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Community-Based Models of Research: Views from the Health Center

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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

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A Practice-based

Research

Network

(PBRN)

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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

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

CDN's Primary Activities

- **Practice-based Research**
- **Education and Training**
- **Professional Development**

CDN's Primary Activities

CDN

PBRN

CBPR

Models of Practice-Based Research

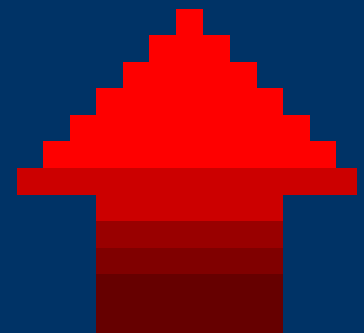
- **Top-Down**

- Researcher-focused
- Funder-focused



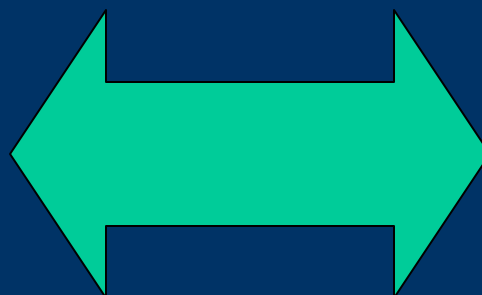
- **Bottom-up**

- Clinician-focused (PBRN)
- Patient-focused (CBPR)



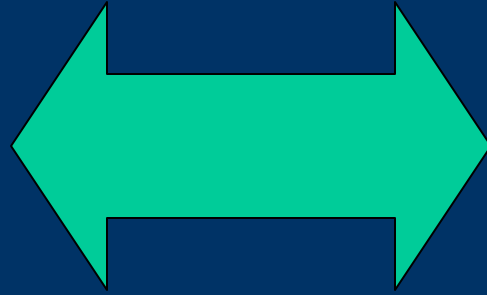
- **Mixed (Bi-directional)**

Clinician



Researcher

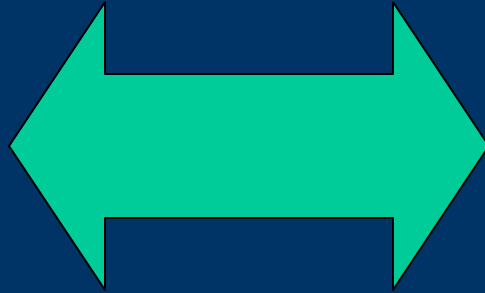
MIXED MODEL



“...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)...”

Macaulay AC Nutting PA Ann. Fam. Med, January 1, 2006; 4(1): 4 - 7.

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)

•Tierney WM, Oppenheimer C, Hudson B, et al. *Ann Fam Med.* 2007;5(3):242-250.

MIXED MODEL



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



Patients & Families



CDN'S RESEARCH PORTFOLIO/MIXED MODEL

HIV/AIDS

**NIAID, NIMH, HRSA,
AmFAR, BMS, DMP, Roche**

CANCER CONTROL

NCI AHCPR

DEPRESSION

**NIDA, SAMHSA,
NIMH**

STRESS MANAGEMENT

NIMH

HYPERTENSION

NHLBI

DIABETES

HRSA

IMMUNIZATIONS

CDC, HRSA, Pharma

MIGRAINE/HEADACHE

Merck

ANEMIA

Ortho Biotech

ASTHMA

EPA, DEP, HRSA

PALLIATIVE CARE

NCI

NUTRITION/PHYS. ACTIV.

RWJ, NYS Atty Gen

PERIODONTAL DISEASE

NIDCR

GENETICS

March of Dimes

PREGNANCY/PRENATAL

NIMH

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

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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

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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)

CDN RECRUITMENT EXPERIENCE 1992-Present

52,465 Patients enrolled

69 % Female

49 % African-American

34 % Latino/a

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 colo-rectal 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

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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,

Outcomes

18 MONTHS: Up-to-Date Pap, mammogram, HFOBT;

5YEARS:sig

10 YEARS: colonoscopy

By chart review

Control

N = 707

Usual Care:
One follow up call

Outcomes

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)

PCM

Usual Care

| | <u>PCM</u> | <u>Usual Care</u> |
|-------------------|------------------|-------------------|
| Breast | 58% → 68% | 60% → 58% |
| Cervix | 71% → 78% | 70% → 70% |
| Colorectal | <u>39% → 63%</u> | 39% → 50% |

all p<0.05

not significant

Dietrich, Tobin, Cassells, et al Annals of Internal Medicine 14(8): 563-571, 2006

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
- **REPLICATED RESULTS for CRC**
(*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 CLINTON 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

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- 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

