Panel 1: Setting the Stage for Dissemination and Implementation

Please submit questions for the panelists to:
PragClinTrialsWkshp@nih.gov

Dissemination Concepts from the ABATE Infection Trial

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Disclosures

Conducting clinical studies in which participating hospitals and nursing homes are receiving contributed antiseptic product from Sage Products, Molnlycke, 3M, Clorox, and Xttrium

Contributing companies have no role in the design, conduct, analysis or publication of these studies.

ABATE Infection Trial
Active Bathing to Eliminate Infection

Trial Design

- 2-arm cluster randomized trial
- 53 HCA hospitals and 194 adult non critical care units
- Includes: adult medical, surgical, step down, oncology
- Excludes: rehab, psych, peri-partum, BMT

Arm 1: Routine Care

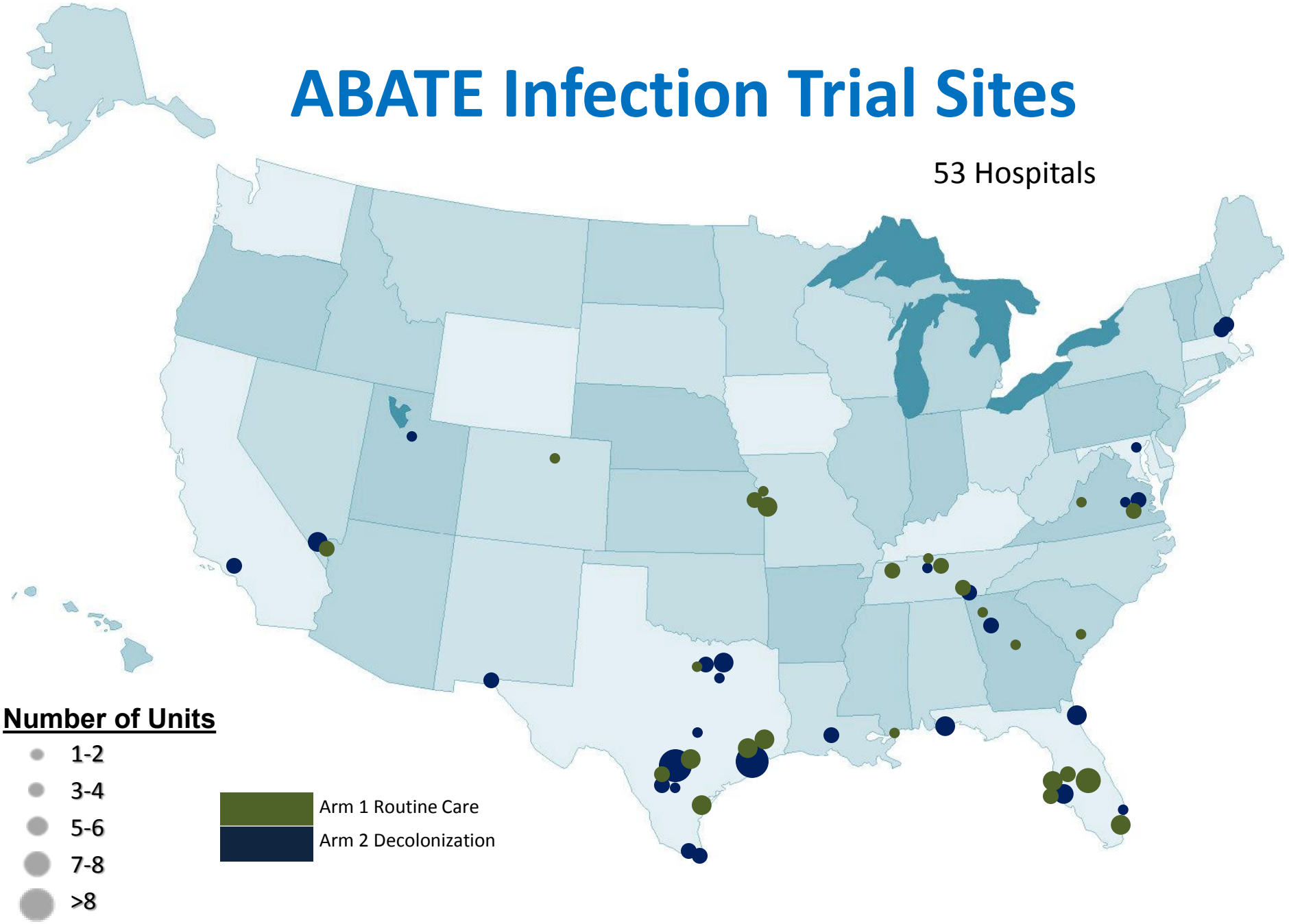
- Routine policy for showering/bathing

Arm 2: Decolonization

- Daily CHG shower or CHG cloth bathing routine for all patients
- Mupirocin x5 days if MRSA+ by history, culture, or screen

ABATE Infection Trial Sites

53 Hospitals



Outcomes

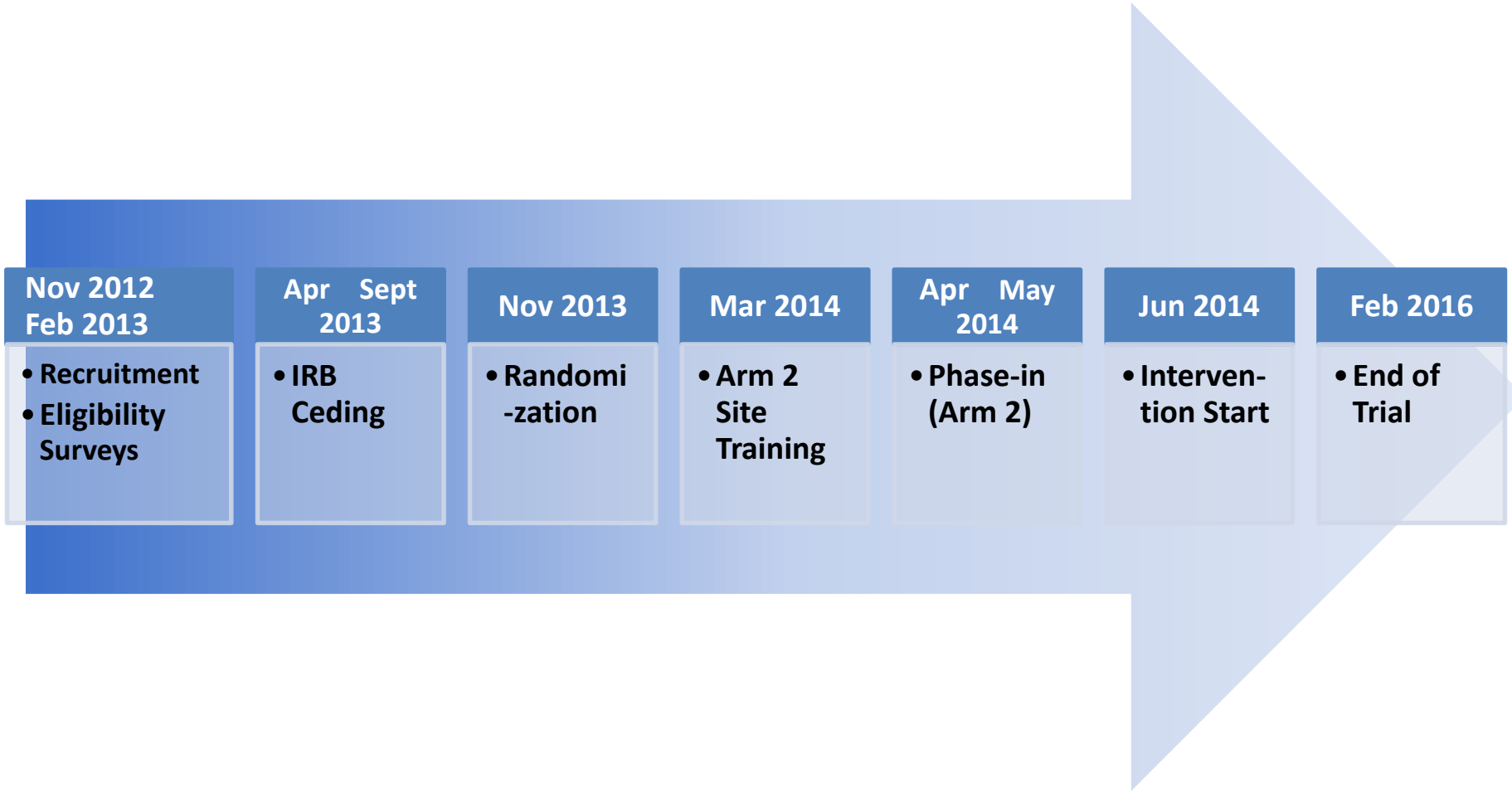
Primary Outcomes

- Unit-attributable clinical cultures with MRSA and VRE

Additional Outcomes

- Bloodstream infections: all pathogens
- Bloodstream contaminants
- Unit-attributable clinical cultures with GNR MDRO
- Unit-attributable clinical cultures with *C. difficile*
- Urinary tract infections: all pathogens
- 30 day readmissions (total and infectious)
- Emergence of resistance (strain collection)
- Cost effectiveness

Trial Timeline



Prior Lessons on Dissemination

REDUCE MRSA Trial: Decolonization in ICUs

- 37% reduction in MRSA clinical cultures
- 44% reduction in bloodstream infections

Post-Publication Response

- Protocol inquiries
- Detailed implementation issues not in paper
  - Compatibility issues
  - Safety details
  - Making the case
- Alternative product questions

N Engl J Med 2013:368:2255-2265

AHRQ Website: Toolkit

Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

Health Care Information | For Patients & Consumers | For Professionals | For Policymakers | Research Tools & Data | Funding & Grants | Centers, Portfolios & Initiatives | News & Events | A A A

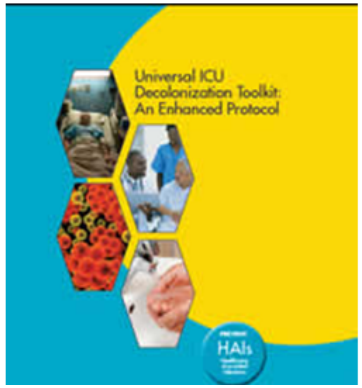
Home > For Professionals > Hospitals & Health Systems > Hospital Resources > Universal ICU Decolonization Protocol

Previous Page | Table of Contents | Download | Next Page

- Clinicians & Providers
- Education & Training
- **Hospitals & Health Systems**
  - Hospital Resources
    - Emergency Department Tools and Resources
    - Emergency Severity Index

Universal ICU Decolonization: An Enhanced Protocol

Publication # 13-0052-EF



Introduction and Welcome

This enhanced protocol is based on materials successfully used in the REDUCE MRSA Trial (**R**andomized **E**valuation of **D**ecolonization vs. **U**niversal **C**learance to **E**liminate Methicillin-Resistant *Staphylococcus aureus*), which found that universal decolonization was the most effective intervention. Universal decolonization led to a 37 percent reduction in MRSA clinical cultures and a 44 percent reduction in all-cause bloodstream infections.

http://www.ahrq.gov/professionals/systems/hospital/universal_icu_decolonization.html

Universal ICU Decolonization Toolkit: An Enhanced Protocol

PREVENT
HAIs
Healthcare-Associated Infections

AHRQ
Agency for Healthcare Research and Quality
Advancing Excellence in Health Care • www.ahrq.gov

Toolkit Contents

Contents

Appendixes

Scientific Rationale

Scientific Rationale

The Burden of Health Care-Associated Infections

Health care-associated infections (HAIs) are a significant cause of illness, death, and excess costs in all health care settings. They affect 1 out of every 20 hospital patients at any given time.[1] Some of the most serious HAIs are those that involve the bloodstream. HAIs also prolong hospitalizations and lead to readmissions.[2,3,4] Finally, patients with HAIs incur large costs, with average direct medical costs of approximately $500-$1,000 per urinary tract infection and $10,000-$20,000 per surgical site infection, central line-associated bloodstream infection, or pneumonia, all of which can be serious enough to incur bloodstream infection.[5]

Importance of the MRSA Subset of HAIs

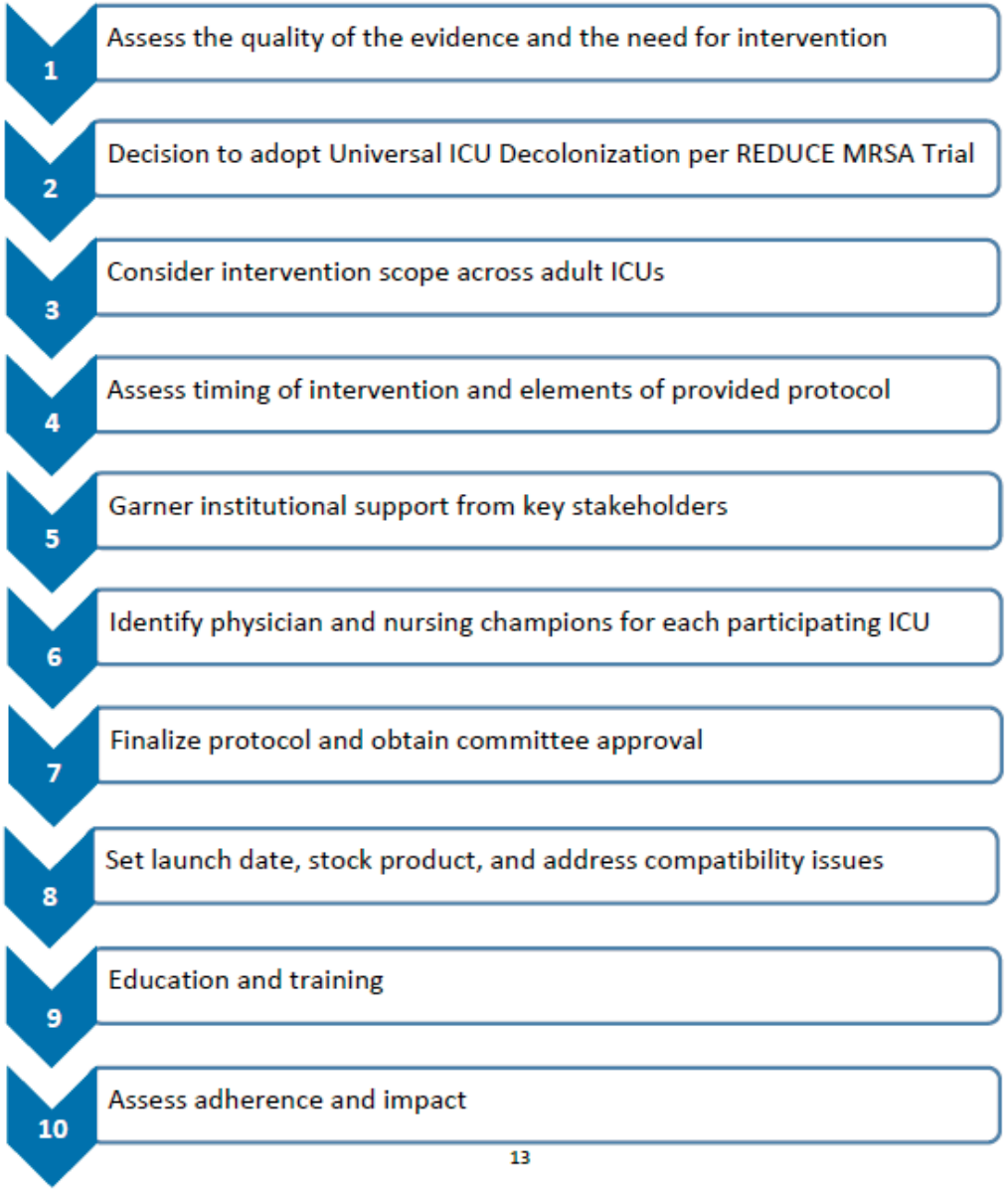
MRSA is arguably the most important single pathogen in health care-associated infection when accounting for virulence, prevalence, diversity of disease spectrum, and propensity for widespread transmission.[6,7,8,9]

Among HAIs in 2009-2010, *S. aureus* was the most common cause of health care-associated infections.[10] Also, it is the most common cause of ventilator-associated pneumonia and surgical site infection and the second most common cause of central-line associated bloodstream infections.[10] Notably, two-thirds of *S. aureus* HAIs were due to MRSA.

