

Betty Tai, Ph.D.

Director

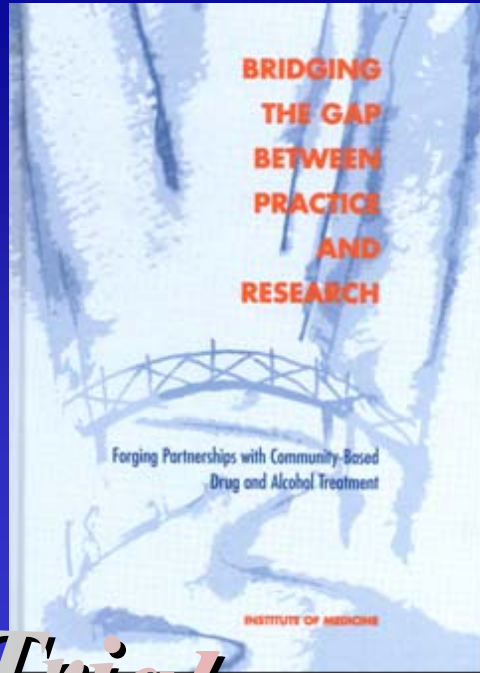
Center for the Clinical Trials Network

National Institute on Drug Abuse





Institute of Medicine,
1998



Steppin' Out
The 12 Step Radio Show

NIDA Clinical Trials Network

Research

*Bridging
the
Gap*

Practice

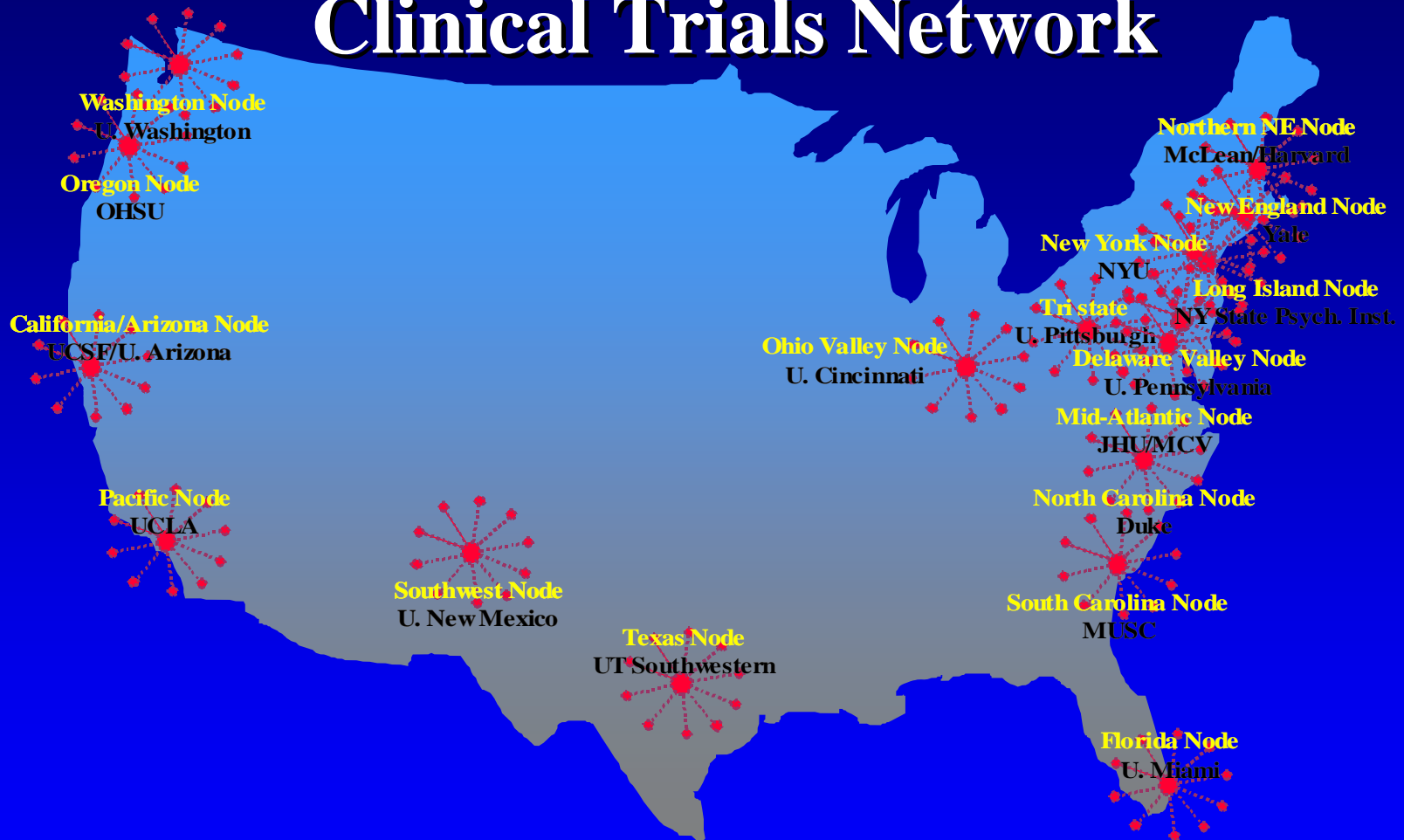
The CTN: 5 Year Vision

Since 2003

- ✓ **Translate Research into Practice**
- ✓ **Revive Medical Involvement in Drug Treatment**
- ✓ **Use CTN as Platform for Additional Research & Training**

