Immunization Completion Rates (4-3-1 & 4-3-1-3-3)

Asthma (EPA, HRSA, DEP)
• Home-based education and assessment predicts lowered ER use

www.CDNetwork.org
Case Studies in Bi-directional Practice-Based Research

• Prevention Care Management (PCM) Projects I, T, II (NCI)

• SMART/EST Women’s Projects I & II (NIMH)
Case Studies in Bi-directional Practice-Based Research

- Prevention Care Management (PCM) Projects I, T, II (NCI)
• Prevention Care Management (PCM) Projects I, T, II
  NCI R01-CA-87776

• **Norris Cotton Cancer Center Dartmouth:**
  Allen Dietrich, MD – PI
  Michael Beach, MD, PhD
  Christina Robinson, MS
  Mary Ann Greene, MS
  Elaine Livingston
  Carol Sox, ENGR
  Cheryl Lofgren

• **CDN**
  Jonathan N. Tobin, PhD – Co-PI
  Andrea Cassells, MPH – Proj Dir
  Richard G. Younge, MD MPH – Med Dir
PCM1 Participating Community Health Centers:

**BROOKLYN**
- Bedford Stuyvesant FHC
- Brownsville Multi-Service FHC
- Sunset Park FHC
- Park Ridge HC
- Family Physician HC

**BRONX**
- Montefiore Comprehensive Family Care Center
- Morris Heights Health Center
- Urban Health Plan

**MANHATTAN**
- Ryan-NENA CHC
- William F. Ryan CHC
- Betances Health Center
- Boriken Community Health Center

**QUEENS**
- Joseph P. Addabbo Family Health Center
NY Prevention Care Manager (PCM) Project
With Dartmouth Medical School – Phase II

Eligibility

Women age 50-69
Scheduled/Walk-in visit during enrollment period
Been a patient at the Health Center for at least 6 months
Overdue for Pap, Mammogram or CRC Screening
N=1413

Randomization

Experimental
N = 706
Prevention Care Manager:
Calls, education, patient navigation,

Control
N = 707
Usual Care:
One follow up call

Outcomes

Experimental
18 MONTHS: Up-to-Date Pap, mammogram, HFOBT;
5YEARS:sig
10 YEARS: colonoscopy
By chart review

Control
18 MONTHS: Up-to-Date Pap, mammogram, HFOBT;
5YEARS:sig
10 YEARS: colonoscopy
By chart review
NY Prevention Care Manager Project (PCM1)

• N = 11 NYC CHCs

• n = 1413 women aged 50-69 years

• Women were randomized to:
  – EXP: PCM Telephone support
  – CON: Usual Care (UC)

• Assessed cancer screening barriers perceived by women

• Provided Telephone Prevention Care Management to overcome barriers

• Outcomes: Up-to-date (USPSTF) status at 18 months for cancer screening for:
  – Breast
  – Cervical
  – Colorectal
NY Prevention Care Manager Project (PCM1)

PCM Approach:

• Prevention Care Managers provided telephone support and assistance toward achieving up to date status;

• Assessed patient-perceived barriers to screening

• Provided needed education and motivational support;

• Helped patients to access services

• Provided follow-up support including:
  • scheduling appointments
  • reminder calls and letters
  • help with transportation
  • directions to screening facilities
**PCM1 Outcomes:**
All 3 Cancer Screening Rates Improved Significantly

(N=1390)

<table>
<thead>
<tr>
<th></th>
<th>PCM</th>
<th>Usual Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast</td>
<td>58% → 68%</td>
<td>60% → 58%</td>
</tr>
<tr>
<td>Cervix</td>
<td>71% → 78%</td>
<td>70% → 70%</td>
</tr>
<tr>
<td>Colorectal</td>
<td>39% → 63%</td>
<td>39% → 50%</td>
</tr>
</tbody>
</table>

all p<0.05       not significant

Clinical Benefits to Practices, Providers & Patients

• Identification of patients in need of clinical preventive services
• Standardized coaching scripts
• Patient Telephone Outreach
• Performance Measures & Feedback
• CME for clinicians
• Staff Education & Training
HOW TO SUSTAIN THESE IMPROVEMENTS?
FIND PARTNERS WITH ALIGNED INTERESTS*
*(& preferably, deeper pockets)

• Conducted PCM Translation (PCMT) Pilot in a Medicaid Managed Care Organization (MCO) with Affinity Health Plan

• Trained MCO Staff to Deliver the PCM Intervention

• REPLICAED RESULTS for CRC
  \textit{(Dietrich, Tobin, Cassells, et al., Annals of Family Medicine, 2007)}

• Now conducting PCM2: a full-scale RCT in NY MMCOs (NCI)
Stress Management and Relaxation Training/Expressive Supportive Therapy
SMART/EST Women’s Projects I & II

SMART/EST I
University of Miami Miller School of Medicine & CDN
PI: Stephen M. Weiss, Ph.D., M.P.H.
Co-PI: Neil Schneiderman, Ph.D.
Co-PI: Jonathan N. Tobin, Ph.D.