Pathogenesis and Preventability of Health Care-Associated Infections

The largest fraction of HAIs are caused by bacteria, such as MRSA, that reside on the skin and in the nose and gain access to the bloodstream, lungs, and bladder by way of devices and incisions that breach normal host defenses. These bacteria may be the patient's normal flora, or they may be new, often antimicrobial-resistant organisms acquired during hospitalization. Current evidence and expert opinion suggests that 65-70 percent of catheter-related bloodstream and urinary tract infections may be preventable.[11]

Appendix A. Steps for Implementing Universal Decolonization



Common Stakeholder Questions

Common stakeholder questions regarding universal decolonization should be anticipated. These include the following:

- **What is the evidence for universal decolonization?**
  See Appendix B.

- **What is the hospital's need for this intervention?**
  See earlier section on assessing the need for the intervention. The response to this question should include consideration of hospital rates of MRSA and bloodstream infection, national guidelines, regulation, and any relevant State legislation.

- **What is the cost of this intervention and how is it justified?**
  See the earlier section on developing a business case.

- **Who is supportive of this intervention?**
  Be prepared to demonstrate support from key stakeholders as described above.

- **Is universal decolonization just about reducing MRSA?**
  No. In fact, the REDUCE MRSA Trial found that the best strategy for reducing bloodstream infections due to all pathogens was universal decolonization consisting of

Appendix D. Universal ICU Decolonization Nursing Protocol

The following is a nursing protocol for adult ICUs implementing Universal Decolonization. The REDUCE MRSA Trial found a 44 percent reduction in all-cause bloodstream infections and a 37 percent reduction in MRSA clinical cultures when using this protocol as it is written. Modifications to this protocol may be done; however, variations may not achieve the same results as in the trial.

Key Elements

1. Daily chlorhexidine (CHG) bathing for duration of ICU stay.
2. 5-day mupirocin administration during ICU stay.
3. Cessation of ICU screening (if not required by law).

Detailed Protocol

For each adult ICU patient, each day:

1. Stop admission ICU screening (if not required by law).
2. Determine if any CHG exclusion criteria exist.
    a. CHG allergy.
3. Determine if any mupirocin exclusion criteria exist.
    a. Mupirocin allergy.
    b. Nasal packing or physical inability to use mupirocin.
4. Bathe patient with CHG daily, starting on day 1 of ICU admission, for entire ICU stay.
5. Administer mupirocin to patient twice a day, starting on day 1 of ICU admission, for 5 days or until ICU discharge (if prior to 5 days).
6. If patient is readmitted, restart the protocol for both CHG and mupirocin.
7. Stop protocol upon discharge or transfer from the ICU.

Frequently Asked Questions by Staff

Decolonization

1. **What is Universal Decolonization?**
   Your ICU will be decolonizing all patients with mupirocin and CHG. This will include applying nasal mupirocin twice daily for 5 days. You will be using CHG for all bathing needs (below the jawline) for the entire ICU stay.

2. **Do MRSA-negative patients receive decolonization?**
   MRSA-negative patients should also receive mupirocin and chlorhexidine. Prior ICU policies for preoperative patients should remain as before. This decolonization protocol applies to ALL ICU patients, regardless of their MRSA status.

3. **Should the protocol continue to be applied to ICU patients who are temporarily transferred out for radiologic or surgical procedures?**
   Yes. The protocol should continue for patients being transferred for procedures in radiology and surgery. Mupirocin and the daily CHG bath can be applied during the time when the patient is physically in the ICU. In the event the patient is incontinent and being sent to radiology, communicate that the patient is on this intervention and, if needed, use the standard clean up available in radiology (i.e. barrier cloths) and upon returning to the ICU use the protocol for incontinence clean up.

4. **Some ICU patients leave the ICU for a short time and return in less than 24 hours. When these patients return, does the mupirocin 5-day regimen pick up where they left off (e.g., Day 3) or start over at Day 1?**
   The protocol begins anew for each readmission, regardless of the duration of absence.

5. **Does Universal Decolonization affect the use of chlorhexidine for preoperative bathing?**
   No. If your hospital already has a policy for preoperative bathing with CHG, then this practice should continue.

6. **Does Universal Decolonization affect the use of skin preps before a surgical procedure?**
   No. Standard skin preps prior to a surgical procedure or for a bedside procedure should be utilized on patients. Presurgical or preprocedure preps with CHG plus alcohol or an iodophor-based solution plus alcohol are considered the standard of care.

7. **Some of the ICU patients can perform their own bed bath. What should be used and can the patient do it themselves?**

Universal ICU Decolonization

DO

- Use chlorhexidine (CHG) baths in place of daily bathing with soap and water.
- Massage firmly into skin to bind skin proteins and prevent bacteria for 24 hours.
- Give CHG baths every day for entire ICU stay.
- Use nasal mupirocin twice a day for 5 days of ICU stay.
- Only use CHG-compatible lotions.
- Restart entire protocol for readmitted ICU patients.
- Clean 6 inches of tubing closest to body.
- Use over superficial wounds, including stages 1 and 2 decubitus ulcers.

DON'T

- Do NOT use above jawline.
- Do NOT rinse or wipe off CHG. Let air dry.
- Do NOT flush CHG cloths (discard in trash, not toilet or commode).
- Do NOT continue protocol after ICU discharge.
- Do NOT include patients who are allergic to mupirocin and/or CHG.

Universal ICU Decolonization Protocol for CHG Bathing

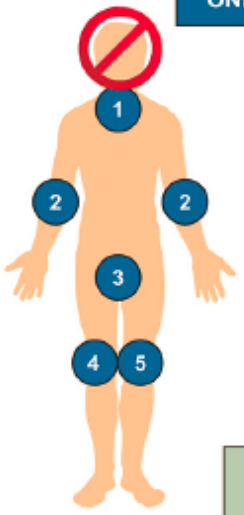
- Chlorhexidine gluconate (CHG) replaces routine bathing for entire ICU stay.
- Do NOT use soap below the jawline. Certain soaps and lotions can inactivate CHG.
- Only use CHG-compatible lotions and/or barrier products.
- Dispose of all cloths in the trash. Do NOT flush.

BATHE WITH CHG USING FIRM MASSAGE TO REMOVE BACTERIA

INCONTINENCE:
- Clean with chux and water, NOT soap.
- Then bathe with CHG cloths, air dry.
- Use as many CHG cloths as needed.
- Apply CHG compatible barrier.
- Repeat throughout the day, as needed.

LINES AND TUBES:
- CHG is safe on lines, tubes, and devices.
- Bathe with CHG right up to dressing.
- Okay to bathe over occlusive dressings.
- After bathing skin, clean 6 inches of tubes/Foley nearest patient.

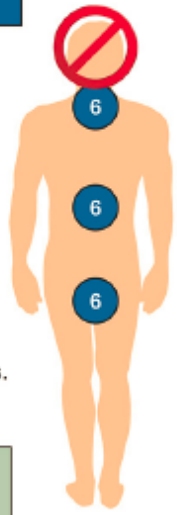
ONLY USE CHG CLOTHS *BELOW* THE JAWLINE



Front

1. Neck, shoulders, and chest.
2. Both arms and hands.
3. Abdomen then groin and perineum.
4. Right leg and foot.
5. Left leg and foot.
6. Back of neck, back, and then buttocks.

Skin may feel sticky for a few minutes.
Do NOT wipe off. Allow to air dry.

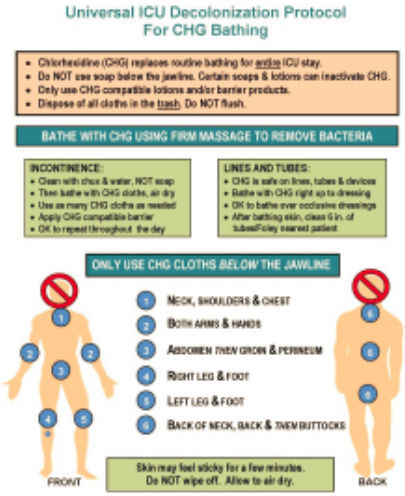


Back

Universal ICU Decolonization

Just in Time Training

1. **STOP all admission MRSA screens unless screening is required by law or surgical protocol.**
2. **Continue to place patients known to be MRSA-positive in contact isolation.**
3. **Decolonization Protocol:**
   - Mupirocin ointment twice a day for 5 days only.
   - Chlorhexidine (CHG) bathing cloths for ALL bathing needs for entire ICU stay.
   - Decolonization stops when patient is discharged or transferred out of the ICU.
   - If readmitted or transferred to a participating ICU, protocol begins anew.
4. **How to Bathe:**
   - You should be assigned an RN trained on the universal decolonization protocol for bathing to oversee this process (buddy system).
   - A CHG bathing wall poster is posted in each ICU room (see image below).
   - Only use CHG cloths below the jawline.
   - Let air dry. Do NOT wipe or rinse off.
   - Do NOT flush cloths. Discard in trash.
   - Do NOT use soap (can inactivate CHG).
   - For incontinence, clean debris with chux (water if needed), cleanse with CHG cloth, and then use CHG-compatible barrier product.



_____ **Please return completed form to the Unit Charge Nurse**

Signature

_____ _____ _____/_____/_____

Print Last Name **Print First Name** **Date**

Appendix F. CHG Bathing Skills Assessment

Please record your observations when monitoring a patient being bathed with CHG.

Observed CHG Bathing Practices

Please circle your answer:

Y	N		Cleanses entire neck area well including skin folds and around lines.
Y	N		Massages skin *firmly* with CHG cloth to ensure adequate cleansing .
Y	N		States rationale for not using soap below jaw line at any time.
Y	N		Uses all six cloths and more if needed.
Y	N		Cleans armpit and back of knee well.
Y	N		Cleans in between toes and fingers.
Y	N		Cleans between all folds in perineal and gluteal area.
Y	N		Wipes occlusive and semi-permeable dressing with CHG cloth.
Y	N		Cleans tubing, lines, and drains closest to body (after emptying drains).
Y	N		Bathing is completed with no skin below jaw line missed.
Y	N	N/A	Uses CHG on superficial wounds, rash, and stage 1 & 2 decubitus ulcers.
Y	N	N/A	Uses on closed surgical wounds.
Y	N		Allows to air dry/does not wipe off CHG.
Y	N		CHG bathing documented.

Queries to Bathing Assistant/Nurse

1. Do you ever use soap in conjunction with a CHG bathing cloth? If so, when?

_____

2. Do you reapply CHG after an episode of incontinence?

_____

3. If a patient needs freshening up/second bath, do you use CHG cloths or a different product?

_____

4. Are you comfortable applying CHG to superficial wounds?

_____

5. Are you comfortable applying CHG to stage 1 & 2 decubitus ulcers?

_____

6. Are you comfortable applying CHG to closed surgical wounds?

_____

7. Do you ever wipe off the CHG after bathing?

_____

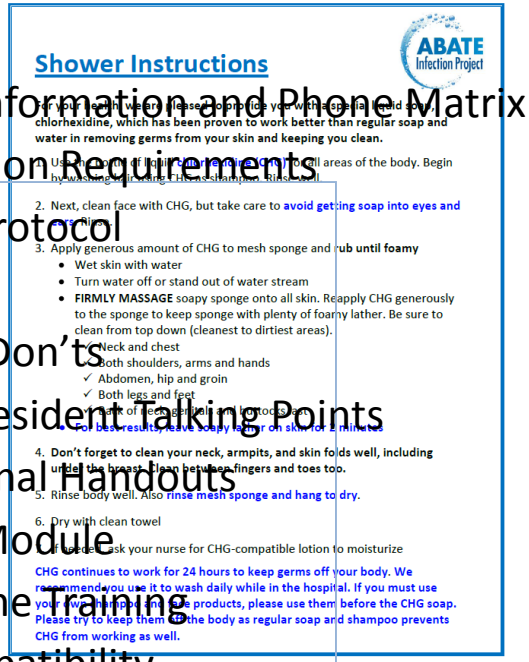
Translation Outside of ICUs

Anticipated Differences and Problems

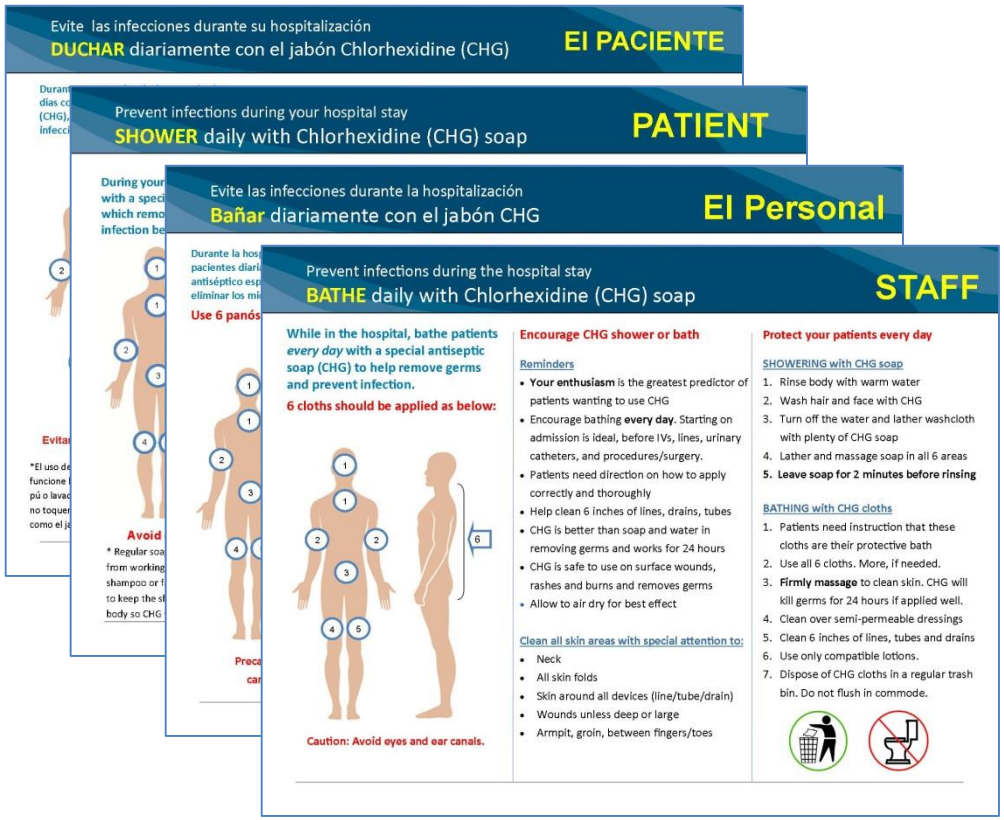
- Lower risk population
- Less standardized than ICUs
- Diverse types, variable practices
- Not used to daily bathing
- More patients per nurse
- Nurses don’t do the bathing, higher staff turnover
- Training is harder, empowerment is harder
- No bathing documentation
- Larger population, higher inventory and costs
- Patients are awake

Educational Materials

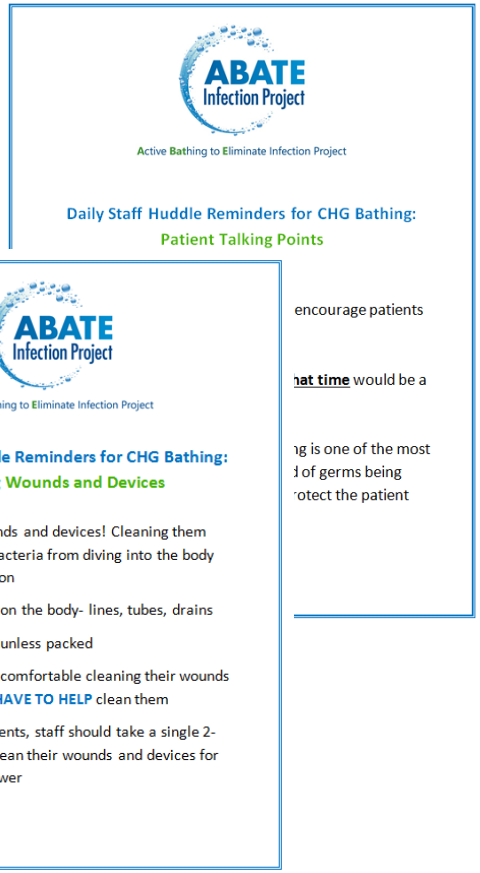
- Contact Information and Phone Matrix
- Participation Requirements
- Nursing Protocol
- FAQ
- Do's and Don'ts
- Patient/Resident Talking Points
- Instructional Handouts
- Training Module
- Just in Time Training
- CHG Compatibility
- Safety and Side Effects
- Compliance Documentation