National Drug Abuse Treatment

Clinical Trials Network



A research infrastructure of 17 RRTCs & 240 CTPs across 34 States, and Puerto Rico

The Drug Abuse Treatment Community

Rehab Centers

Betty Ford Center
Hazelden Foundation
Caron Foundation

Hospitals

Kaiser Permanente
VA Hospitals
Mayo Clinic
Mercy Hospital
RWJ Medical Center

Therapeutic Community

Odyssey House
Center for Drug-Free Living
Walden House, Phoenix House
Na'Nizhoozi Center
Homeward Bound

Methadone Clinics

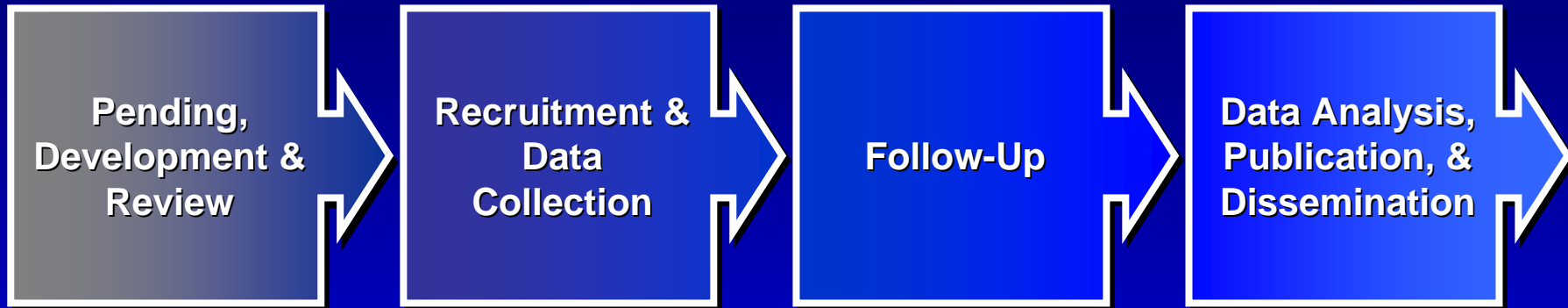
Evergreen Treatment Services
Addiction Research & Treatment Corp.
Bi-Valley Medical Clinic
Hartford Dispensary

Social Model

Behavioral Model

Medical Model

The CTN Trials (1999 – now)



CTN 0031
CTN 0032

CTN 0027
CTN 0028
CTN 0029
CTN 0030

CTN 0014

CTN 0001
CTN 0002
CTN 0003
CTN 0004
CTN 0005
CTN 0006
CTN 0007
CTN 0008
CTN 0009
CTN 0010
CTN 0011
CTN 0012
CTN 0013
CTN 0015
CTN 0016
CTN 0017
CTN 0018
CTN 0019
CTN 0020
CTN 0021

Medications: 9
Behavioral Interventions: 11
HIV/HCV Interventions: 4
Others: 3

Summary of Trial Progress

	2005 - Present	From 1999
# trials started	4	22
# completed enrollment	8	18
# completed follow-up	7	17
# data locked	7	17
# patients enrolled	1000	> 7000

Pharmacological Therapies

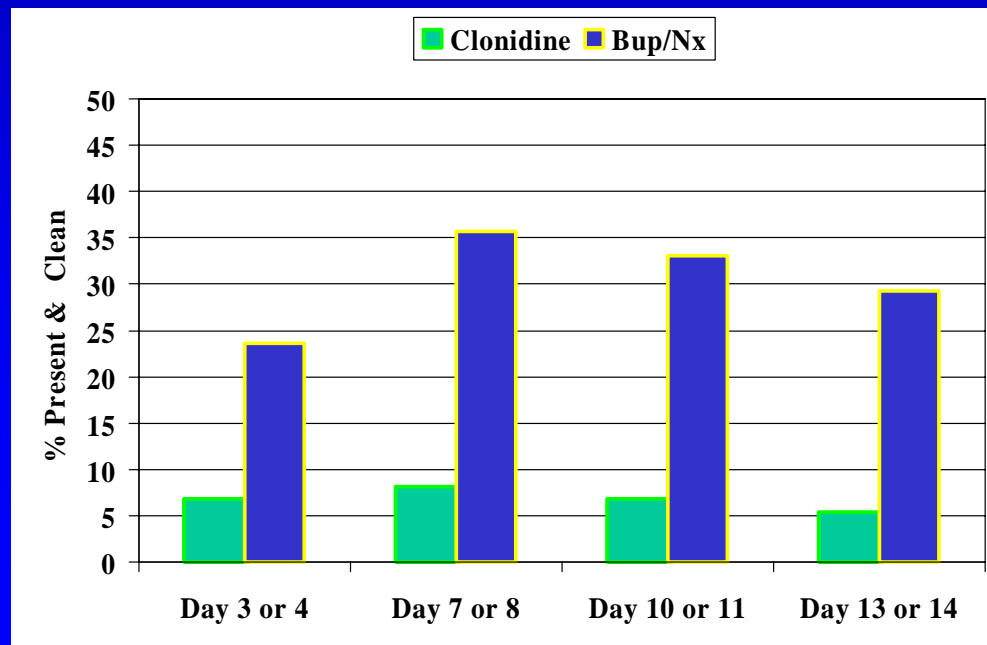
- Buprenorphine/Naloxone (Suboxone)
 - Bup/Nx vs Clonidine in detox
 - Bup/Nx vs Methadone (liver function)
 - Bup/Nx for adolescents
 - Bup/Nx for prescription opiate dependence
- Osmotic-Release Methylphenidate (Concerta)
 - Adult smokers with ADHD
 - Adolescent substance users with ADHD
- Nicotine replacement in drug treatment

