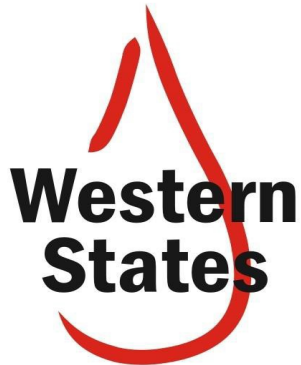


Registries – strategies promoting success: Hemophilia Treatment Center Perspectives



**Federal Hemophilia
Treatment Centers**
California+Hawaii+ Nevada+Guam



Judith R. Baker, DrPH, MHSA

Public Health Director

Regional Hemophilia Network Administrator

Advisory Committee on Heritable Disorders in Newborns and Children

August 13, 2021

Disclosure

Findings and conclusions are the author's.

They do not necessarily represent the official position of:

- U.S. Hemophilia Treatment Center Network,
- Western States Regional Hemophilia Network,
- Center for Inherited Blood Disorders.

- No conflicts

Hemophilia Treatment Centers (HTC) perspectives

- ◆ Q: what factors promote registry funding and sustainability for heritable disorders?
- ◆ **A: Regional Networks & Public Health Tactics:**
 - ◆ Registries -- complex interventions
 - ◆ Exist in individual organizations & broader socio-political context.
 - ◆ *Apply network & implementation science*

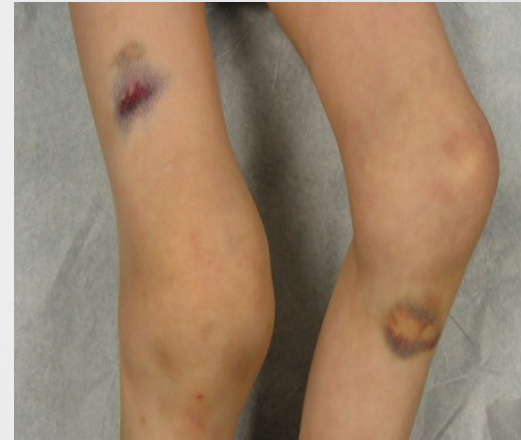
US Hemophilia Treatment Center Network: *40+ year old Regional Model*

HTC Level: Expert *teams* provide rare disorder care:

- ◆ Improved survival: 40% lower mortality¹
- ◆ 40% fewer hospitalizations² and ER visits²
- ◆ Decreased school and work absenteeism³
- ◆ High School graduation rates favorable⁴
- ◆ Lower costs, increased employment⁵
- ◆ Quality of Life scores⁶ and satisfaction high⁷

■ Documenting – *multiple registries*

¹Soucie *Blood* 2000; ²Soucie *Haemophilia* 2001; ³Monahan, *Am J Preventive Medicine* 2011; ⁴Drake *Am J Preventive Medicine* 2010; ⁵Zhou *J Medical Economics* 2015; ⁶Poon *Haemophilia* 2012; ⁷Riske *Haemophilia* 2020



Public Law 9463: *The Public Health Service Act Establishing the Hemophilia Diagnostic and Treatment Center Program*. NO.1131. Washington, DC: Government Printing Office; 1975.

HTC Services

- Diagnosis
- Treatment
- Prevention
- Education
- Counseling
- Outreach
- **Research**
- **Surveillance**
- Pharmacy
- Care Coordination

Settings: Outpatient, Inpatient, Community

Comprehensive (Integrated) Care



Why *regions*? Capacity... Sustainability

◆ **Problems:**

- ◆ Rare genetic disorder expertise is SCARCE.
- ◆ Clinician experts isolated, diseases complex
- ◆ Registry implementation: often a footnote

◆ ***One Solution: Regionalization***

- ◆ *Share expertise across geography – obligation*
- ◆ Leadership, oversight, technical assistance – *use public health, network & implementation science strategies*

HRSA/MCHB Regional Structure

Mountain

Oregon Health Science University

Regional Directors & Administrators – 1990 mandate

Northern

Great Lakes Hemophilia

Great Lakes

Hemophilia of Michigan

New England

Mount Sinai – New York

MidAtlantic

Children's Hospital Philadelphia

Western/Region IX

Center for Inherited Blood Disorders









Southeast

Hemophilia of Georgia

Great Plains

University of Texas - Houston

140+ HTC's in US HTC Network

-  New England
-  MidAtlantic
-  Southeast
-  Great Lakes
-  Northern States
-  Great Plains
-  Mountain States
-  Western States