Educational Materials

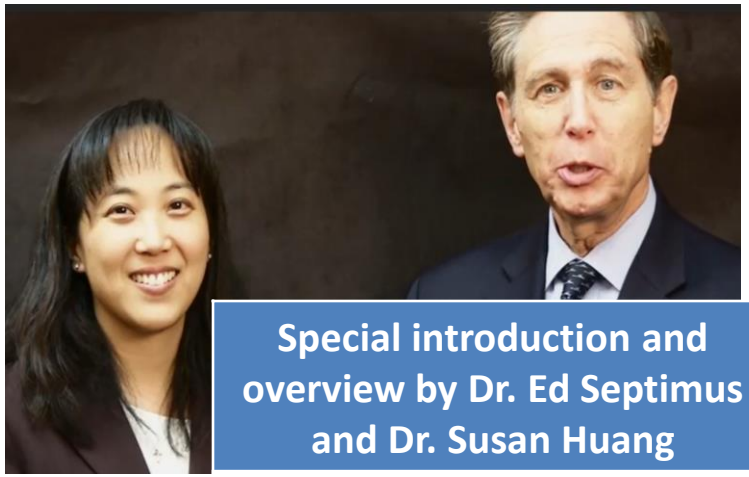


Instructional Handouts Provided in English and Spanish

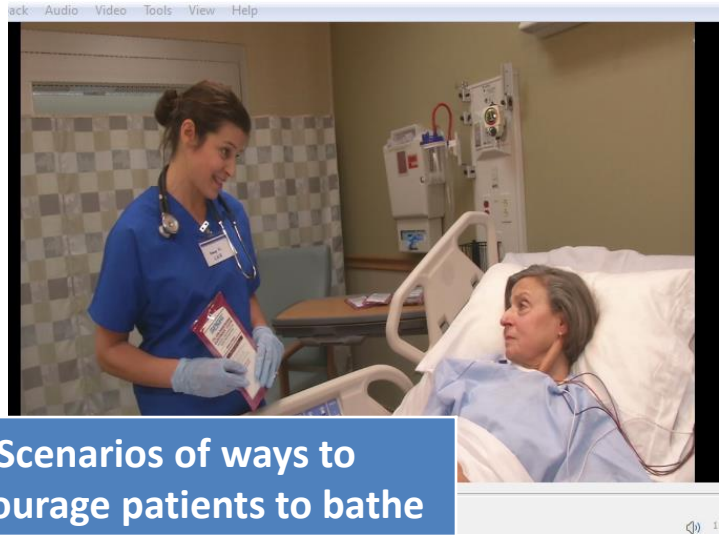


Huddle Documents Covering 14 Topics

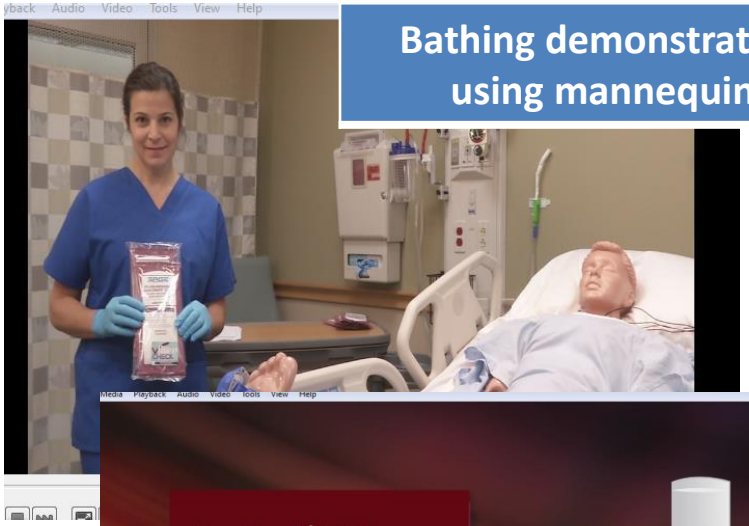
Training Video



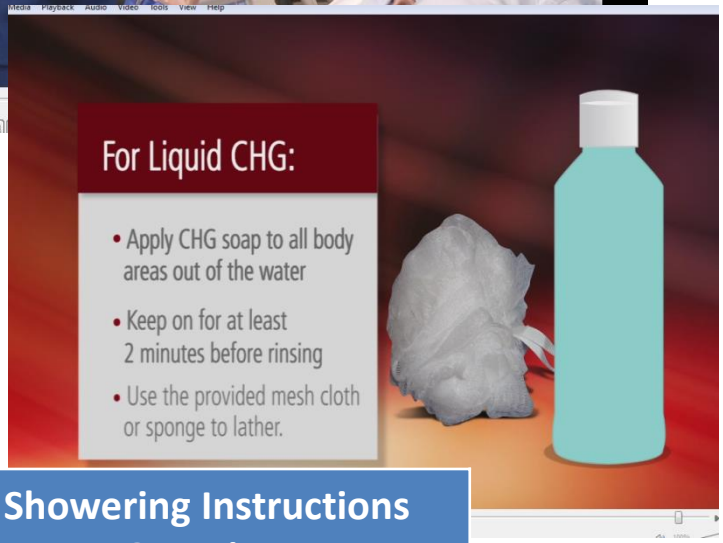
Special introduction and overview by Dr. Ed Septimus and Dr. Susan Huang



Scenarios of ways to encourage patients to bathe

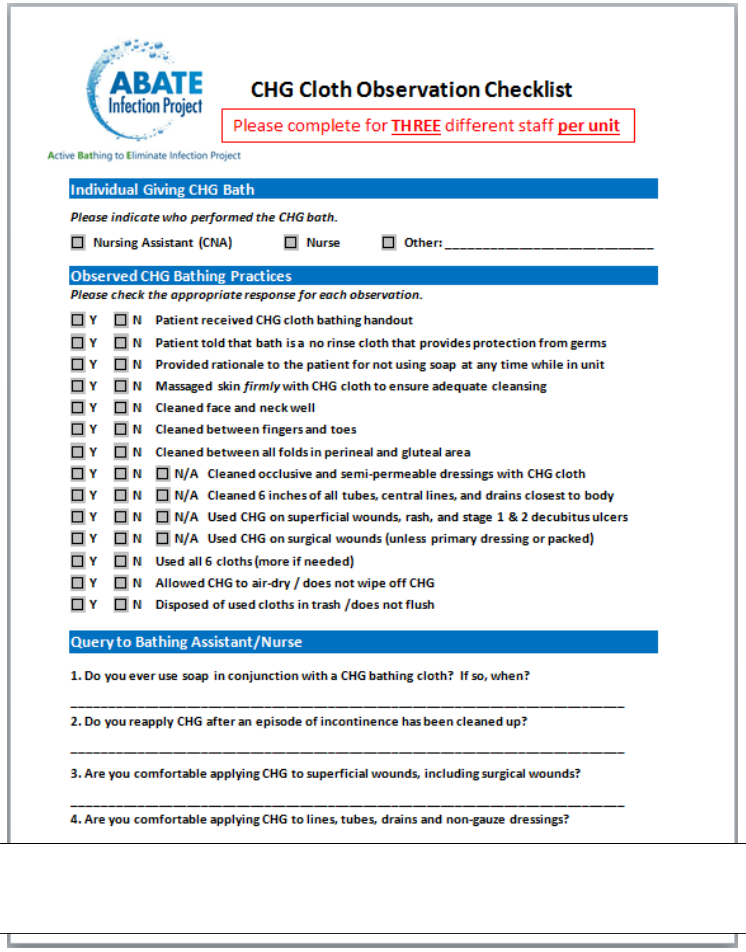


Bathing demonstration using mannequin



Showering Instructions Overview

Quarterly Staff and Patient Compliance Assessments



ABATE Infection Project

Active Bathing to Eliminate Infection Project

CHG Cloth Observation Checklist

Please complete for THREE different staff per unit

Individual Giving CHG Bath

Please indicate who performed the CHG bath.

☐ Nursing Assistant (CNA) ☐ Nurse ☐ Other: _____

Observed CHG Bathing Practices

Please check the appropriate response for each observation.

☐ Y ☐ N Patient received CHG cloth bathing handout
☐ Y ☐ N Patient told that bath is a no rinse cloth that provides protection from germs
☐ Y ☐ N Provided rationale to the patient for not using soap at any time while in unit
☐ Y ☐ N Massaged skin *firmly* with CHG cloth to ensure adequate cleansing
☐ Y ☐ N Cleaned face and neck well
☐ Y ☐ N Cleaned between fingers and toes
☐ Y ☐ N Cleaned between all folds in perineal and gluteal area
☐ Y ☐ N ☐ N/A Cleaned occlusive and semi-permeable dressings with CHG cloth
☐ Y ☐ N ☐ N/A Cleaned 6 inches of all tubes, central lines, and drains closest to body
☐ Y ☐ N ☐ N/A Used CHG on superficial wounds, rash, and stage 1 & 2 decubitus ulcers
☐ Y ☐ N ☐ N/A Used CHG on surgical wounds (unless primary dressing or packed)
☐ Y ☐ N Used all 6 cloths (more if needed)
☐ Y ☐ N Allowed CHG to air-dry / does not wipe off CHG
☐ Y ☐ N Disposed of used cloths in trash /does not flush

Query to Bathing Assistant/Nurse

1. Do you ever use soap in conjunction with a CHG bathing cloth? If so, when?

_____

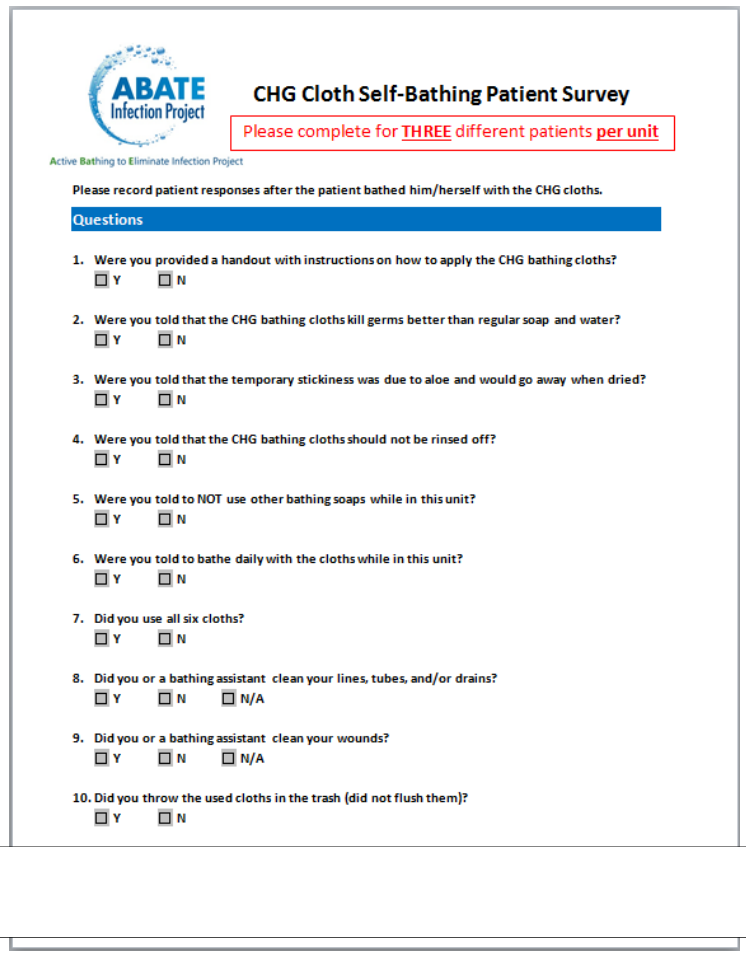
2. Do you reapply CHG after an episode of incontinence has been cleaned up?

_____

3. Are you comfortable applying CHG to superficial wounds, including surgical wounds?

_____

4. Are you comfortable applying CHG to lines, tubes, drains and non-gauze dressings?



ABATE Infection Project

Active Bathing to Eliminate Infection Project

CHG Cloth Self-Bathing Patient Survey

Please complete for THREE different patients per unit

Please record patient responses after the patient bathed him/herself with the CHG cloths.

Questions

1. Were you provided a handout with instructions on how to apply the CHG bathing cloths?
☐ Y ☐ N

2. Were you told that the CHG bathing cloths kill germs better than regular soap and water?
☐ Y ☐ N

3. Were you told that the temporary stickiness was due to aloe and would go away when dried?
☐ Y ☐ N

4. Were you told that the CHG bathing cloths should not be rinsed off?
☐ Y ☐ N

5. Were you told to NOT use other bathing soaps while in this unit?
☐ Y ☐ N

6. Were you told to bathe daily with the cloths while in this unit?
☐ Y ☐ N

7. Did you use all six cloths?
☐ Y ☐ N

8. Did you or a bathing assistant clean your lines, tubes, and/or drains?
☐ Y ☐ N ☐ N/A

9. Did you or a bathing assistant clean your wounds?
☐ Y ☐ N ☐ N/A

10. Did you throw the used cloths in the trash (did not flush them)?
☐ Y ☐ N

Dissemination Summary

- “How to Guides” are essential for dissemination
- Brief and visually appealing
- Cover several facets
- Flyers, videos, postings
- Integrate into work flow, approval processes
- Editable
- Tailored for target population (patients and staff)
- Free

Setting the Stage for Sustainable Implementation: Lessons Learned from A Decade of US Trauma Care System Pragmatic Trials

Douglas Zatzick, MD
Professor Department of Psychiatry & Behavioral Sciences
University of Washington School of Medicine

Funded by Grant UH3 MH106338-02

NIH Collaboratory *Rethinking Clinical Trials®*
Health Care Systems Research Collaboratory

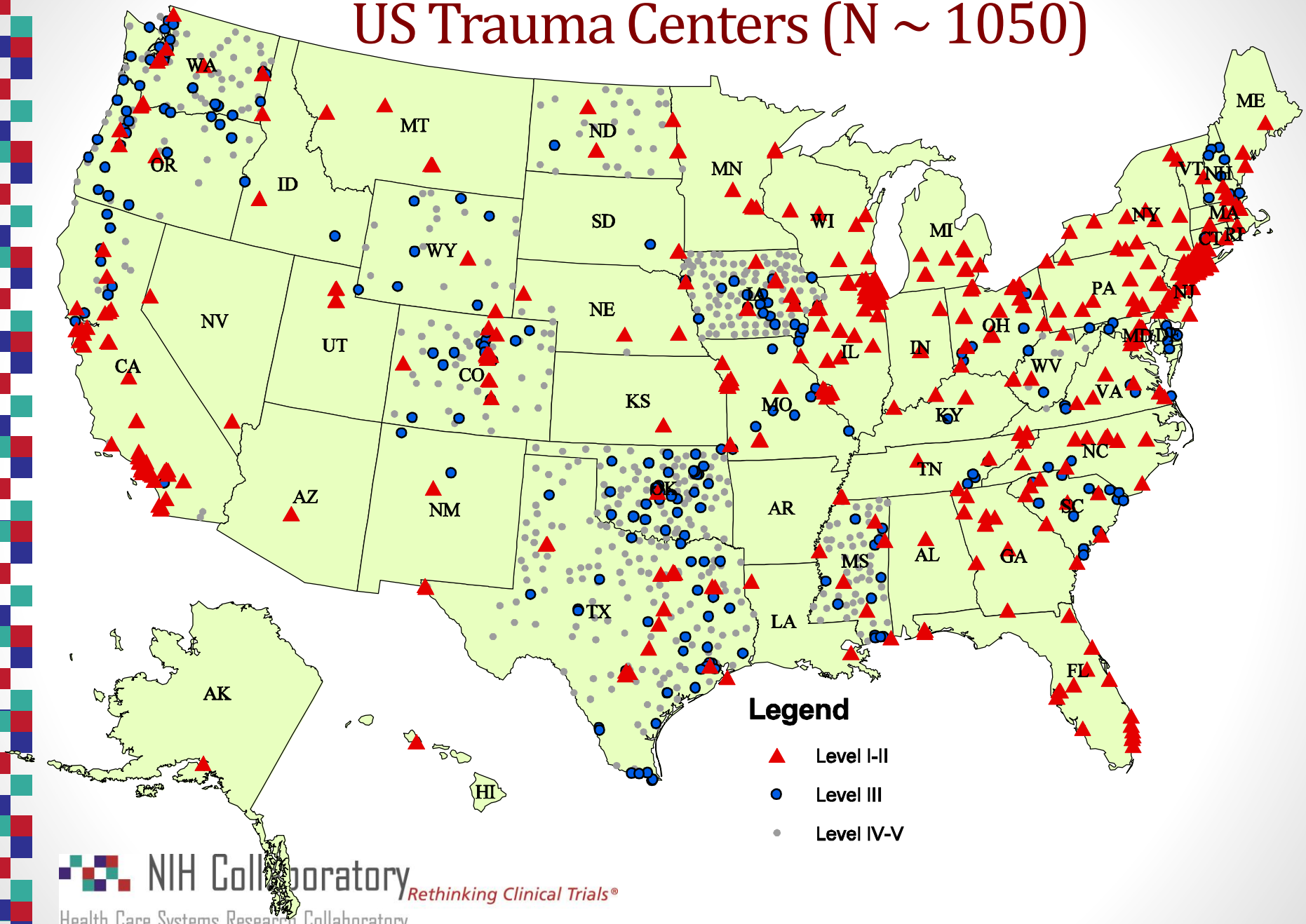
Overview

- TSOS pragmatic trial aims & design
- Background: Heterogeneity in US trauma care
- Preparing for the trial: Up-front incorporation of implementation science frameworks
- Preparing for the trial: Harnessing American College of Surgeons' policy momentum
- Trial roll-out: Integrating implementation science and pragmatic trial methods
- Summary of lessons learned and discussion