An Example: Pharmacological Treatment

Buprenorphine Detox: Outpatient

- **NNT for Bup/Nx: $157/46 = 3.4$**
- **NNT for Clonidine: $74/4 = 18.5$**

NNT Clonidine : Bup/Nx = 5.44



On Buprenorphine/Naloxone Practice

- Can be used safely and effectively in community treatment settings (Amass et al, 2004)
- More patients stay in care and complete care with buprenorphine (Ling et al, 2005)
- 7 day taper is as effective as a 30 day taper (Ling et al, under review)
- Programs continue to use
 - Maryhaven, Columbus OH (Brigham et al, in press)
 - Phoenix House, New York, NY (Collins et al, in press)
 - Betty Ford Center, Palm Springs, CA
 - Kaiser-Permanente NW, Portland, OR
 - 100+ maintenance patients

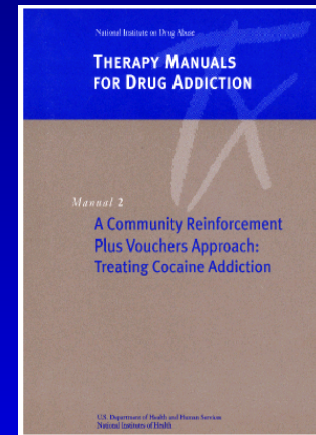
Behavioral Therapies

- (MI or CM) Lower cost motivational incentives
- (MI/MET) Motivational interviewing & enhancement
 - *Adults; pregnant women; Spanish speakers*
- *Seeking Safety – trauma counseling for women*
- *Reducing HIV/HCV risk behavior*
 - *Injection drug use; sex risks for women & men*
- *Job Seekers vocational training; Native Americans*
- Brief Strategic Family Therapy: adolescents
- Counselor feedback
- Telephone Enhancement to Improve Aftercare

An Example: Behavioral Intervention

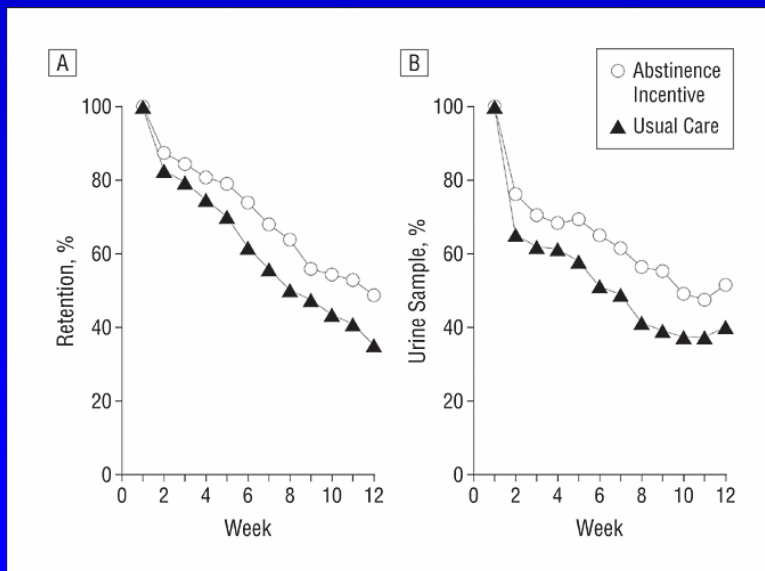
Motivational Incentives/ Contingency Management

- **Over past 10 years**
 - **200+ grants awarded, 100+ articles published**
 - **NIDA published manual in 1998**
- **But not embraced in the community**



Until...