HRSA National Hemophilia Treatment Center Program

<http://mchb.hrsa.gov/programs/hemophilia/>

Leadership

Kathryn McLaughlin, MPH
Project Officer

Alisha Keehn, MPH
Chief, Genetic Services Branch



Emphases

- ◆ *Access to Regional Networks* of coordinated comprehensive care
- ◆ Evaluation (*e.g. registries*)
- ◆ Quality improvement
- ◆ Collaboration

Grant Funding: \$500K/year each region OR ~\$35K each HTC...AND
– access to 340B outpatient drug discount program

Regional Networks *Advance* Public Health Goals for Rare Disorders

PREVENTING CHRONIC DISEASE

PUBLIC HEALTH RESEARCH, PRACTICE, AND POLICY

Volume 13, E05

JANUARY 2016

ESSAY

Public Health and Rare Diseases: Oxymoron No More

Rodolfo Valdez, PhD; Lijing Ouyang, PhD; Julie Bolen, PhD

- **Surveillance** – geographic needs identified
- Health care - regional centers of clinical expertise – specialty access
- Regional provider networks - coordinate diagnosis, treatment & reimbursement
- Knowledge – regional networks & databases: share clinical expertise & long term monitoring

Registry Successes – uniform nationwide, longitudinal

- CDC Surveillance www.cdc.gov/hemophilia
- Hemostasis and Thrombosis Dataset
- National HTC Patient Satisfaction Survey
- Regional Comprehensive Care Data Set

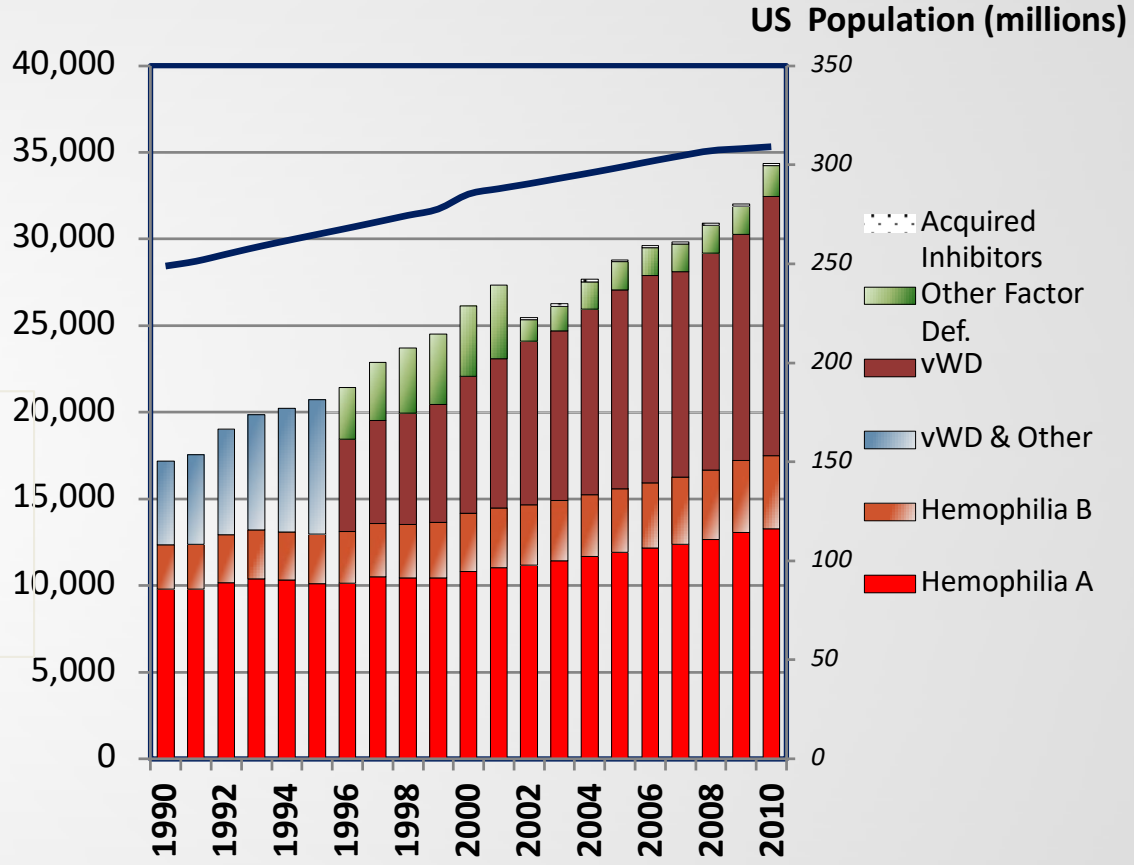
***Funding** – primarily 340B program income reinvested*