TSOS Aims & Study Design

- Research Question: Can a trauma center-based multicomponent intervention reduce PTSD and comorbidity after physical injury?
- 25 US level I trauma centers
- Stepped wedge cluster randomized trial
- Front-line providers at each site trained
- 40 patients per site
- Baseline PTSD & comorbidity medical record screen
- 3, 6 and 12 month follow-up assessments

US Trauma Centers (N ~ 1050)



NIH Collaboratory *Rethinking Clinical Trials®*

Health Care Systems Research Collaboratory

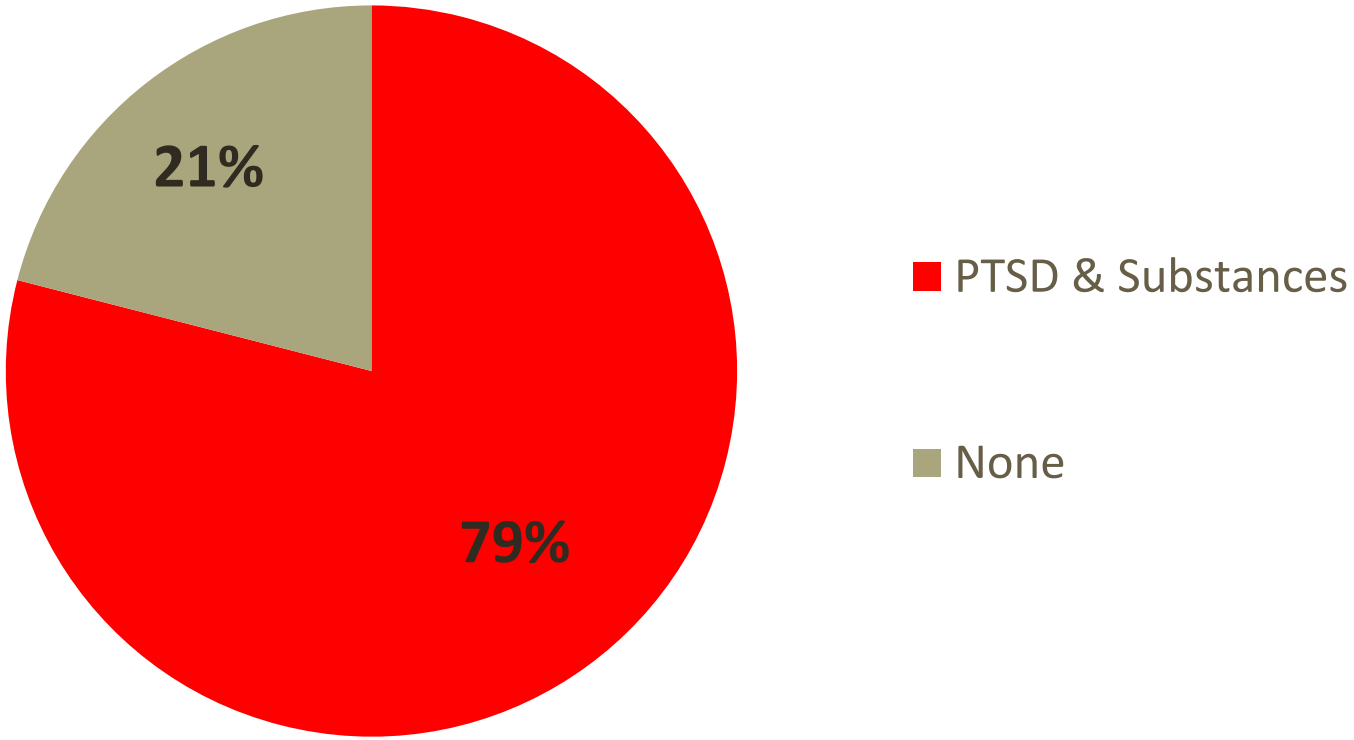
Background: Trauma Care System Patient, Provider & Setting Level Heterogeneity

Paramedic/
Pre-Hospital

Emergency &
Trauma Center

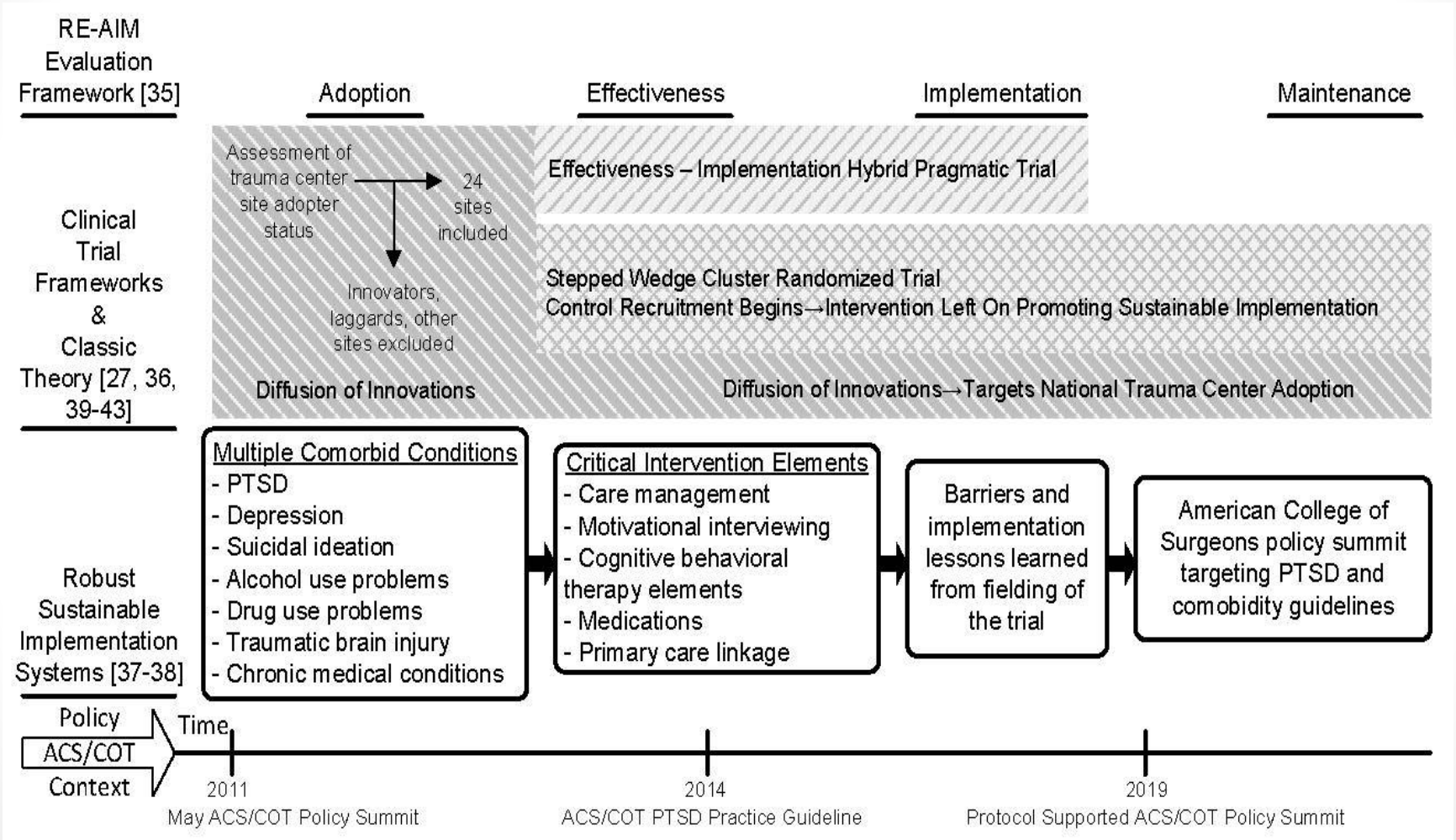
Primary
Care and
Community

Co-morbidity: PTSD, Depression, Suicidal Ideation, TBI & Alcohol and Drug Use Problems Among Randomly Selected Trauma Surgery Inpatients (N=878)



NIH Collaboratory *Rethinking Clinical Trials®*
Health Care Systems Research Collaboratory

Preparing for the Trial: Up-front Incorporation of Implementation Science Frameworks



NIH Collaboratory Rethinking Clinical Trials®
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From: Zatzick, Russo, Darnell, Chambers, Palinkas, Van Eaton, Wang, Ingraham Guiney, Heagerty, Comstock, Whiteside, & Jurkovich: *Implementation Science* 2016

Preparing for the trial: "Make It Happen" Research to Policy Partnership with The American College of Surgeons (Greenhalgh et al 2004, Milbank Quarterly)

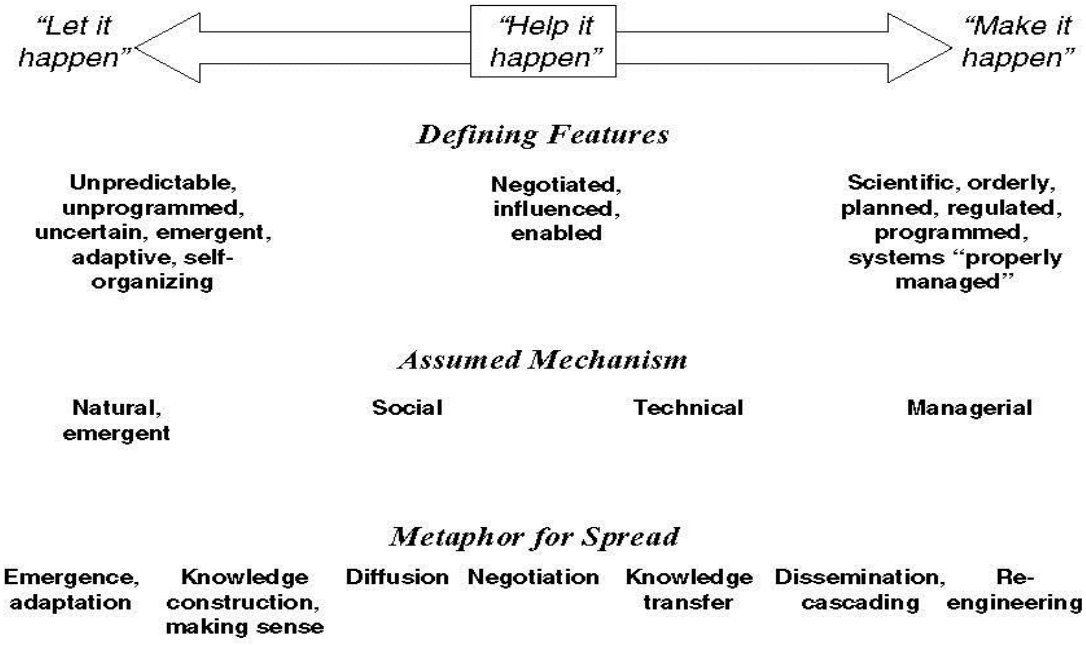
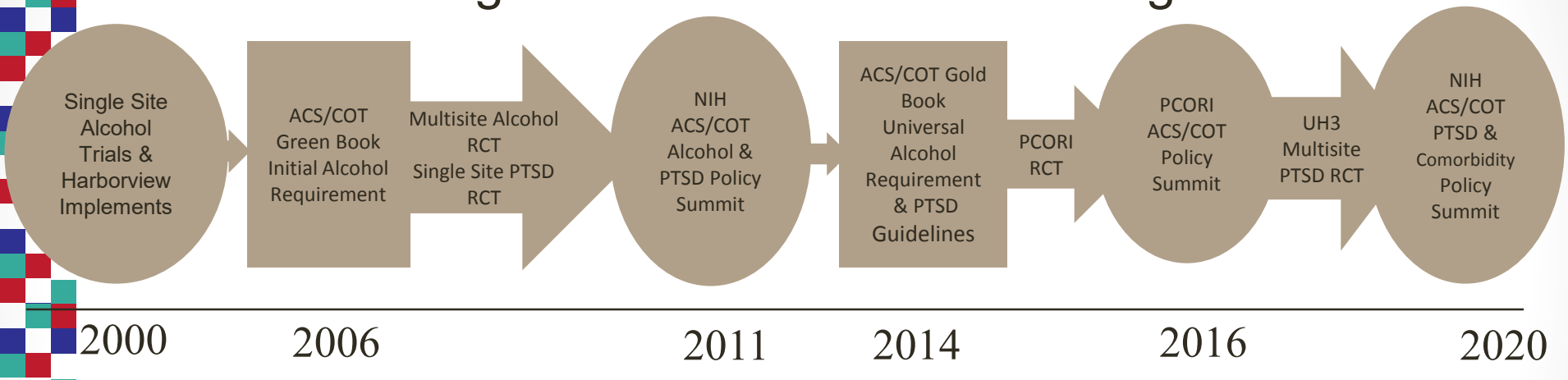