- **CTN's launch of MI Studies (2000)**
- **With practitioners' input**
- **Enhanced the acceptability and sustainability of the intervention**



Results: Motivational Incentives

- Methadone patients reduce use of cocaine (Pierce et al, 2005)
- Outpatients improve retention in care (Petry et al, 2005)
- Outpatients reduce use of methamphetamine (Roll et al, 2006)
- Do not increase the risk of gambling (Petry et.al, 2006)
- Lower cost incentives are effective
- Motivational Incentives are cost-effective (Olmstead, Sindelar & Petry, 2007)

Today's Challenges

- **Integrating drug abuse treatment into mainstream medical practice**

Psychiatric Comorbidity

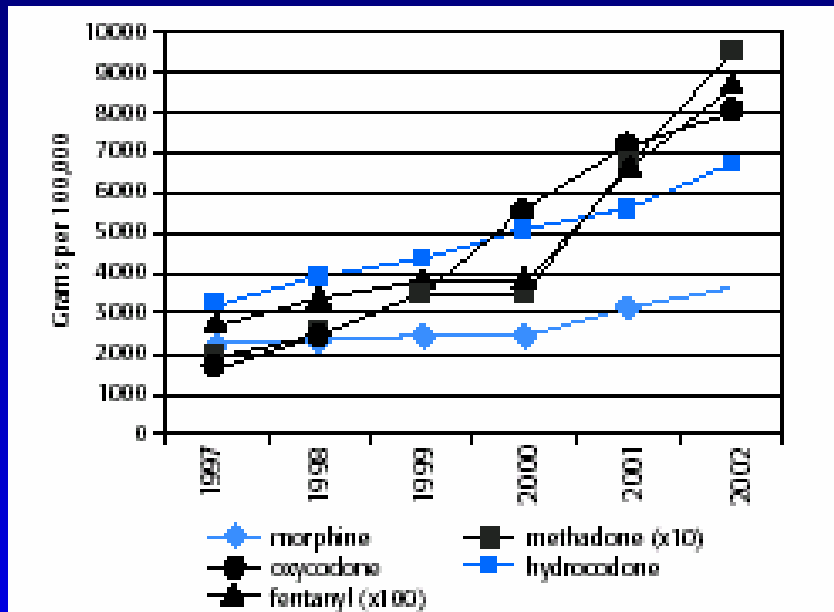
- **ADHD / SUD**
- **PTSD / SUD**
- **Anxiety / SUD**
- **Depression / SUD**

Chronic Illness Comorbidity

- **Pain / SUD**
- **HIV / SUD**
- **HCV / SUD**

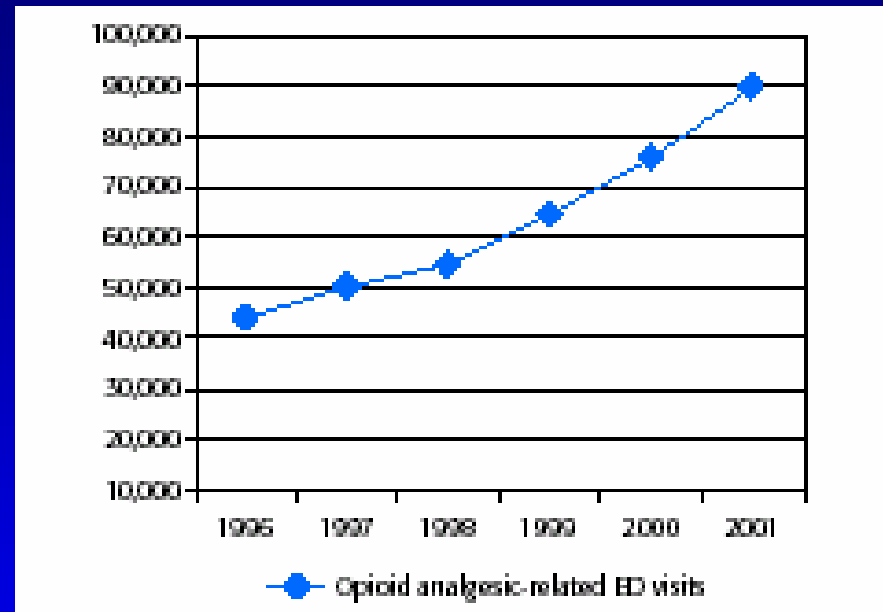
Emerging Public Health Crisis

Therapeutic opioid use in the U.S.
(1997-2002)



Source: U.S. Drug Enforcement Administration. (ARCOS)
Automation of Reports and Consolidated Orders System

Rates of opioid misuse in the U.S.
(1996-2001)



Source: The Drug Abuse Warning Network (DAWN)

• 2003 National Household Survey on Drug Abuse

- **4.7 million** Americans aged 12 and older used opioid analgesics for non-medical purposes in the **prior 30 days**
- **31 million** Americans age 12 and older used prescription medications (largely opioid analgesics) for non-medical purposes in **their lifetime**

CTN 0030: Buprenorphine Treatment of Prescription Opioid Analgesic Addiction

Through the use of existing infrastructure, the CTN has responded promptly to an emerging public health threat:

- Network has vast research experience in the design and implementation of large multi-site trials
- CTPs have substantial experience using buprenorphine
- RRTC investigators collaborated with scientists/clinicians with expertise in pain management
- Enrollment started 6/2006
- NIH Press Release on 3/7/2007