Data Quality – Regional Data Manager/Clinical Research Associate Working Groups

US HTC Network – 20 Year Trends – Hemostasis & Thrombosis Data Set

90% Increase in US HTC
Population 1990 – 2010

Females rose: >230%



US HTC Patient Population by Diagnosis
Baker, Haemophilia 2013

3rd US HTC Patient Satisfaction Survey

www.htcsurvey.com/results

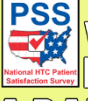
**SECOND
NATIONAL
SURVEY
COMPLETE**



**WHAT
DID WE
LEARN?**



**WHERE IS
INSURANCE
A BARRIER TO
CARE?**



**TEENS
REMAIN
SATISFIED**



**HOW DO
HTCs
HELP
ADOLESCENTS?**



**VOICES
OF
FEMALES
WITH VON
WILLEBRAND
DISEASE**



**OVER
5000
RESPOND**



Each “PSS” ...

- ~5000 HTC patients
- > 90% of HTCs (n=>125)
- Results at US, Regional, HTC Levels

Received: 22 June 2020 | Revised: 31 August 2020 | Accepted: 22 September 2020

DOI: 10.1111/hae.14176

ORIGINAL ARTICLE

Haemophilia WILEY

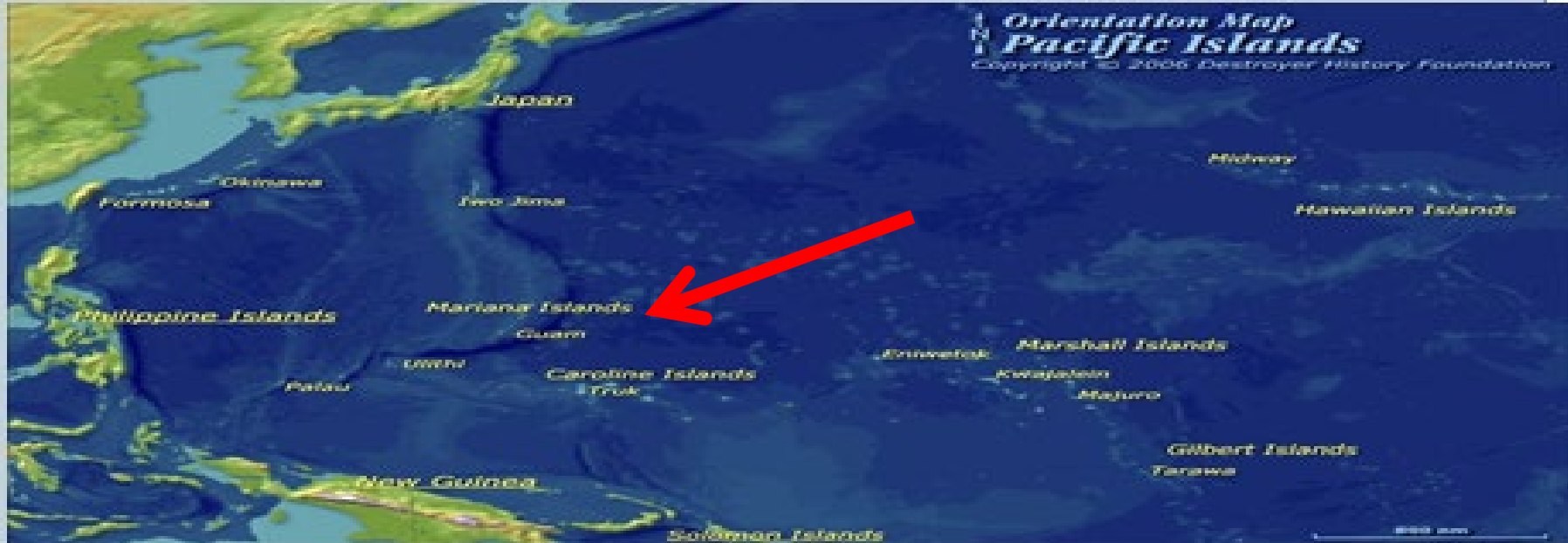
Check for updates

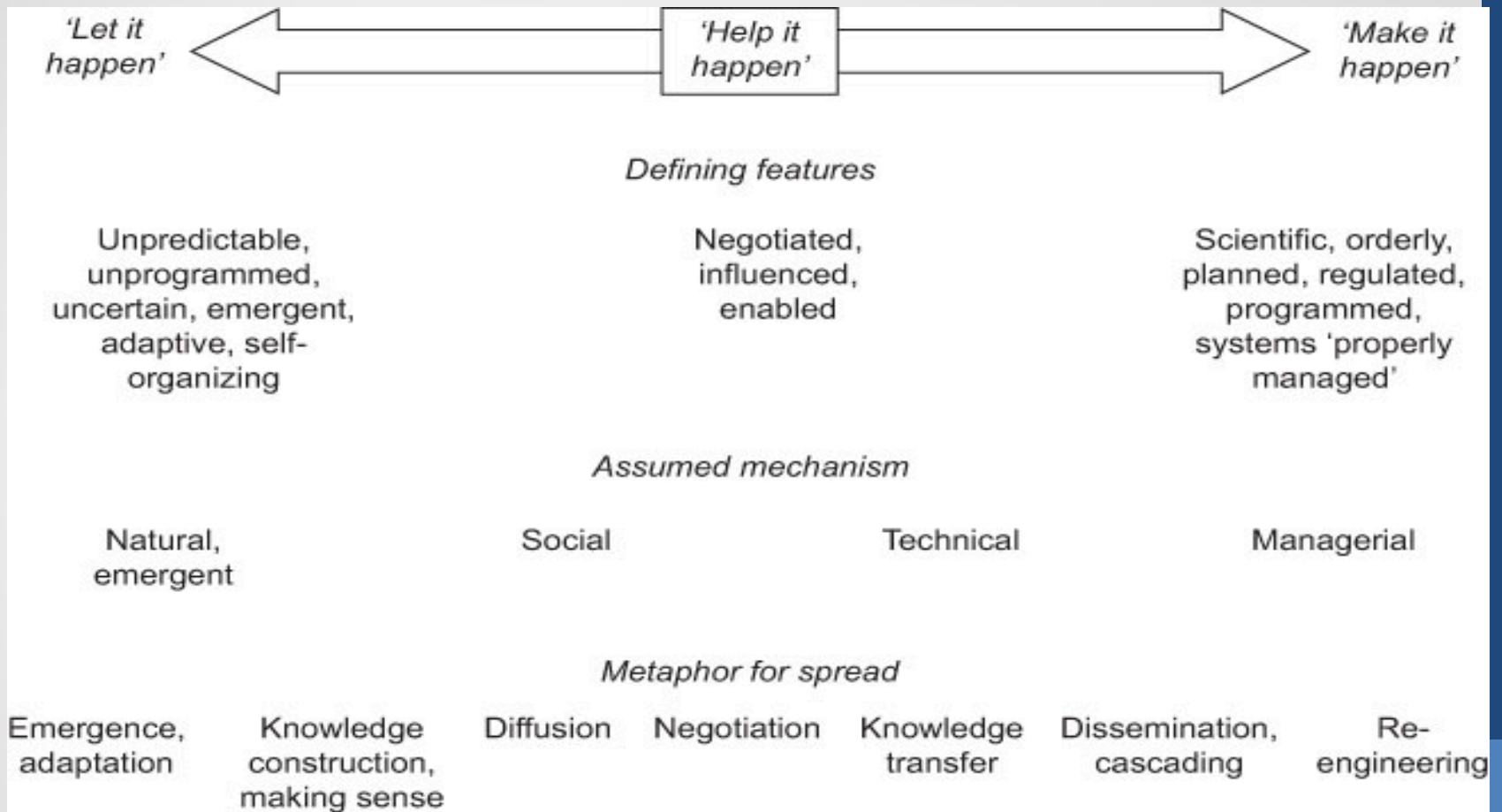
Patient satisfaction with US Hemophilia Treatment Center Care, Teams and Services: The First National Survey