Experimental

Randomization #1

Control

GROUP CBSM+
intervention
(10 sessions)

Healthy Lifestyles (6
sessions)

INDIViduals View
psycho-educational
videos (10 sessions)

Healthy Lifestyles (6
sessions)

GROUP

INDIV

Randomization #2

GROUP

INDIV

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:

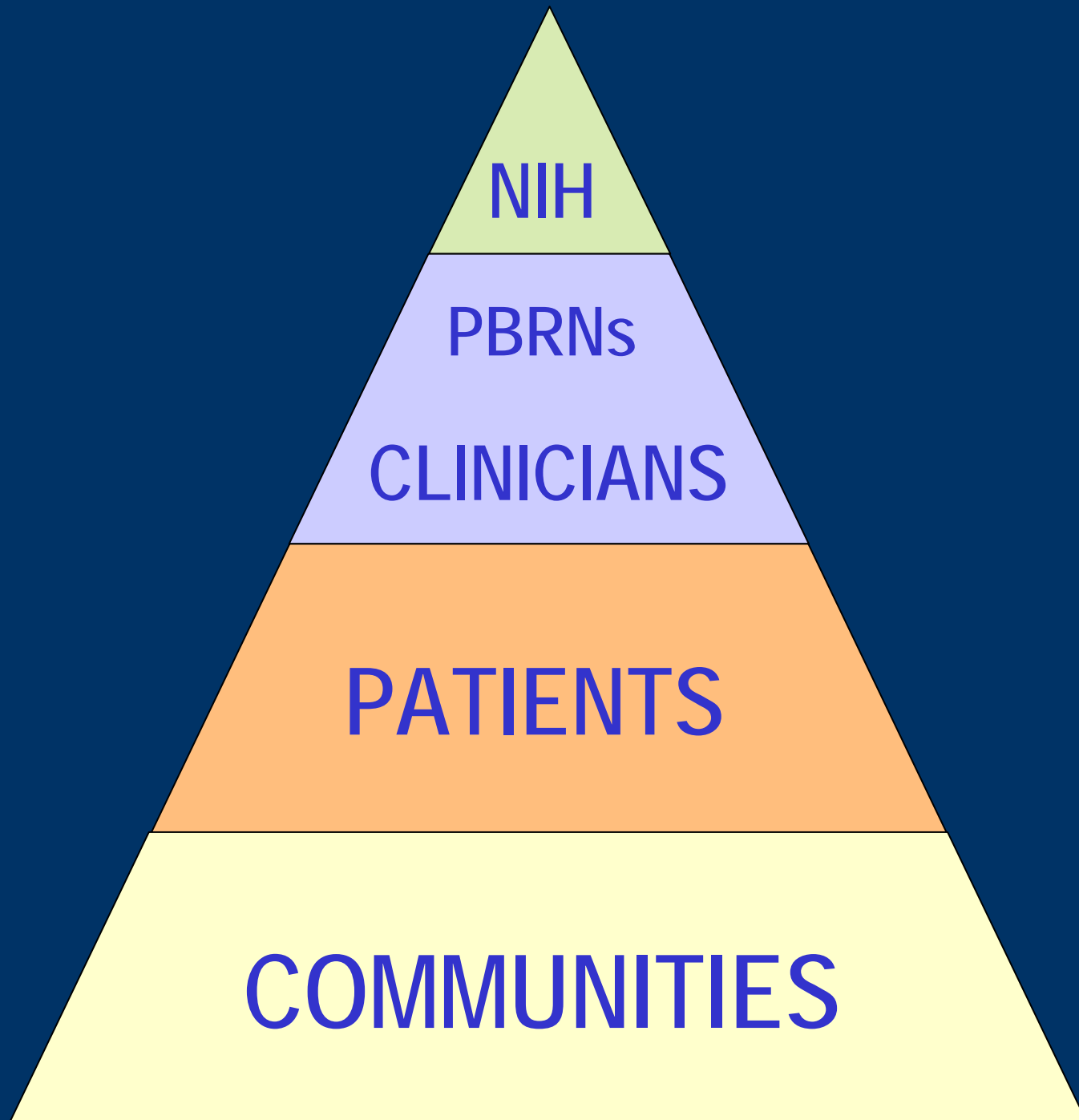
- Design and test effective interventions within established health care delivery systems
- With the goal of providing these effective interventions as the Standard of Care

How Does CDN Conduct Effective and Enduring Bi-directional Translational Research?

- **PRINCIPLES**
- **PARTNERSHIPS**
- **PATIENCE**
- **PERTINENCE**
- **PARTICIPATION**

Translational Research Roadmap

**SUCCESSFUL CLINICAL & PUBLIC HEALTH
OUTCOMES**



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



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