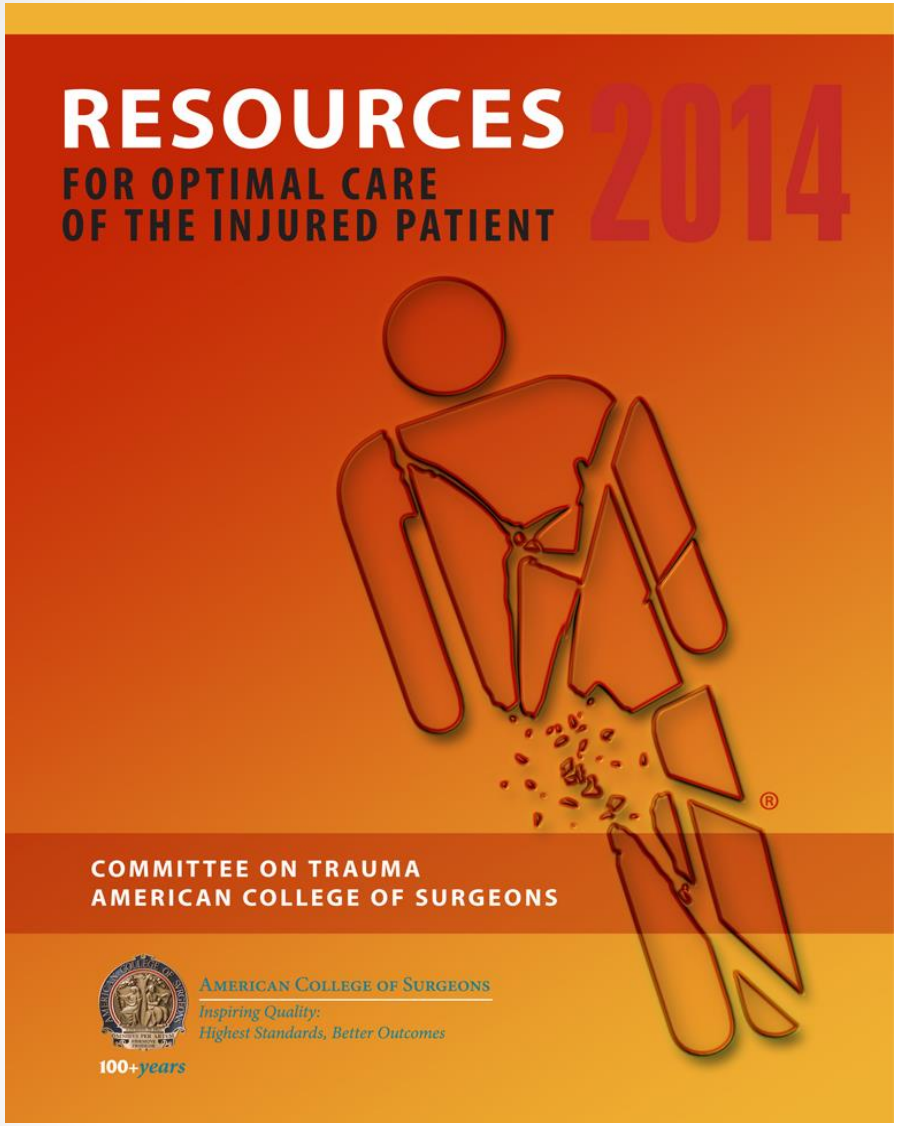
FIGURE 2. Different Conceptual and Theoretical Bases for the Spread of Innovation in Service Organizations

NIH Collaboratory *Rethinking Clinical Trials®*

Health Care Systems Research Collaboratory

American College of Surgeons Policy Partnership Builds Practice Change Momentum Into Trial Design & Roll-out





Alcohol

Universal Screening & Intervention at Level I & II trauma centers

NIH Collaboratory *Rethinking Clinical Trials®*
Health Care Systems Research Collaboratory

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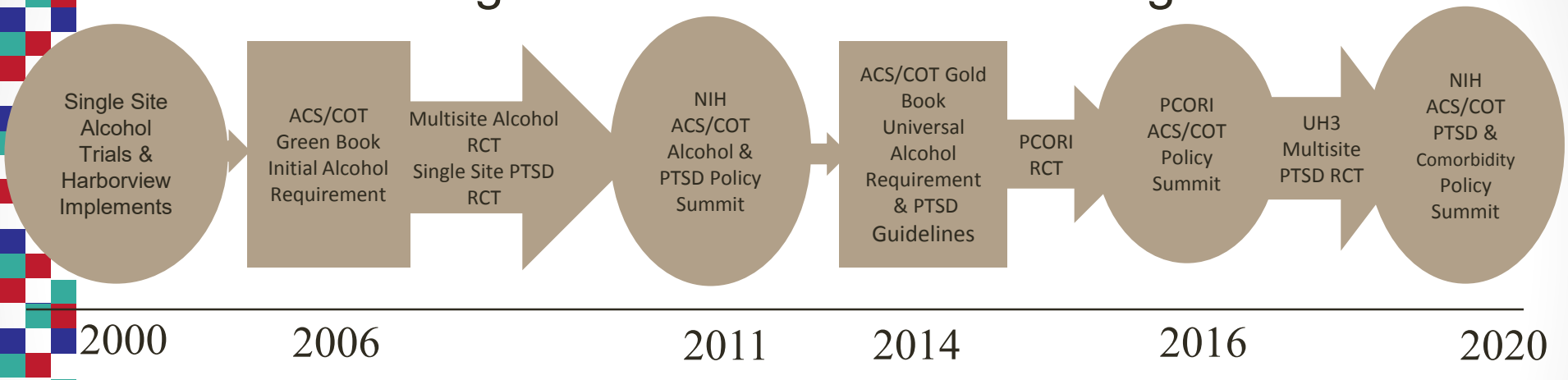
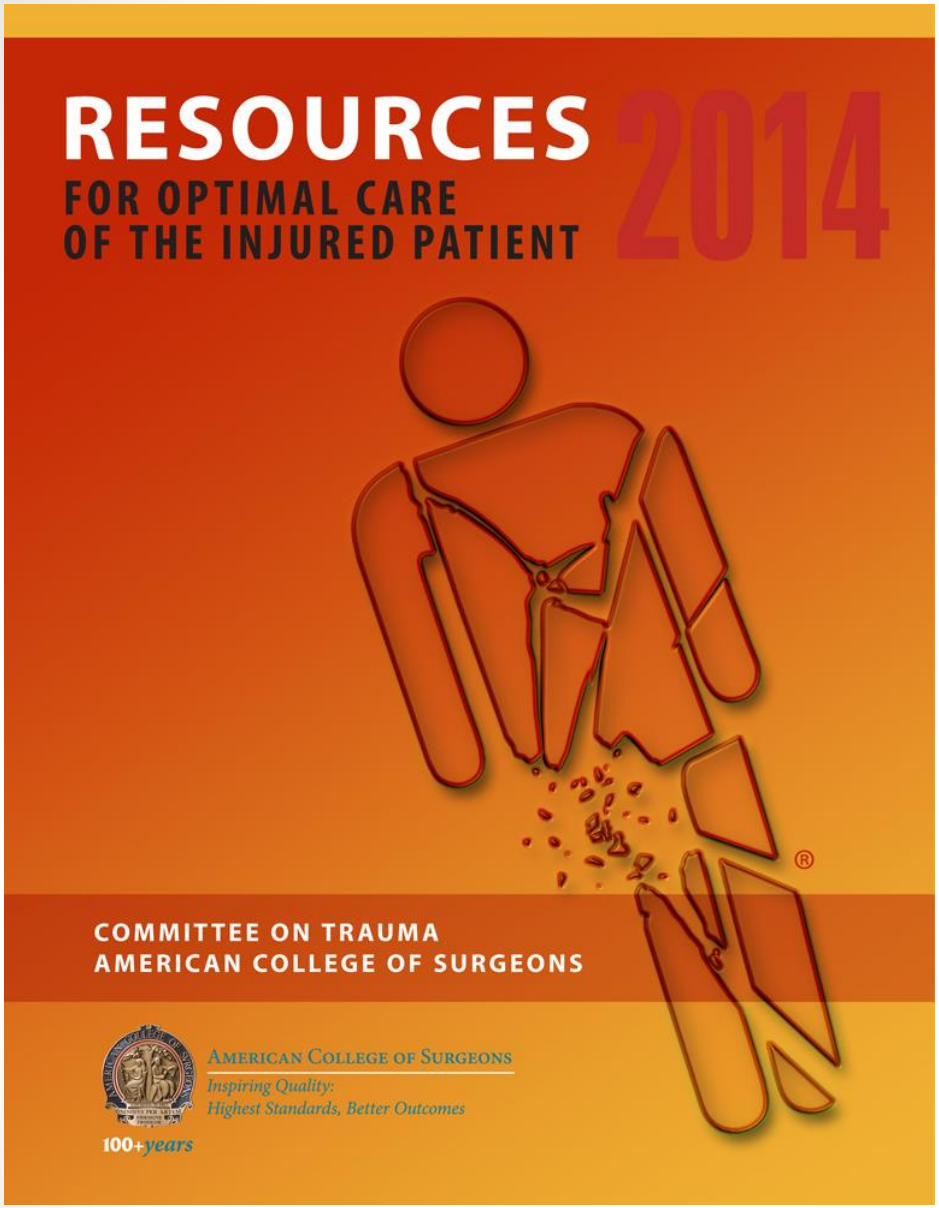




PTSD & Comorbidity

PTSD and depression screening & intervention best practice guideline recommendation

NIH Collaboratory *Rethinking Clinical Trials®*
Health Care Systems Research Collaboratory

Trial Roll-out: Stepped Wedge Design Targets Practice Change by Beginning with Provider Feedback on Control Patients

Why TSOS? The Problem

Traumatic injury:

- PTSD, depression, suicidal ideation
- High risk behaviors (e.g., alcohol)
- Traumatic brain injury, all common

Patients "sail off of a flat earth" after trauma center care

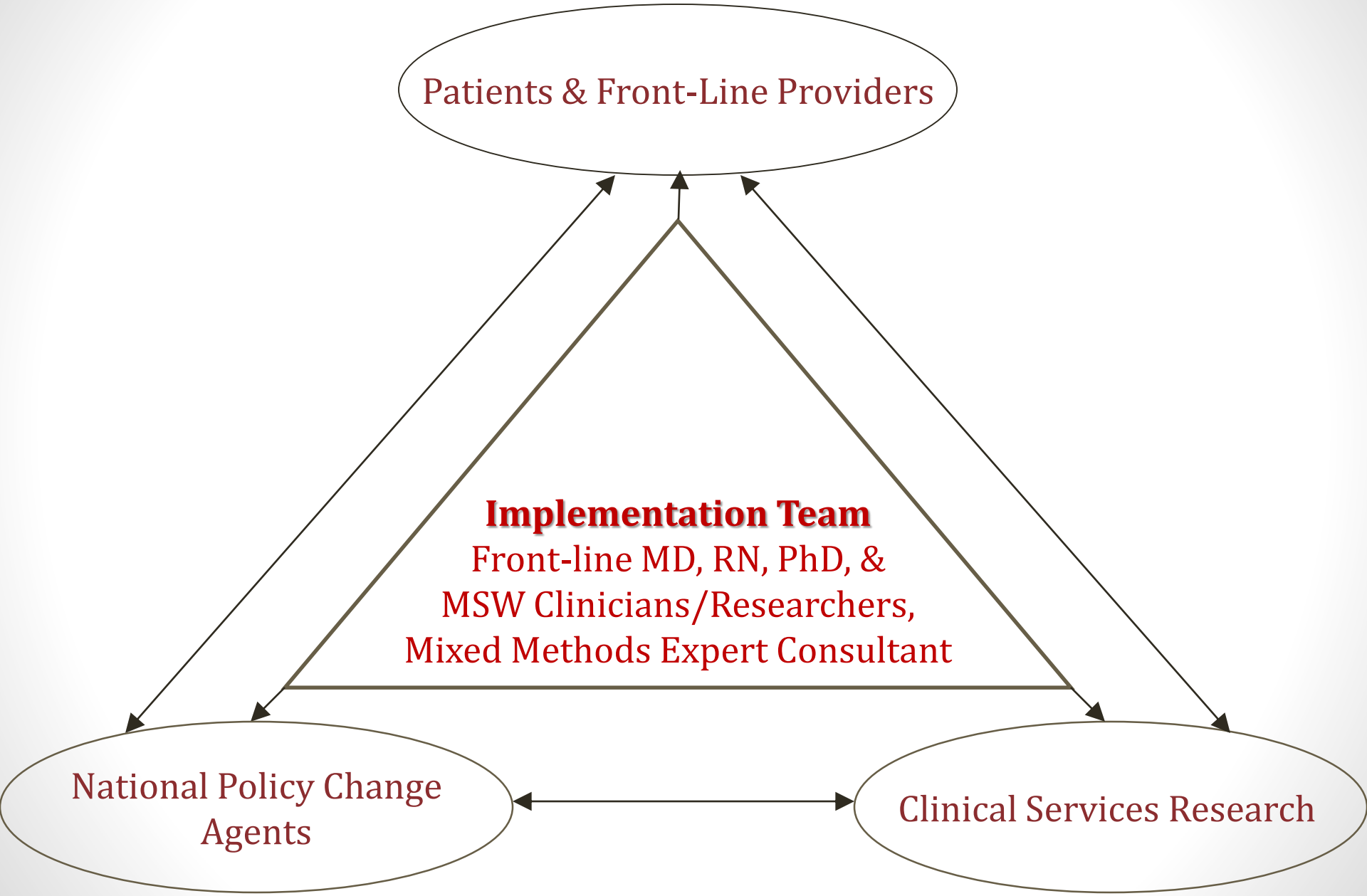
From Darnell & Zatzick TSOS Training Slide Set

Trial Roll-out: Integrating Implementation Science & Pragmatic Trial Methods

-Pragmatic trials aim to minimize cost per subject randomized

- Methods development can meld pragmatic trial constraints & implementation science process evaluations

Embedded Clinical, Research & Policy Implementation Team



Mixed Methods: Rapid Assessment Procedures

- Immersive participant observation by study team members
- Study team members record field notes during trial roll-out
- Field observations regularly reviewed with mixed methods expert team member

Implementation Science & Acute Care Regulatory Policy: Lessons Learned

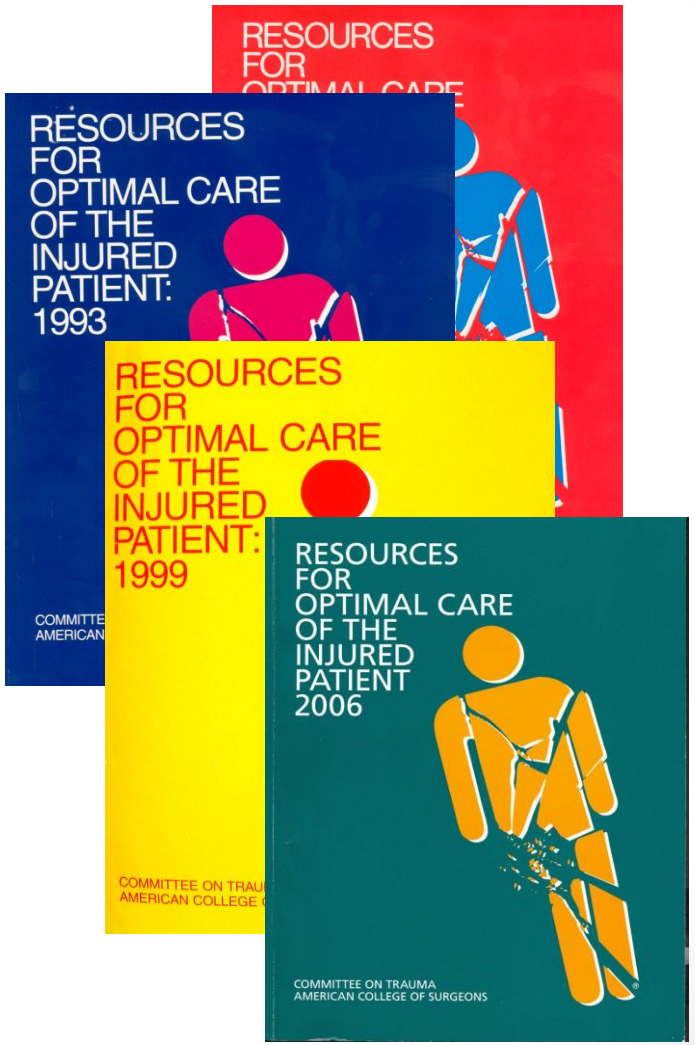
- Regulatory policy ensures site familiarity with screening and intervention requirements
- Regulatory policy mandates verification site visits
- Fidelity to high quality procedures not assured
- Provider training vulnerable to turnover