Brenda Riske¹ | Rick Shearer¹ | Judith R. Baker²

How to implement registries in...Guam?

- Halfway between Australia and Japan
- Same Time Zone as Sydney





Greenhalgh et al. *Millbank Quarterly* 2004. Conceptual framework for the spread of innovations in service organizations

Framework for Creating a Regional Healthcare System



Collective Impact Model

Commitment of a group of actors from different sectors to a common agenda for solving a complex social problem.

Kania, Stanford Social Innovation Review 2011

Transform - Tactics

Common Agenda

- Keeps all parties moving towards the same goal

Common Progress Measures

- Measures that get to the TRUE outcome

Mutually Reinforcing Activities

- Each expertise is leveraged as part of the overall

Communications

- This allows a culture of collaboration

Backbone Organization

- Takes on the role of managing collaboration

Successful Networks

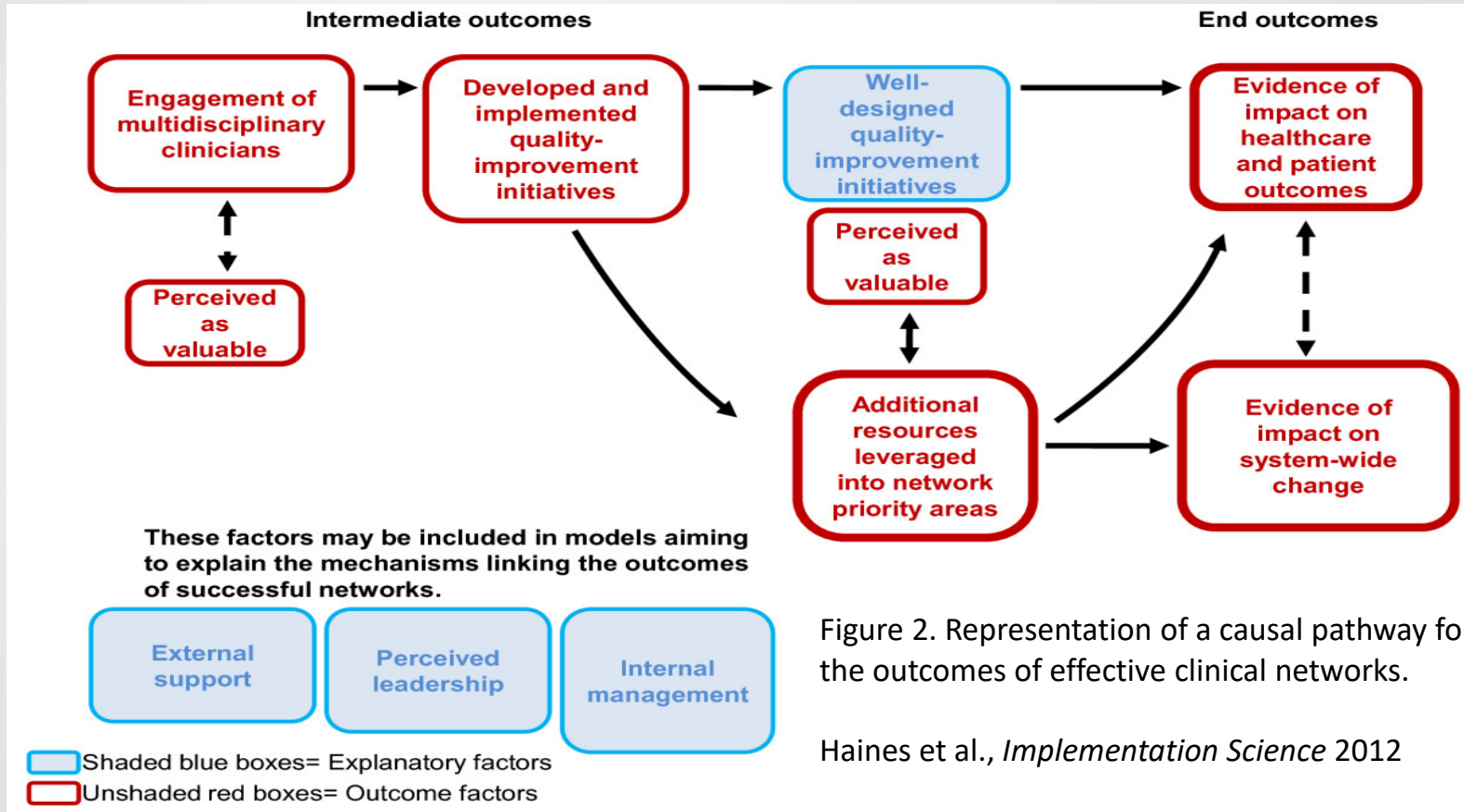


Figure 2. Representation of a causal pathway for the outcomes of effective clinical networks.