Integrating HIV Testing and Counseling into Drug Treatment

- 1,000,000 people in the United States are infected with HIV
 - 40,000 new cases each year
 - 250,000 – 300,000 of persons living with HIV are unaware they are infected
 - $\frac{1}{4}$ of persons who test HIV-positive fail to return to receive results
- Drug addiction is major transmission vector, via injection and sexual risk behaviors
- CDC recommends routine HIV testing in outpatient health care settings
 - Drug treatment programs????
- FDA approved HIV Rapid Testing Technology

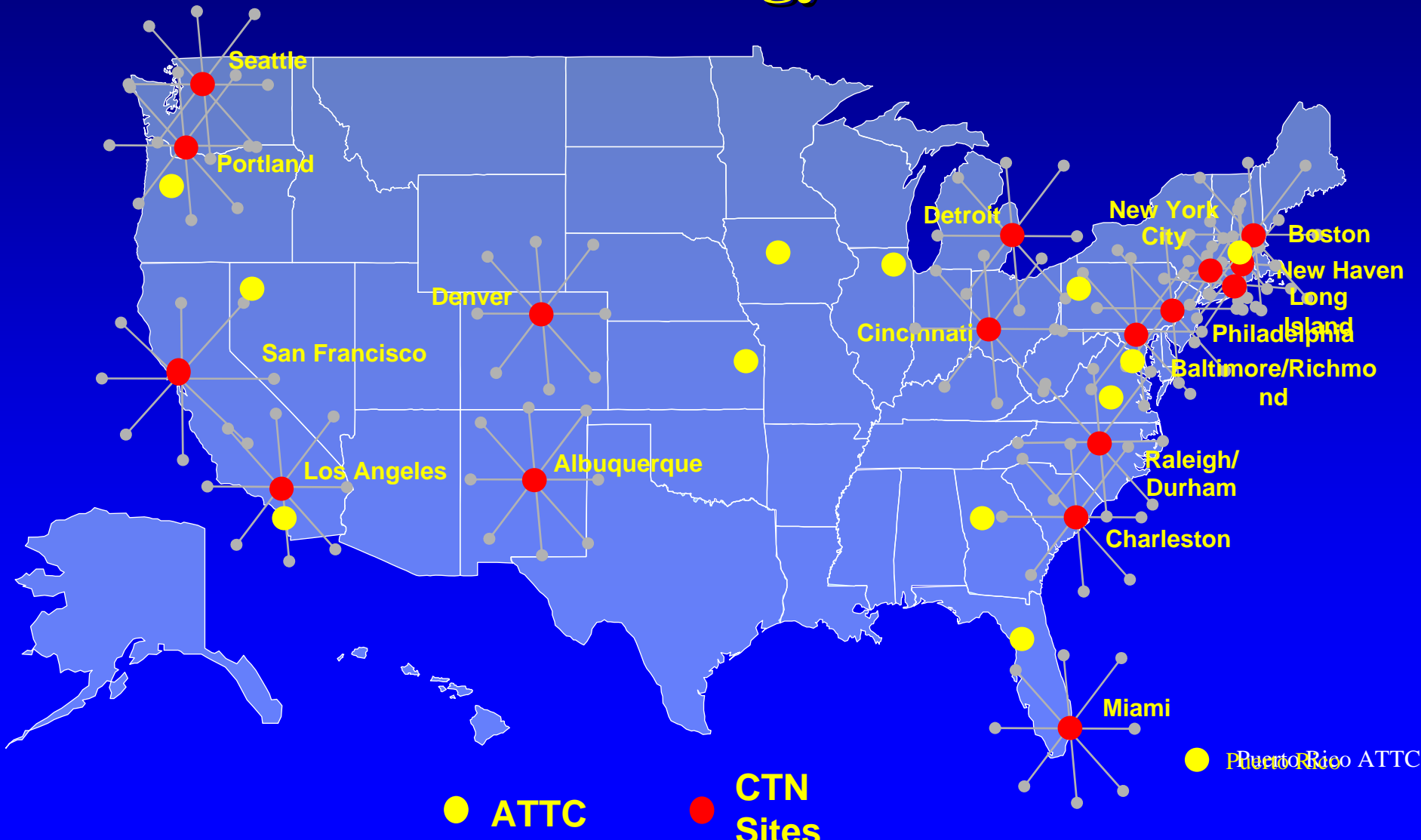
CTN 0032: HIV Rapid Testing and Counseling in Drug Treatment

What is the most effective testing strategy to increase rates of HIV testing and communication of results?

What is the most effective testing strategy to reduce risk behaviors?