Summary

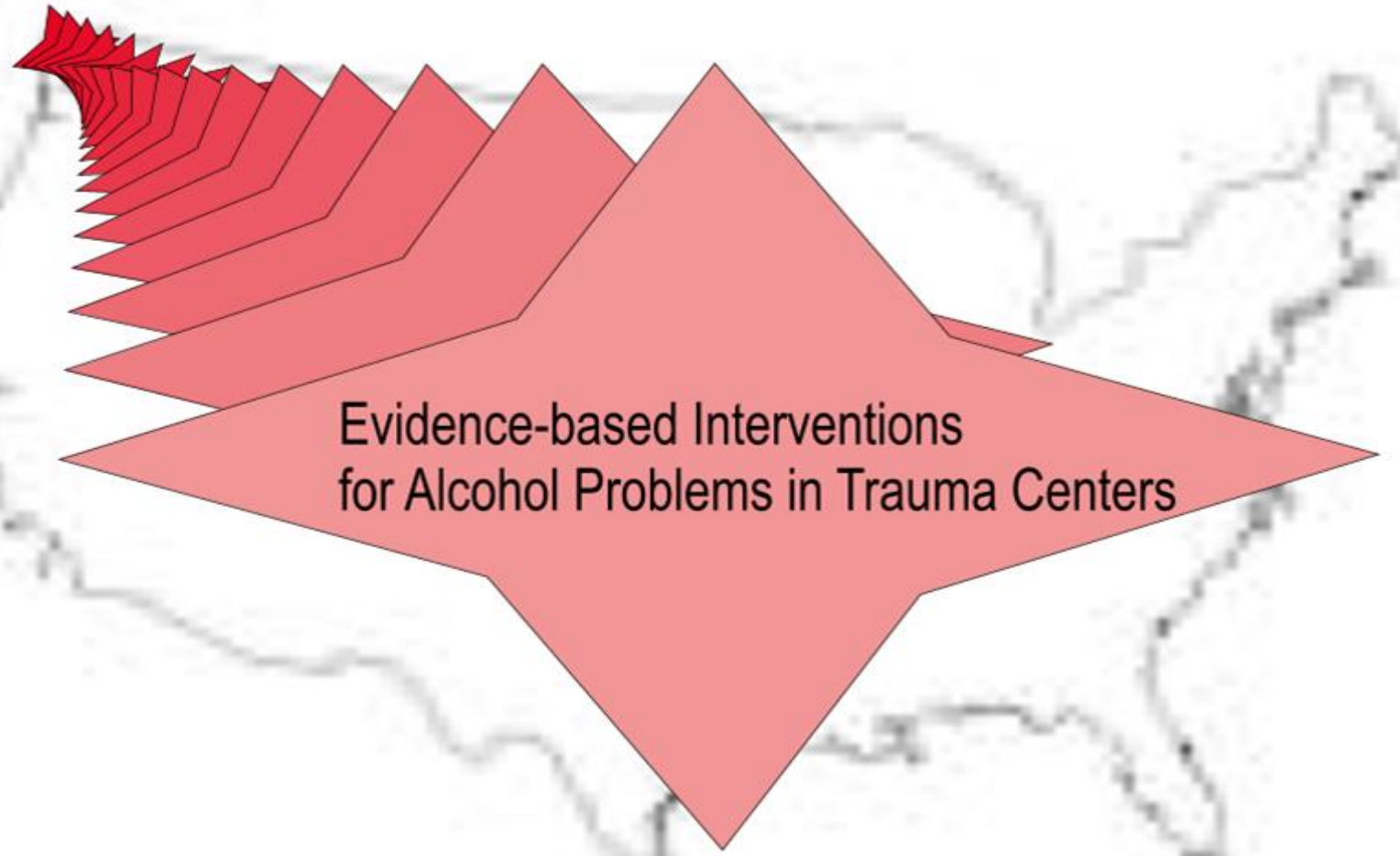
- Implementation science frameworks can inform design and roll-out of pragmatic trials
- Pragmatic trial constraints inform modification of implementation science methods
- Embedded clinical, research and policy teams may facilitate sustainable implementation of trial results within health care systems

American College of Surgeons' Committee on Trauma

- 1976 1st Book
- 2006 "Green Book"



Disseminating Organizational Screening & Brief Interventions (DO-SBIS)



Setting the stage of dissemination & implementation

Gloria D. Coronado, PhD; Mitch Greenlick Endowed Investigator in Health Disparities Research
Beverly B. Green, MD, MPH; Kaiser Permanente Washington Research Institute

Presentation outline

- Background on STOP CRC
- Aligning policy to raise CRC screening as a priority
- Applying familiar improvement approaches
- Partnerships for sustainability
- Summary and wrap-up

Topic 1

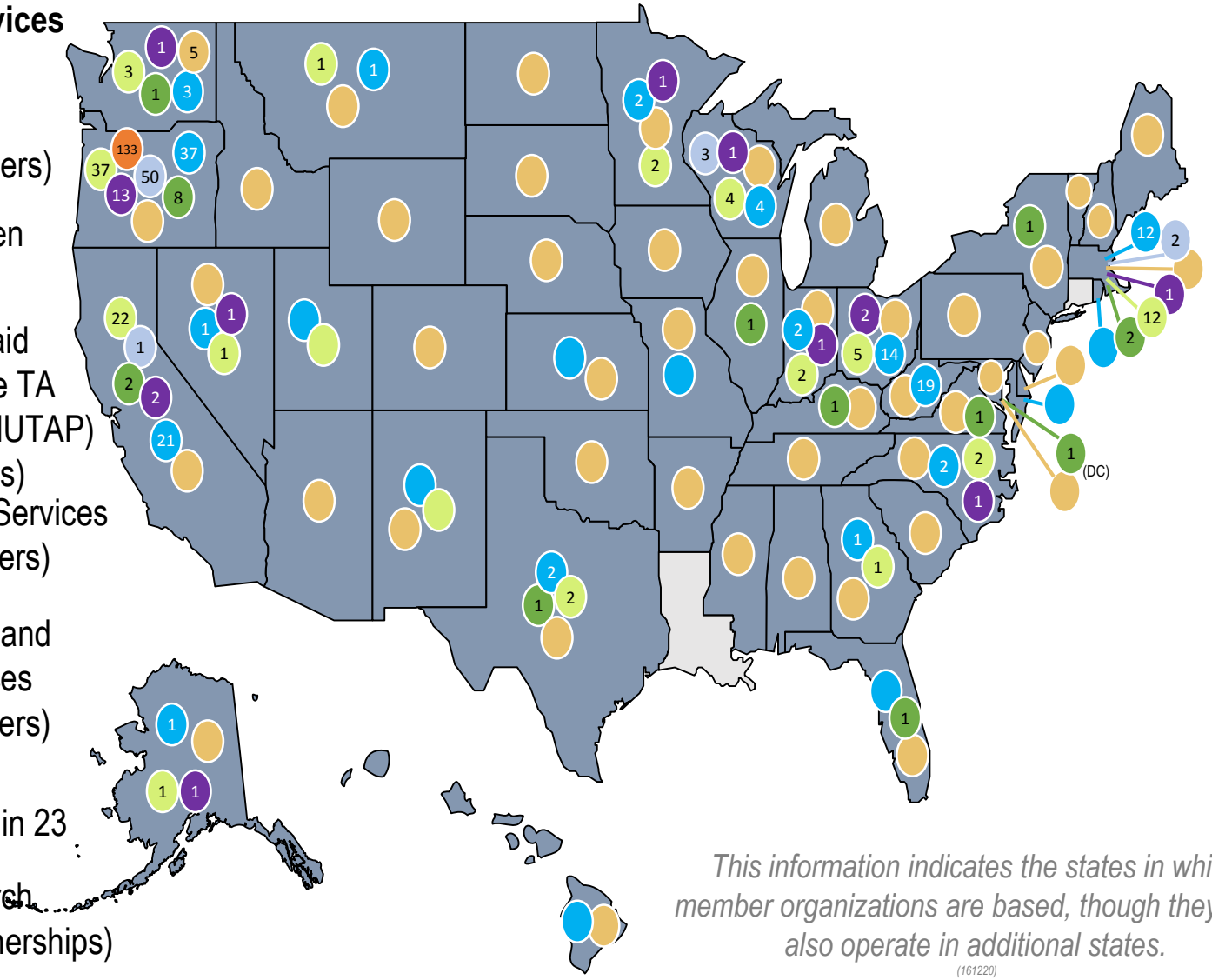
Background on STOP CRC

- STOP CRC is a cluster-randomized trial of 26 community health center clinics in Oregon and California
- STOP CRC tests the effectiveness and implementation of a direct-mail program to raise CRC screening rates

Where is OCHIN Today?

OCHIN Products/Services

- OCHIN Epic (95 total members)
- OCHIN NextGen
- Oregon Medicaid Meaningful Use TA program (OMMUTAP) (133 total clinics)
- OCHIN Billing Services (24 total members)
- OCHIN Broadband Network Services (56 total members)
- Acuere QOL (Organizations in 23 states)
- OCHIN Research (20 active partnerships)

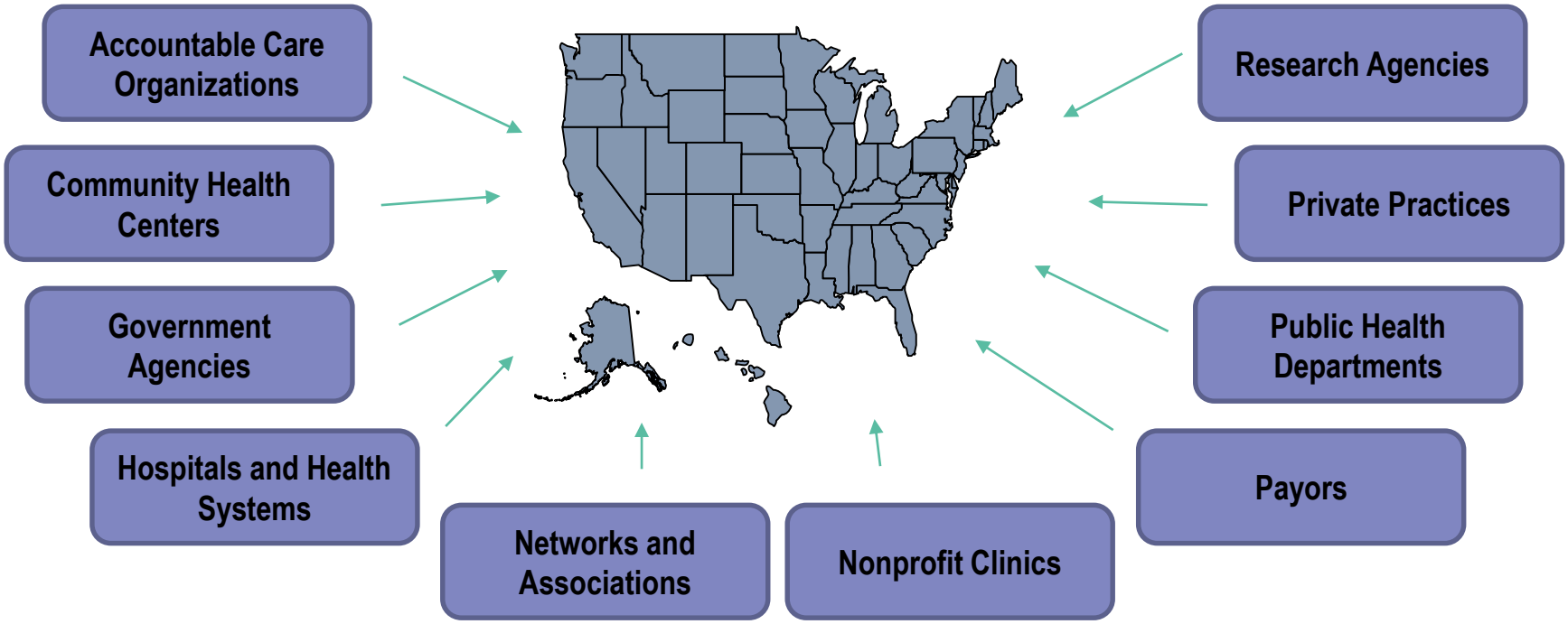


This information indicates the states in which member organizations are based, though they may also operate in additional states.

(161220)

Who is OCHIN Serving?

- OCHIN supports organizations located in all **50 states**, partnering with **289 organizations** with **10,000 clinicians** serving over **10 Million patients**.



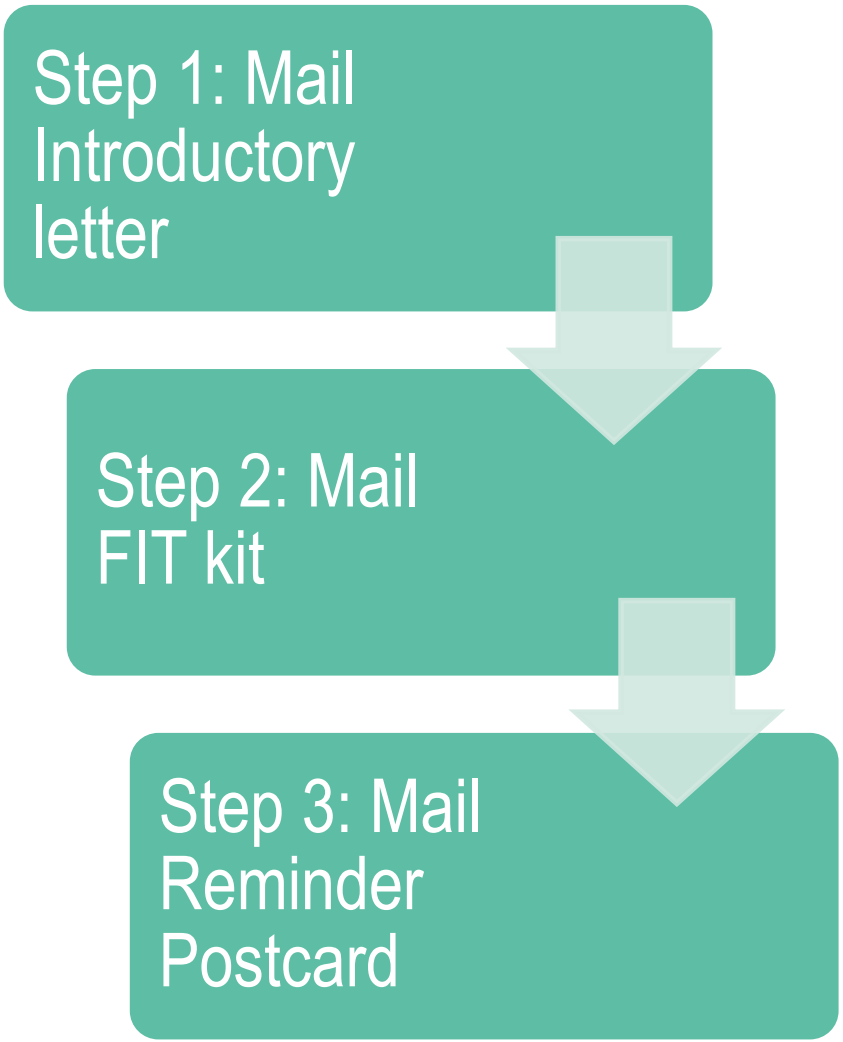
STOP CRC intervention

EMR tools in Reporting Workbench, driven by Health Maintenance;

Step-wise exclusions for:

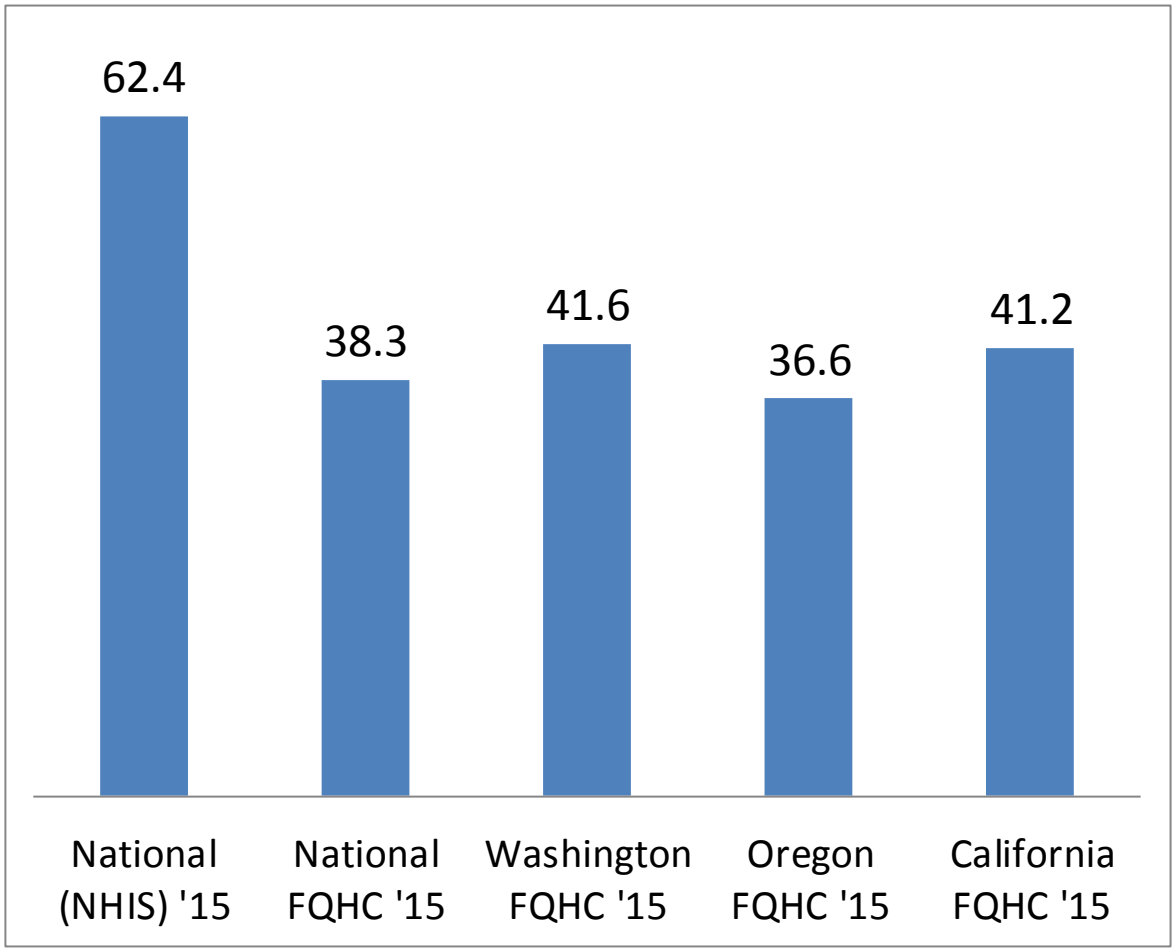
- Invalid address
- Self-reported prior screening
- Completion of CRC screening