SMART/EST II
University of Miami Miller School of Medicine & CDN
PI - Miami: Stephen M. Weiss, Ph.D., M.P.H.
Co-PI: Neil Schneiderman, Ph.D.
Project Director: Mary Ishii, Psy.D.

PI - NY/NJ: Jonathan N. Tobin, Ph.D.
Co-PI: Anita Vaughn, MD
Co-PI: Elizabeth Brondolo, Ph.D.
Project Directors: Yolene Gousse, MPH & Joanne Camille, Ph.D.

NIMH RO1-MH-61208
& RO1-MH-55463
SMART/EST
Women’s Project I

Participating Community Health Centers

New York NY
• ST. VINCENT HOSPITAL
• BETANCES HEALTH UNIT
• COMMUNITY RESEARCH INITIATIVE ON AIDS (CRIA)
• LESBIAN AND GAY CENTER

Brooklyn NY
• CARIBBEAN HOUSE

Bronx NY
• COMMUNITY FAMILY PLANNING COUNCIL
• MORRIS HEIGHTS HEALTH CENTER

New Brunswick NJ
• ERIC B. CHANDLER COMMUNITY HEALTH CENTER

Summit NJ
• VAUXHALL CHC

Newark NJ
• NEWARK HEALTH CENTER/LUDLOW
SMART/EST Women’s Project II

NY/NJ Community Health Centers

New York NY
- ST. VINCENT HOSPITAL
- BETANCES HEALTH UNIT
- COMMUNITY HEALTHCARE NETWORK
- RYAN/CHELSEA CLINITON COMMUNITY HEALTH CENTER
- RYAN/NENA COMMUNITY HEALTH CENTER

Brooklyn NY
- AFAM MULTI-SPECIALTY MEDICAL GROUP
- BEDFORD STUYVESANT FAMILY HEALTH CENTER

Bronx NY
- URBAN HEALTH PLAN
- MORRIS HEIGHTS HEALTH CENTER
- HISPANIC AIDS FORUM

New Brunswick NJ
- ERIC B. CHANDLER COMMUNITY HEALTH CENTER

Newark NJ
- NEWARK HEALTH CENTER/LUDLOW

MIAMI Recruitment Sites
- Jackson Memorial Hospital Special Immunology Clinic
- South Florida AIDS Network
- Care Resources
- Center for Positive Connections
- Borinquen Health Center
- Dade County Health Department
- Liberty City Health Center
SMART/EST II
Acknowledgements

MIAMI
• Mabel Algeciras
• Brunette Anglade
• Robert Gutierrez
• Sandra Page
• Madelyn Miranda, Psy.D.
• Alexa Tapanes
• Karmen Gadsden
• Heidi Stanley, PhD
• Desh Asthana, Ph.D.
• Mahendra Kumar, Ph.D.
• Adarsh Kumar, Ph.D.
• Michele Jean-Gilles, Ph.D.
• J. Bryan Page, Ph.D.

• Olga Villar, Psy.D.
• Michalda Exavier
• Mimi Doll
• Arthur LaPerriere, Ph.D
• Shvawn Baker, PharmD
• Virginia Locascio
• Lisa Metsch, Ph.D.
• Suzanne Lechner, Ph.D.
• Susan Luck, R.N.
• Ob/Gyn Nursing staff

NY/NJ
• Andrea Cassells, MPH
• Ronald Harrist, PhD
• Kay Kimball, PhD
• Yolene Gousse, MPH
• Joanne Camille, PhD
• Gael Donchance, BA
• Tina Kanmaz, PharmD
• Antronette Yancey, MD MPH
• CJ Segal-Isaacson, EdD RD
• Edwin Krales, RD, CDN
• Anya Romanowski, MS, RD
• Clinical Directors Network (CDN) Recruitment & Assessment Staff
• CHC Site Staff
• St. John’s University Intervention Staff
Case Studies in Bi-directional Practice-Based Research