National Drug Abuse Treatment Clinical Trials Network The Addiction Technology Transfer Centers



Blending Initiative

- **SAMHSA-NIDA collaboration through ATTCs**
- **Blending products:**
 - Buprenorphine Awareness
 - Short-Term Opioid Withdrawal Using Buprenorphine: Findings and Strategies
 - SMART Treatment Planning: Utilizing the ASI
 - MI Assessment: Supervisory Tools for Enhancing Proficiency
 - Promoting Awareness of Motivational Incentives

An Example: MI Assessment: Supervisory Tools for Enhancing Proficiency (MIA:STEP)

Blending Team objectives and assumptions:

- Develop a package that promotes the use of MI
- Provide tools useful to community providers
- Field does not need another MI training package
- MI skills erode quickly **WITHOUT** feedback and coaching following training

MIA:STEP Blending Product

- 1. Briefing materials**
- 2. Summary of the MI Assessment intervention**
- 3. Results of the NIDA CTN research**
- 4. Teaching tools for enhancing and assessing MI skills**
- 5. Interview rating guide and demonstration materials**
- 6. Supervisor training curriculum**

MIA:STEP

CTN Research Utilization

Good Supervisory Practices for MI

- Training provided by Southwest Node (UNM)
- Directed by Dr. Bill Miller and Dr. Terry Moyers
- Candidates from 15 CTN nodes participated
- Taught by experienced CTP clinicians
- Trainees submitted tapes for critiques
- Goals:
 - A network of competent MI supervisors
 - A cadre of on site supervisors for the CTPs

The CTN Dissemination Library

<http://ctndisseminationlibrary.org>

- **Housed and maintained by Washington Node**
- **Single point of access to all CTN materials approved for public sharing**
 - **Protocols, tools, publications, blending products**
 - **Training schedules, future meeting dates, etc.**
- **Library Usage Statistics (updated 5-4-07):**
 - **2007 Total visitors (Jan-April): 2,379**
 - **2007 Pages downloaded (Jan-April): 7,417**
 - **2006 Total visitors: 4,459**
 - **2006 Pages downloaded: 15,064**

CTN Data Sharing

<http://www.ctndatashare.org>

**Secondary analysis on rich database —
CTN 0001, 0002, 0005, 0006, 0007, 0008, 0011...**

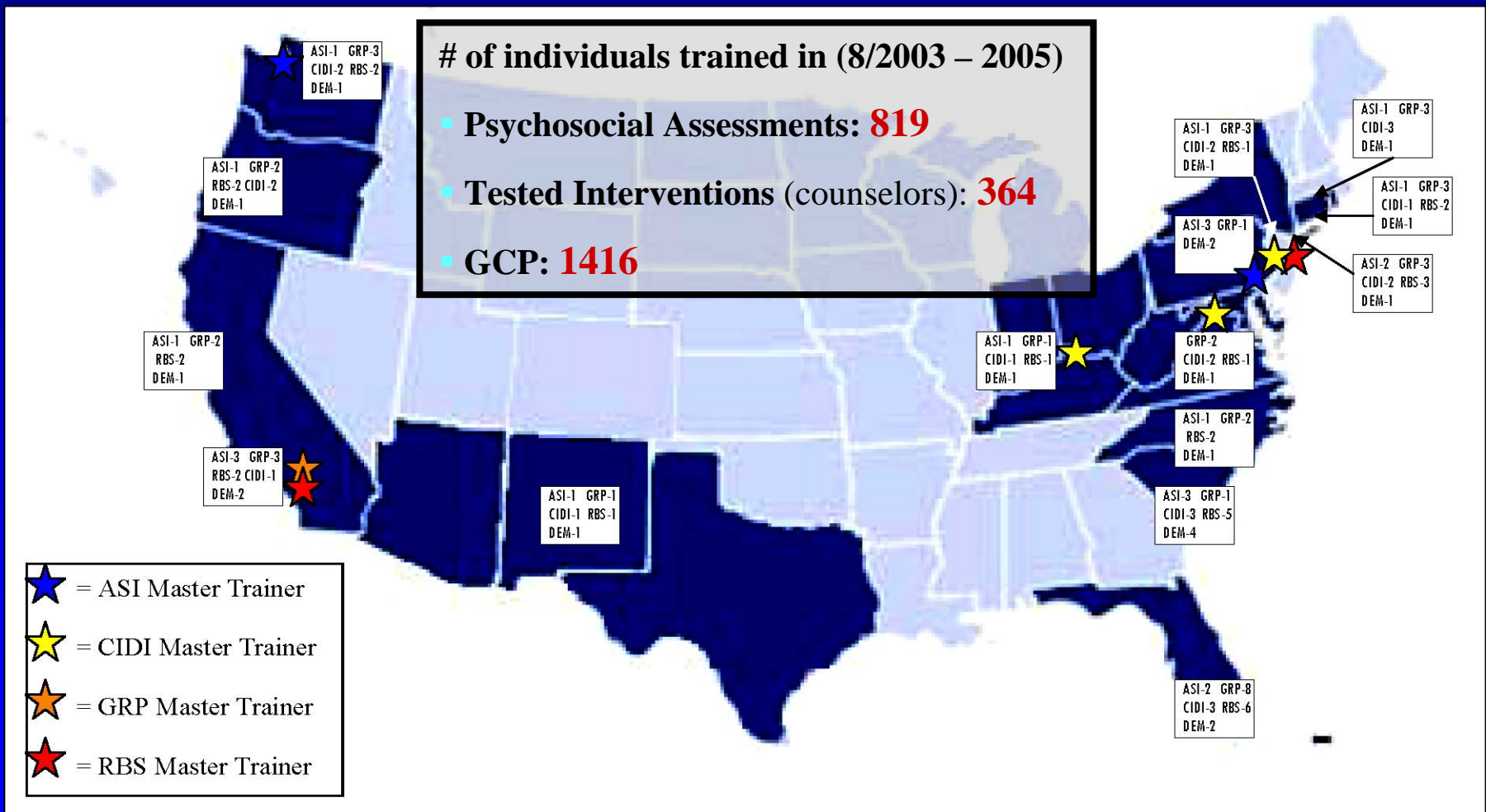
- **CDISC standardized**
- **HIPAA Compliant**
- **CTN Public data/documents include:**
 - **Data sets (SAS and ASCII)**
 - **Defined file (aka data dictionary)**
 - **Annotated Case Report Forms**
 - **Study protocol and reference to study publication of primary outcomes**