Improvement cycle (e.g. Plan-Do-Study-Act)



Colon cancer screening rates

Screening in Federally Qualified Health Centers



Source: National Health Interview Survey and Uniform Data Systems

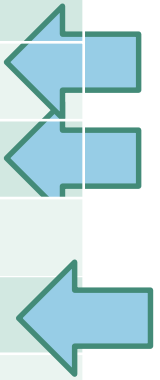
Topic 2

Aligning policy to raise CRC screening as a priority

- Affordable Care Act: Medicaid expansion, Preventive Health Mandate
- Medicaid incentives in Oregon
- Oregon legislation impacting colonoscopy coverage

Medicaid expansion's impact

State	Pre-ACA average monthly enrollment	Total Monthly Medicaid/CHIP enrollment	Percent change
Alaska	122,334	125,616	3%
California	9,157,000	12,636,680	38%
Oregon	626,356	1,055,198	69%
Texas	4,441,605	4,666,144	5%
Washington	1,117,576	1,735,511	55%
Wyoming	67,518	64,462	-5%



Washington increase: 625,847 (21% adults)
Oregon increase: 429,651 (29% adults)

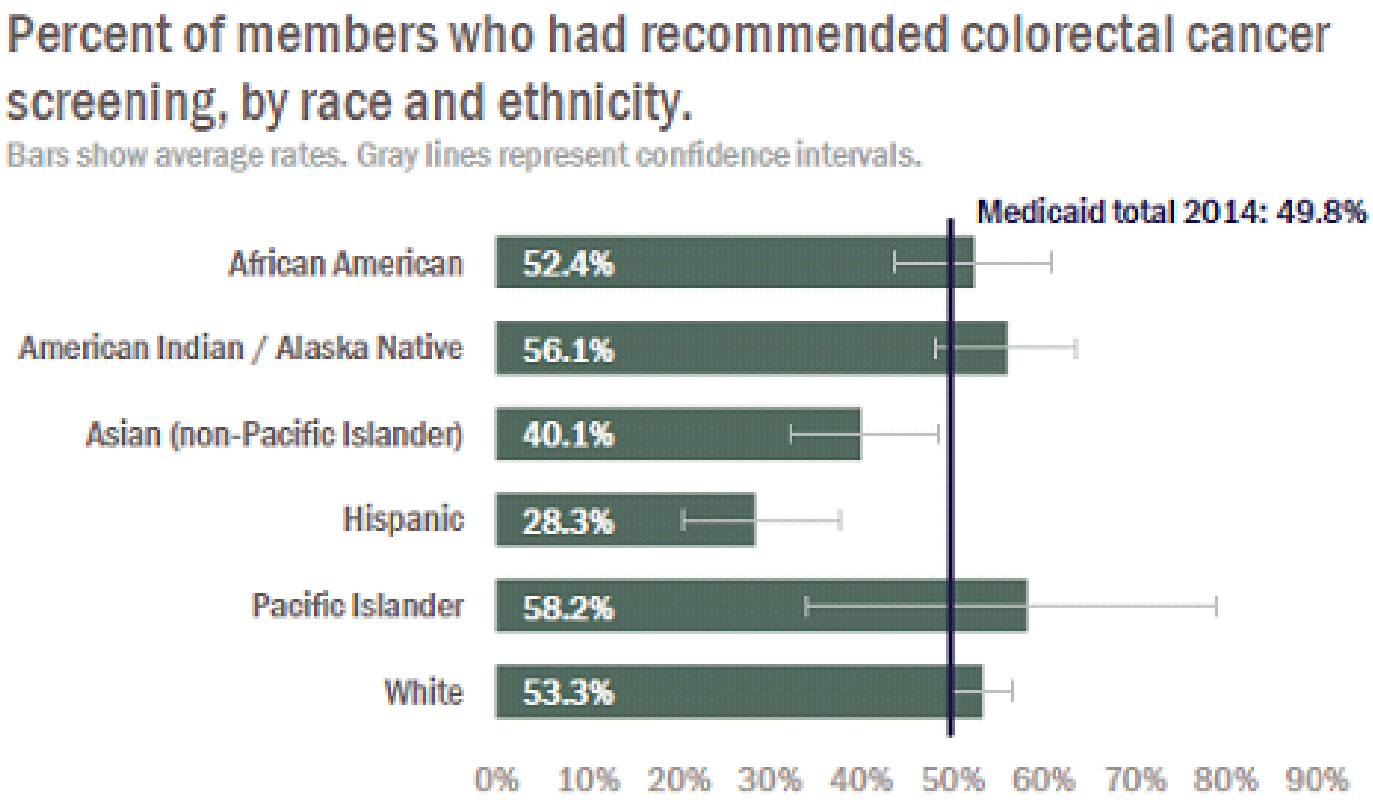
Centers for Medicare and Medicaid, 2015

Medicaid expansion pronounced in 50 – 64 group

	Before Medicaid Expansion Dec 2013	After Medicaid Expansion June 2014	% change
	N	N	%
All ages	659,114	971,095	47.3%
< 19	372,639	426,130	14.4%
19 – 21	20,996	41,625	98.3%
22 – 35	90,356	193,078	113.7%
36 – 50	70,203	147,184	109.7%
51 – 64	57,295	124,418	117.2%
65 +	47,625	38,660	-18.8%

Oregon Health Authority 2014

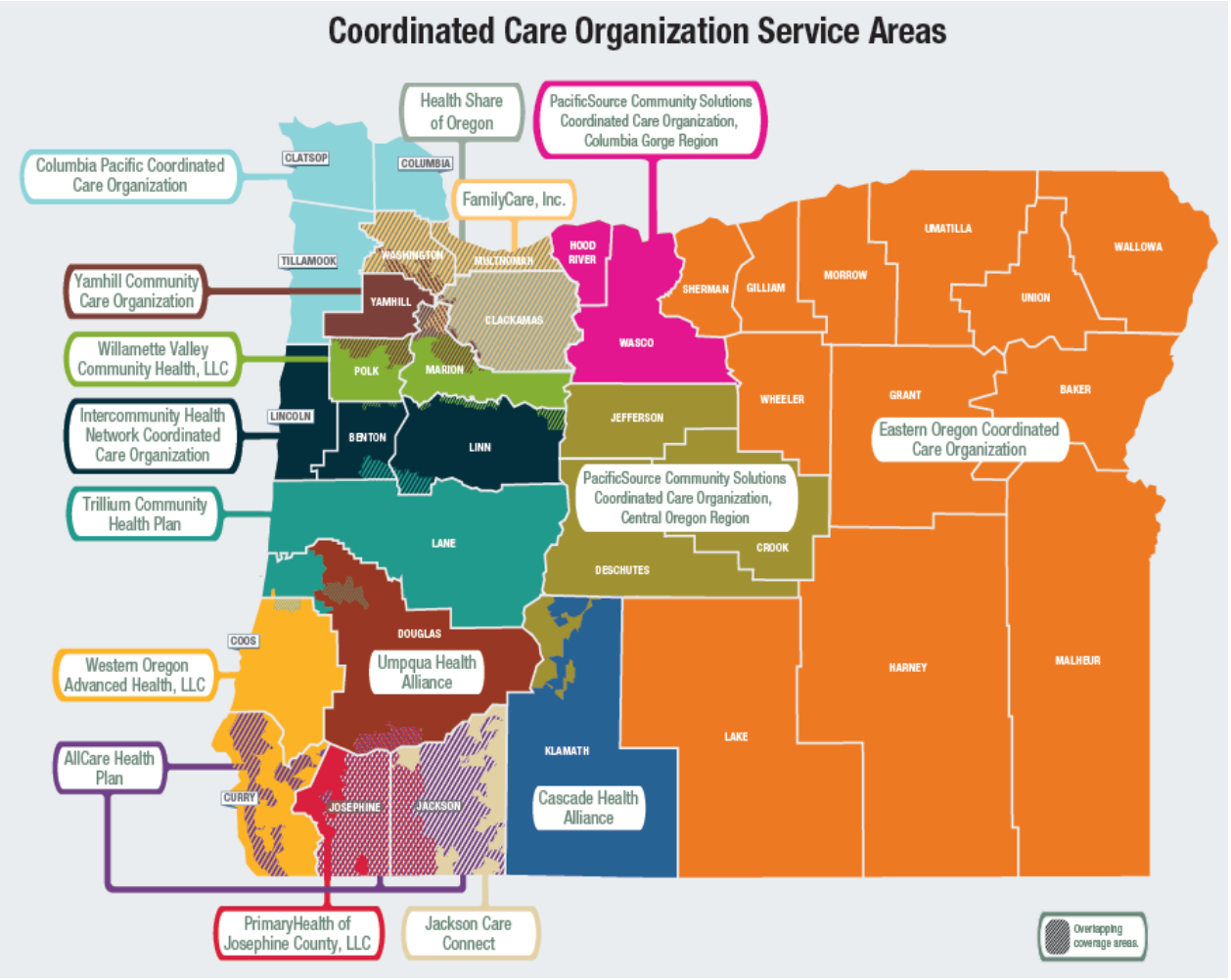
Oregon Medicaid CRC screening rates suboptimal and marked by pronounced health disparity



Oregon Health Authority 2015

CRC screening incentivized metric for OR Medicaid Health Plans/ CCOs

- Coordinated Care Organizations are networks of health care providers who deliver coordinated care to Medicaid enrollees.
- CCO Metrics and Scoring Committee adopted CRC screening as an incentivized metric in 2013 – 47% benchmark.

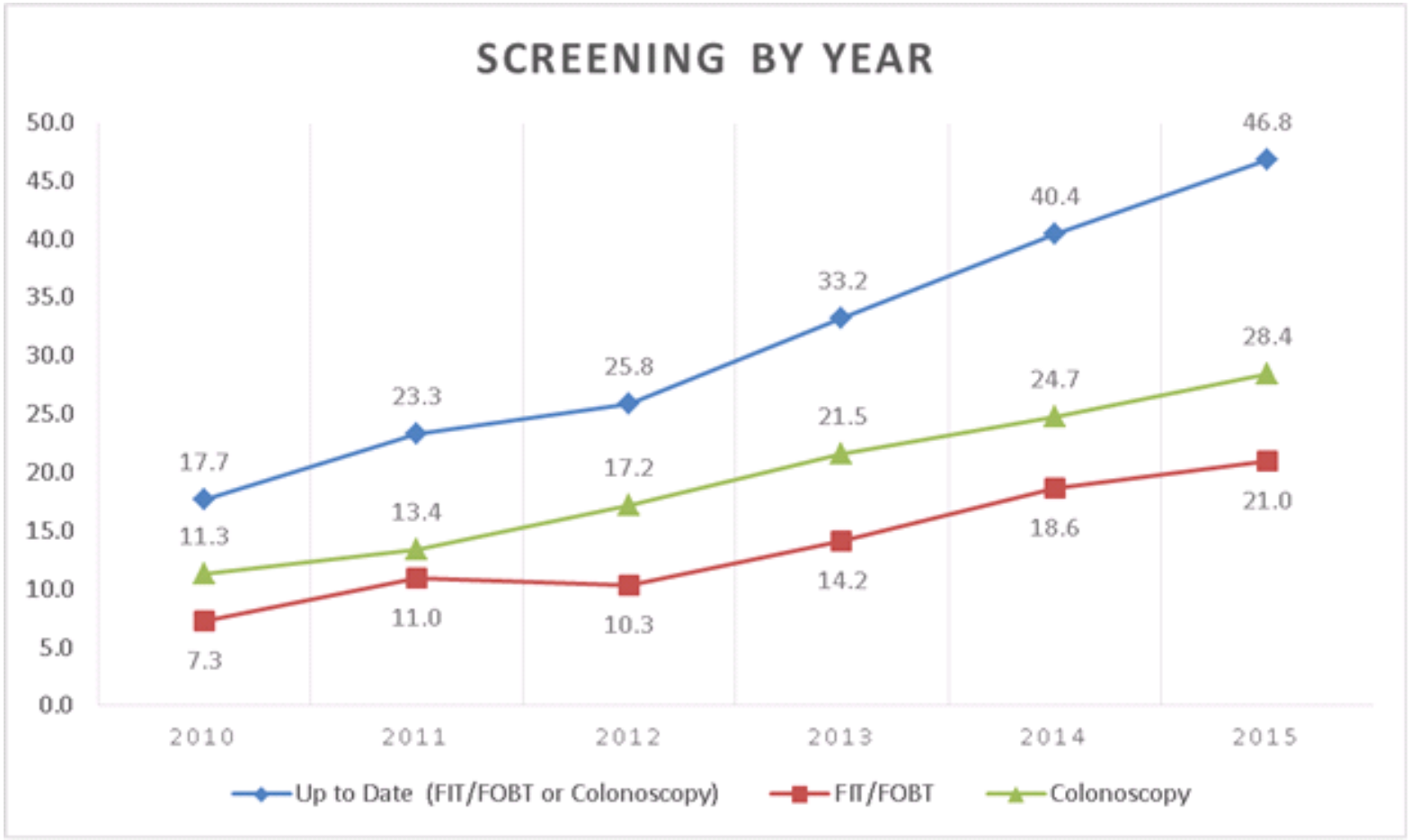


CRC Screening Legislation

- 2014 Oregon passed legislation that requires insurance companies to treat to colonoscopy as a screening colonoscopy, even if polyps are removed. This means that patients who go in for a screening colonoscopy and have polyps removed will not be charged co-pays and deductibles.

- 2015 Oregon passed legislation that prohibits insurance companies from imposing patient co-pays or deductibles for follow-up colonoscopies when a FIT test is positive. This means to there is no financial barrier to follow-up colonoscopy for insured patients.