- SMART/EST Women’s Projects I & II (NIMH)
SMART/EST II (NIMH)

Eligibility

- Women
  - N=454
- Age 18 and over
- Living with HIV/AIDS
- English, Spanish or Haitian Creole speaking

Randomization #1

Experimental

GROUP CBSM+ intervention (10 sessions)
Healthy Lifestyles (6 sessions)

Randomization #2

GROUP
INDIV

Control

INDIViduals View psycho-educational videos (10 sessions)
Healthy Lifestyles (6 sessions)

Follow-Ups

- 6 MONTHS
- 12 MONTHS
- 24 MONTHS
SMART/EST Women’s Project II

Methods:

• Randomized Controlled Trial (RCT)
• N=454 multi-cultural HIV+ women
• Randomized to a Multi-component Intervention
  – Stress Management/Relaxation consisting of a combination of
    • Cognitive-Behavioral Therapy (CBT)
    • Expressive Supportive Therapy (EST)
  – Healthy Living (HL) including
    • Rx Adherence
    • Safer Sex
    • Harm Reduction
    • Nutrition
    • Physical Activity
SMART/EST Women’s Project II

Methods:

- Participants were randomized into:
  - Group (G) [didactic, interactive, video]
  - Individual (I) [video only]

- Both G and I received 16 two-hour sessions

- Sessions & Assessments in English, Spanish, Haitian Creole

- MIAMI: single AMC location

- NY/NJ: 8 HRSA-funded CHCs
SMART/EST Women’s Project II

PRIMARY OUTCOMES

• Antiretroviral Rx Adherence
  – modified ACTG questionnaire
  – ARV Rx Adherence >90%

• Beck Depression Inventory
  – BDI III Depressed >10

• HIV Viral Load (VL)
  – VL Undetectable <400 copies/ml

ASSESSMENTS(T=5):
Baseline, Post Intervention
6, 12, 24 months
The SMART/EST Women’s Project II

SIGNIFICANT RESULTS

• Improved ARV Rx adherence

• Decreased HIV viral load

• Decreased depression in moderately depressed women

• Enhanced emotional well-being and quality of life

• Significant findings for nutrition, alcohol use, safer sex practices
SUSTAINABILITY OF CLINICAL SERVICES & OUTCOMES?
PROVIDE NEW SKILLS FOR EXISTING STAFF

• Real-time training for CHC Clinicians
• Ongoing Clinical Supervision in CBT
• TA & Support for Conducting Group Visits

• Re-deploying existing Health Education and Ancillary/Support Services once patient distress has been reduced
• Focusing on
  • Active Coping
  • Patient Self-Management Strategies

• Tied to Reimbursement for Clinical Services as part of standard of care

• Ready to begin SMART/EST III Professional Development & Implementation (CDC)
Methodological Adaptations are Necessary to Reconcile the Dual Roles of Clinician as Researcher vs. Clinician as Healer
Research Design Considerations

1. Testing Innovative Interventions which may benefit patient care & outcomes vs. pure “lab” studies

2. RCTs (unlike observational studies) may require modified designs

3. Selection of Control Condition/Group requires attention to patient needs
   - Placebo
   - Active Treatments
   - Usual Care
   - Wait-list/Time-Lag (Early vs Late)
   - Cross-over
   - Other Designs
Potential Solutions to NIH Roadmap Strategy

Primary Care PBRNs are needed in order to:

• Design and test effective interventions within established health care delivery systems

• With the goal of providing these effective interventions as the Standard of Care
How Does CDN Conduct Effective and Enduring Bi-directional Translational Research?

• PRINCIPLES
• PARTNERSHIPS
• PATIENCE
• PERTINENCE
• PARTICIPATION
Translational Research Roadmap
SUCCESSFUL CLINICAL & PUBLIC HEALTH OUTCOMES

NIH
PBRNs
CLINICIANS
PATIENTS
COMMUNITIES

www.CDNetwork.org
CLINICAL DIRECTORS NETWORK, INC. (CDN)

Jonathan N. Tobin, PhD
President/CEO
CDN
5 West 37th Street - 10th Floor
New York City NY 10018 USA
Tel (212) 382-06-99 ext 234
Tel (212) 382-06-99 ext 227
Fax (212) 382-06-69
JNTobin@CDNetwork.org
www.CDNetwork.org
www.eClinician.org