The CTN Platform

- **Ancillary and/or stand alone studies:**
 - **Health services/genetics/training methods studies from various NIDA Divisions (31)**
 - **Psychometric study from NIAAA (1)**
- **SBIR/STTR (2)**
- **Secondary analysis on rich database (4)**
- **Minority pre-doc/post-doc training (10)**
- **NIDA INVEST Scholars (planned)**
- **K12 training platform (50)**
- **CTN training networks**

The CTN: Creating a Training Network

Where There was None Before: Current Trainers and Master Trainers



Concluding Comments

- Research and practice can be bridged
 - Researchers and practitioners can collaborate productively
 - Community drug treatment can benefit from CTN research
 - Treatment research can benefit from CTPs' involvement
 - CTPs can recruit patients and conduct quality RCTs successfully
 - CTPs can become interested in research and independently secure research funding

From the Oregon/Hawaii Node

- Adapt (Roseburg, OR)
 - HRSA Rural Health Outreach Program to integrate behavioral health care in a health clinic
 - State award to apply community reinforcement therapy to work with problem gamblers
- ChangePoint (Portland, OR)
 - CSAT award to implement Matrix methamphetamine treatment model

The Oregon/Hawaii Node (continued)

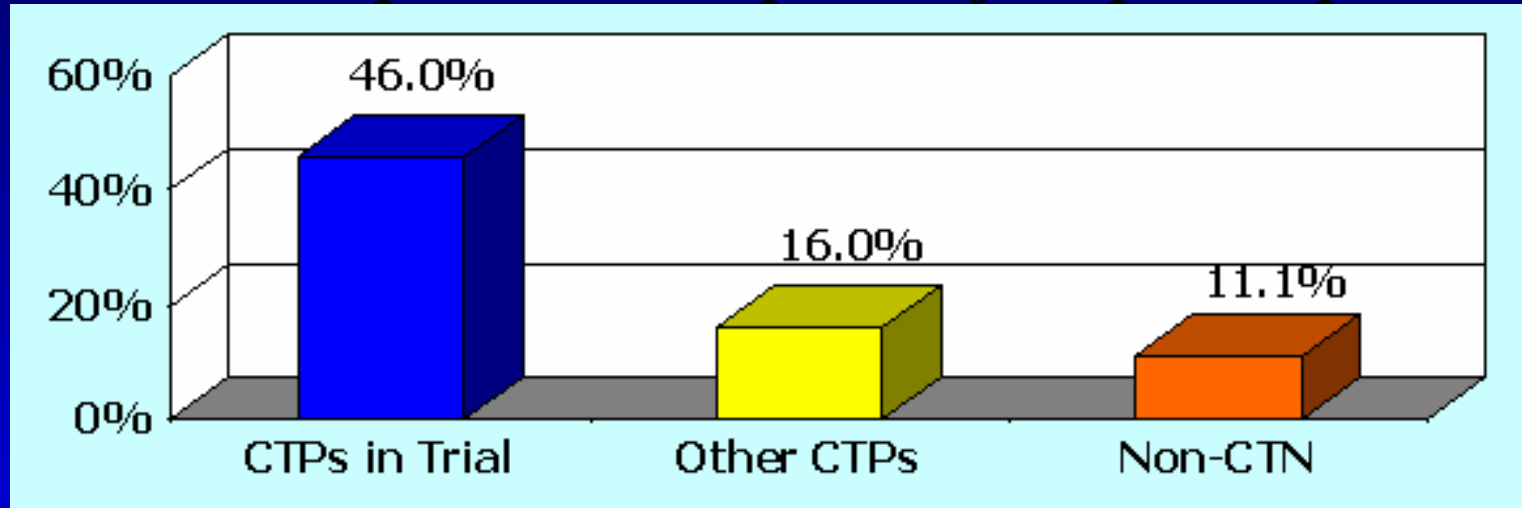
- CODA (Portland, OR)
 - RWJF award to participate in the Network for the Improvement of Addiction Treatment
 - HRSA demonstration to integrate buprenorphine into HIV primary care
- Kaiser Permanente (Portland, OR)
 - NIDA award to study adoption of buprenorphine
 - NIMH award to study recovery from serious mental illness

The Oregon/Hawaii Node (continued)