Haines et al., *Implementation Science* 2012

Consolidated Framework for Implementation Research - CFIR

Common language for
the context of
implementation:
Internal and external

Damschroder et al *Implementation Science* 2009

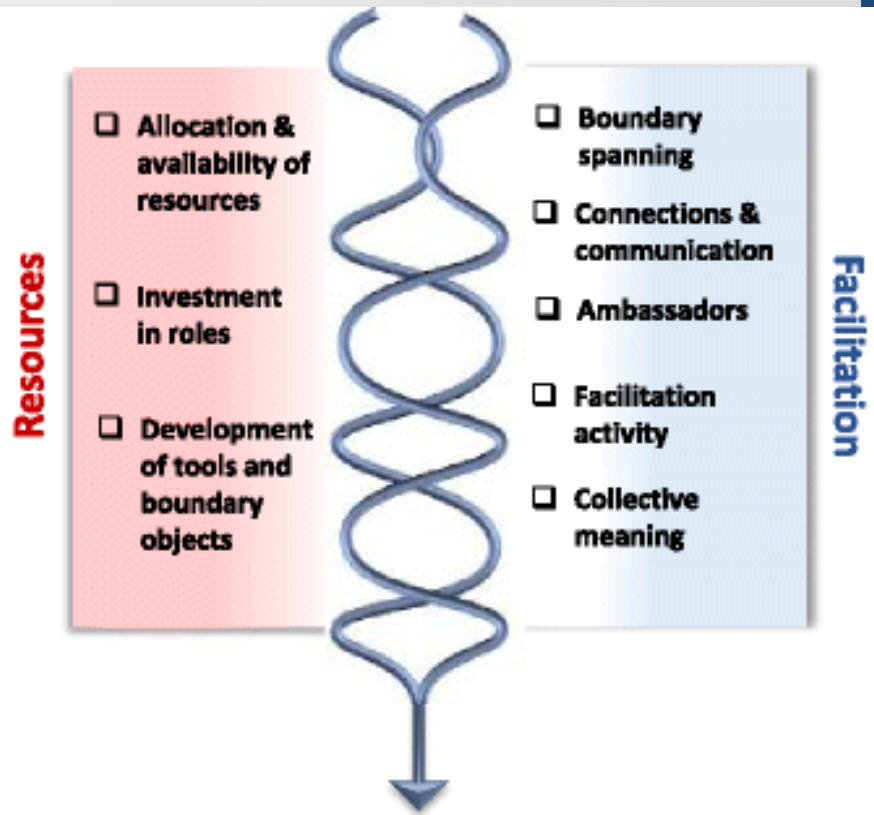
Domains = 5	Constructs = 26
<u>Intervention</u> Characteristics	<u>Intervention</u> Source Evidence Strength and Quality Relative Advantage Adaptability Triability Complexity Design Quality and Packaging Cost
Outer Setting	Patient Needs and Resources Cosmopolitanism Peer Pressure External Policy and Incentives
Inner Setting	Structural Characteristics Networks and Communications Culture <u>Implementation</u> Climate Readiness for <u>Implementation</u>
Characteristics of Individuals	Knowledge and Beliefs About the <u>Intervention</u> Self-Efficacy Individual Stage of Change Individual Identification With Organization Other Personal Attributes
<u>Process</u>	Planning Engaging Executing Reflecting and Evaluating

Boundary spanning – key to structuring effective collaborations

Interplay of resources and facilitation.

Credible individuals → cross boundary work, facilitation and direct impacts.

Example: Hemophilia Regional Directors & Administrators



Spanning Boundaries

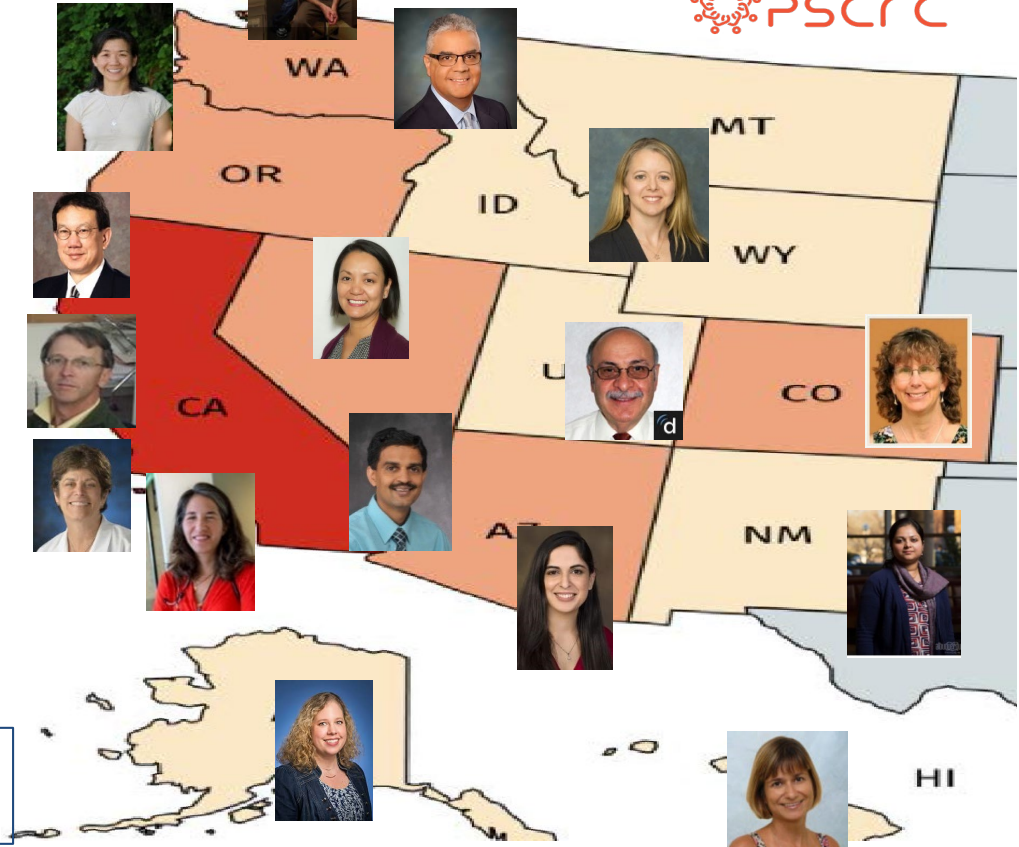
HRSA – 2014 – Regionalizes Sickle Cell Treatment Demonstration Project Grants

CIBD / SCDF Leads

SCDF Community Based-Organization Lead



Clinical Partners



CBOs - Oregon, Arizona, Colorado, and Nevada



Jeffrey Smith Adult Sickle Cell Clinic at MLK Jr Outpatient Center

Los Angeles, CA (EST 2016)

THE CARE YOU'VE ALWAYS WANTED!