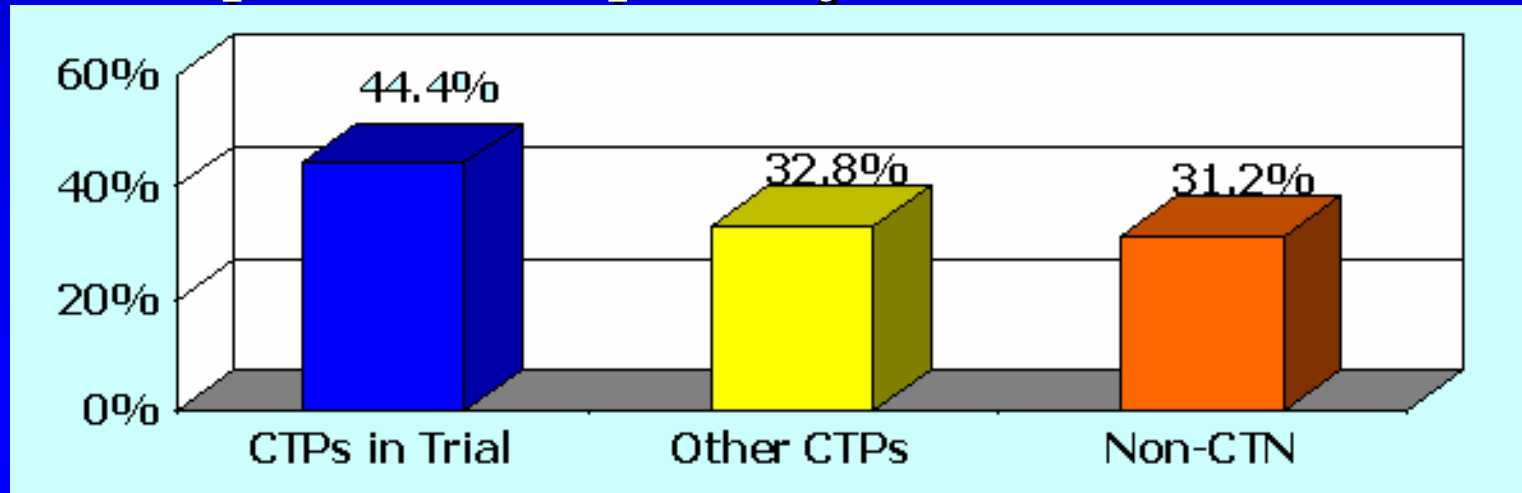
- Native American Rehabilitation Association
 - CSAT award to treat methamphetamine use
 - CDC award to reduce tobacco use
- New Directions Northwest (Baker City, OR)
 - Participates in CJ-DATS
 - Oregon Practice Improvement Collaborative
- Willamette Family (Eugene, OR)
 - CSAT award for treating adolescent women
 - CMHS award to integrate care for adolescent women

Research Utilization

An Example with Adoption of Buprenorphine



An Example with Adoption of Motivational Incentives



IECRN Best Practices (29/267)

NIDA CTN

The NIH Roadmap Initiative
Inventory and Evaluation
of Clinical Research Networks

Acknowledges participation of:

*National Drug Abuse Treatment
Clinical Trials 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

- ✓ Trust & respect between researchers and practitioners
- ✓ Hybrid model to impact practice
- ✓ Data center has strong cutting edge IT support

CCTN Staff

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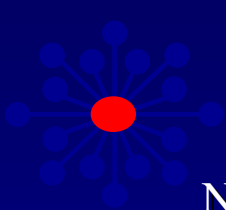
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Number of Participants Randomized and in the Database by Protocol and Node

Protocol	DV	MA	NE	OR	NY	PA	FL	GL	OV	RM	SC	LI	NC	WA	CA - AZ	SW	NNE	TX	ATS	ALL	Target	Enrollment
CTN-0001						18	55	17	19			4								113		Closed
CTN-0002	37			25	74	46			48											230		Closed
CTN-0003		43	92	62	51					102		44	63	59						516		Closed
CTN-0004	200		161			135														496		Closed
CTN-0005		100		300	23															423		Closed
CTN-0006	55	27	81			88				92	111									454		Closed
CTN-0007	65	180			106	52														403		Closed
CTN-0009					72			20			39	80	14							225		Closed
CTN-0010	3	52											30			39	30			154		Closed
CTN-0011								99			120		120							339		Closed
CTN-0013									135				10			55				200		Closed
CTN-0014						43	302		71				5		60					481		Closed
CTN-0015			7		34		105		106		66			35						353		Closed
CTN-0017				88				62		109				171			202			632		Closed
CTN-0018	89		83			52			111		33	44	31	55	48	48				594		Closed
CTN-0019	82		40			21			144		53	40	83	52						515		Closed
CTN-0020		207		60				102			52				65	56	86			628		Closed
CTN-0021				113			92			65		85				107				462		Closed
CTN-0027	33		57	36	2	55								34	46					263	1000	Open
CTN-0028	5	5					10		7	17	15						20	7		86	300	Open
CTN-0029				21	24				80			22					26			173	252	Open
CTN-0030				4	3	17			9		5						30	4	29	101	648	Open