Ellen Rothman, MD, Chief Medical Officer
Susan Claster, MD, Clinic Director
Anthony Wells, Community Health Worker



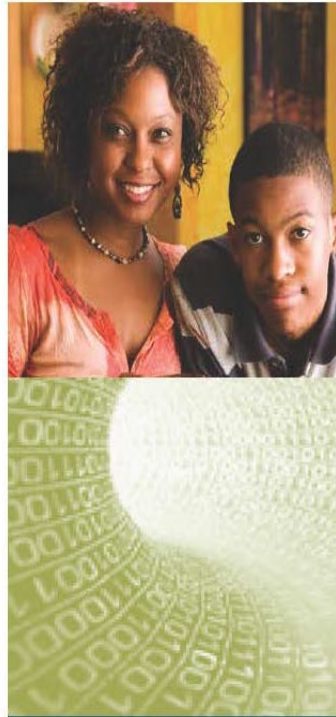
Why Los Angeles?

51% of Californian adults with SCD live in L.A.

*SCD mortality higher in L.A. than rest of the country**

No comprehensive clinic besides Kaiser

*Powars *Medicine* 2005



Longitudinal Data Collection
for Sickle Cell Disease in California:
History, Goals and Challenges



Addressing the Need: California State Action Plan 2018

California Sickle Cell Action Plan 2018 Executive Summary



Prepared by California Sickle Cell Stakeholders under the leadership of the Pacific Sickle Cell Regional Collaborative. For more information visit pacificscd.org or casicklecell.org



Late 2018, early 2019...

- Assembly member Mike Gipson – our champion.
- January 2019 – Draft legislation based on priorities in CA Sickle Cell State Action Plan.
- February 2019 – Mr. Gipson introduces AB 1105, establishing the policy framework.
- June 2019 - **\$15M funded** - part of Governor's Budget -3 years. Grant to CIBD and contract with Tracking California. ***Networking California for Sickle Cell Care***



Assemblymember, Mike Gipson

NCSCC - BUILDING CAPACITY IN MANY AREAS *SIMULTANEOUSLY*

Network of Clinics

**Two New Clinics
in Year 1**

*Of at least 5
Centers for
Californians with
Sickle Cell
Disease*

**Nearly 10 clinics
- Year 2**

Workforce

Education

Mini-Credential
for APP Students

Lecture Series
for license
Clinicians

Bootcamp
Tele-mentoring
Clinical rotations

Community Health
Worker

Surveillance & Data

**Expand
surveillance**

to better
characterize
trends statewide

Outreach & Education

**Enhance
Outreach &
Education**

RFAs



Networking California
for Sickle Cell Care

Networking California for Sickle Cell Care

Year 1 Report



Section Titles	Subsection Titles	Page Number(s)
Executive Summary		3-4
Introduction		5
Clinical Networks	I. Meetings with Potential Clinics	5-6
	II. Identification of Adult sickle cell disease Clinics	6
	III. Expansion of Telemedicine Services	6
	IV. Setting up a SCD clinical Hub and Spoke model	6-7
Work Force Development	I. Hemoglobin Trait Counselor Training	7
	II. Pilot of a Mini-Credential Course	8
	III. CIBD Serves as Clinical Rotation Site	8
	IV. Expanding Mini-Credential Course to APPs	8-9
	V. SCD Education to Practicing Physician Assistants statewide	9
	VI. Development and Commencement of CHW Training	9
Surveillance & Data Collection	I. Real World Evidence Project	9-10
	II. SCDF Acquired Penelope, a Case Management Software	10
	III. Data Think Tank	10
	IV. Surveillance with Public Health Institute's Tracking California	10-11
Outreach and Education	I. Onboarding of Community Based Organizations	11-12
	II. Call for Grants	12-13
	III. NCSCC Website Launched	13-14
	IV. Strengthened Newborn Screening Follow-Up Services	14
	V. Strengthening the SCD Transition Program in Los Angeles	15
	VI. NCSCC Innovations in Healthcare Delivery	15
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Conclusion		16
Partner Organizations		17
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Regionalization –

‘10 Essential Public Health Services’

Registries succeed in this context



<https://www.cdc.gov/stltpublichealth/publichealthservices/essentialhealthservices.html>

Take Aways

Invest in regional approach for capacity & sustainability

Practical innovation to promote rare heritable disorder healthcare delivery and registries

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THANK YOU!



**Federal Hemophilia
Treatment Centers**
California+Hawaii+ Nevada+Guam

30



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CIBD
Center For Inherited
Blood Disorders