CRC screening rates in STOP CRC clinics

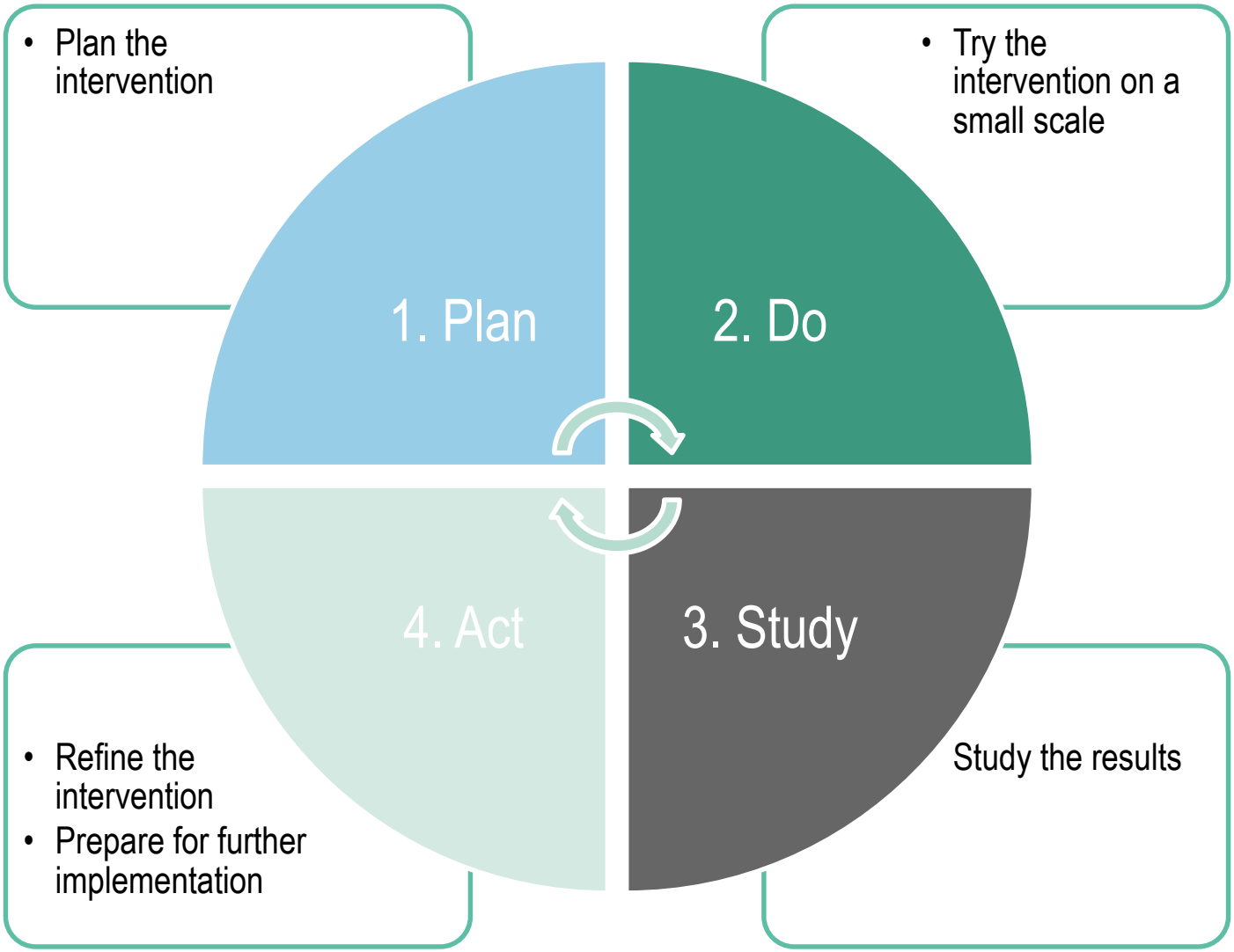


Topic 3

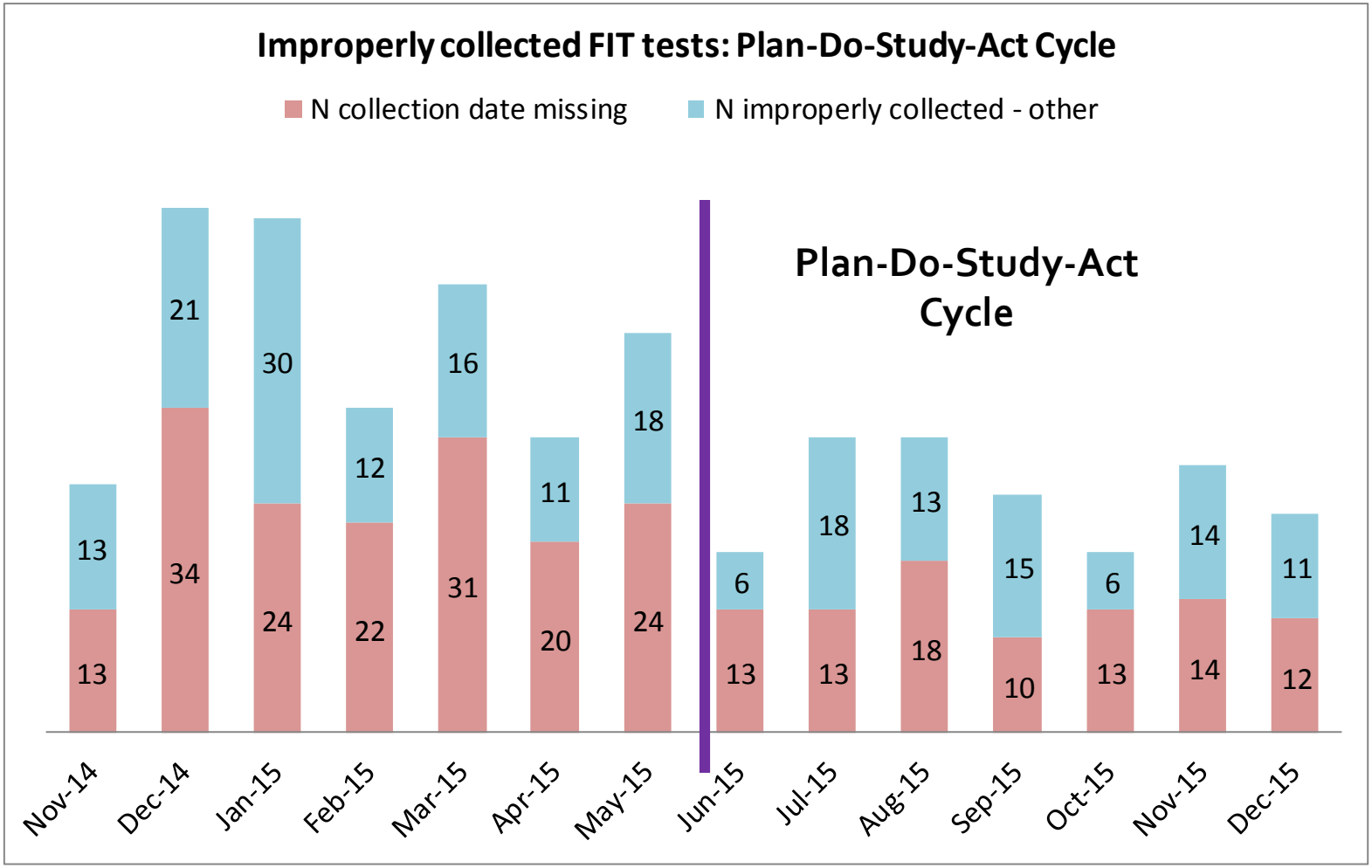
Applying familiar improvement approaches

- Using Plan Do Study Act Cycles

Process Improvement: Plan –Do –Study –Act

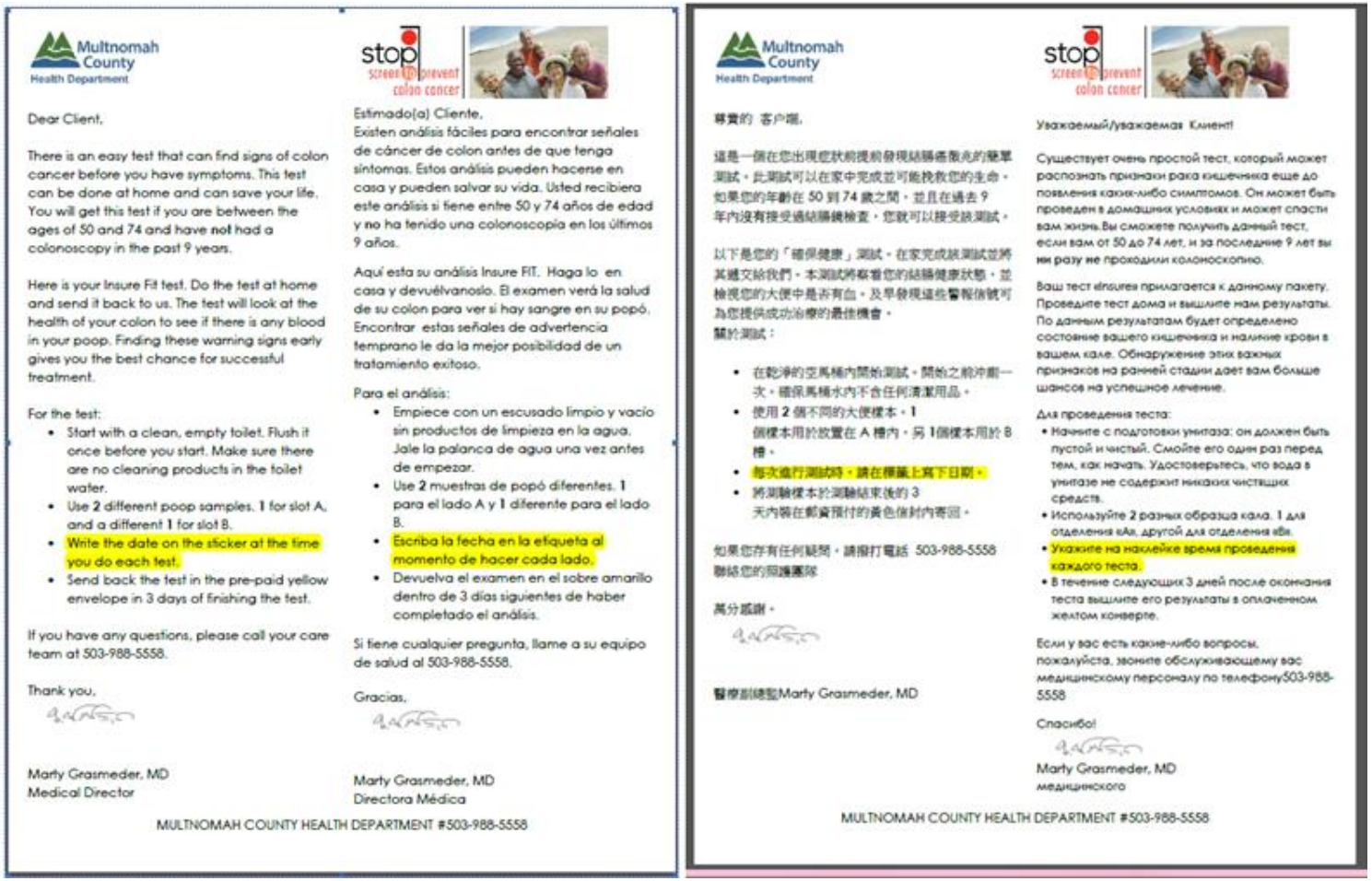


PDSA #2: Improving FIT sample collection



Source: Multnomah County Health Department

Action taken: Highlighted instruction on letter



Multnomah County
Health Department

Dear Client,

There is an easy test that can find signs of colon cancer before you have symptoms. This test can be done at home and can save your life. You will get this test if you are between the ages of 50 and 74 and have not had a colonoscopy in the past 9 years.

Here is your Insure Fit test. Do the test at home and send it back to us. The test will look at the health of your colon to see if there is any blood in your poop. Finding these warning signs early gives you the best chance for successful treatment.

For the test:

- Start with a clean, empty toilet. Flush it once before you start. Make sure there are no cleaning products in the toilet water.
- Use 2 different poop samples. 1 for slot A, and a different 1 for slot B.
- Write the date on the sticker at the time you do each test.
- Send back the test in the pre-paid yellow envelope in 3 days of finishing the test.

If you have any questions, please call your care team at 503-988-5558.

Thank you,

Marty Grasmeder, MD
Medical Director

stop screen & prevent colon cancer

Estimado(a) Cliente,
Existen análisis fáciles para encontrar señales de cáncer de colon antes de que tenga síntomas. Estos análisis pueden hacerse en casa y pueden salvar su vida. Usted recibiera este análisis si tiene entre 50 y 74 años de edad y no ha tenido una colonoscopia en los últimos 9 años.

Aquí esta su análisis Insure FIT. Haga lo en casa y devuélvanoslo. El examen verá la salud de su colon para ver si hay sangre en su popó. Encontrar estas señales de advertencia temprano le da la mejor posibilidad de un tratamiento exitoso.

Para el análisis:

- Empiece con un escusado limpio y vacío sin productos de limpieza en la agua. Jale la palanca de agua una vez antes de empezar.
- Use 2 muestras de popó diferentes. 1 para el lado A y 1 diferente para el lado B.
- Escriba la fecha en la etiqueta al momento de hacer cada lado.
- Devuelva el examen en el sobre amarillo dentro de 3 días siguientes de haber completado el análisis.

Si tiene cualquier pregunta, llame a su equipo de salud al 503-988-5558.

Gracias,

Marty Grasmeder, MD
Directora Médica

MULTNOMAH COUNTY HEALTH DEPARTMENT #503-988-5558

Multnomah County
Health Department

尊貴的 客户端,

這是一個在您出現症狀前提前發現結腸癌徵兆的簡單測試。此測試可以在家中完成並可能挽救您的生命。如果您的年齡在 50 到 74 歲之間，並且在過去 9 年內沒有接受過結腸鏡檢查，您就可以接受該測試。

以下是您的「確保健康」測試。在家完成該測試並將其遞交給我們。本測試將檢查您的結腸健康狀態，並檢視您的大便中是否有血。及早發現這些警報信號可為您提供成功治療的最佳機會。
關於測試：

- 在乾淨的空馬桶內開始測試。開始之前沖廁一次。確保馬桶水內不含任何清潔用品。
- 使用 2 個不同的大便樣本。1 個樣本用於放置在 A 槽內，另 1個樣本用於 B 槽。
- 每次進行測試時，請在標籤上寫下日期。
- 將測驗樣本於測驗結束後的 3 天內裝在郵資預付的黃色信封內寄回。

如果您存有任何疑問，請撥打電話 503-988-5558 聯絡您的照護團隊

萬分感謝，

醫療副總監Marty Grasmeder, MD

stop screen & prevent colon cancer

Уважаемый/уважаемая Клиент!

Существует очень простой тест, который может распознать признаки рака кишечника еще до появления каких-либо симптомов. Он может быть проведен в домашних условиях и может спасти вам жизнь.Вы сможете получить данный тест, если вам от 50 до 74 лет, и за последние 9 лет вы ни разу не проходили колоноскопию.

Ваш тест «Insure» прилагается к данному пакету. Проведите тест дома и вышлите нам результаты. По данным результатам будет определено состояние вашего кишечника и наличие крови в вашем кале. Обнаружение этих важных признаков на ранней стадии дает вам больше шансов на успешное лечение.

Для проведения теста:

- Начните с подготовки унитаза: он должен быть пустой и чистый. Смойте его один раз перед тем, как начать. Удостоверьтесь, что вода в унитазе не содержит никаких чистящих средств.
- Используйте 2 разных образца кала. 1 для отделения «А», другой для отделения «В».
- Укажите на наклейке время проведения каждого теста.
- В течение следующих 3 дней после окончания теста вышлите его результаты в оплаченном желтом конверте.

Если у вас есть какие-либо вопросы, пожалуйста, звоните обслуживающему вас медицинскому персоналу по телефону503-988-5558

Спасибо!

Marty Grasmeder, MD
медицинского

MULTNOMAH COUNTY HEALTH DEPARTMENT #503-988-5558

Source: Multnomah County Health Department

Action taken: Added reminder with instruction

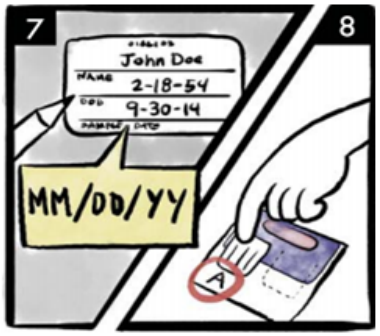
- Don't forget to put the date you collected your poop sample
- No olvide poner la fecha en la que recolectó la muestra de popó.
- 别忘了填寫您採集大便樣本的日期。
- Не забудьте указать дату, когда вы собрали анализ кала

Last Name, First Name
DOB: 01/01/1980
MRN: 1234567

Date:_____

Last Name, First Name
DOB: 01/01/1980
MRN: 1234567

Date:_____



Source: Multnomah County Health Department

Reactions to PDSA used in research

Providers and clinic staff had favorable reactions

"But the [PDSA] process itself, we kind of do that organically already without calling it a PDSA. So now it's nice to have a form and a template that we can work by so that we can get feedback … and come up with questions like 'What about if we did this?' or 'Who's going to do that?' So it's good to have that template to work from."

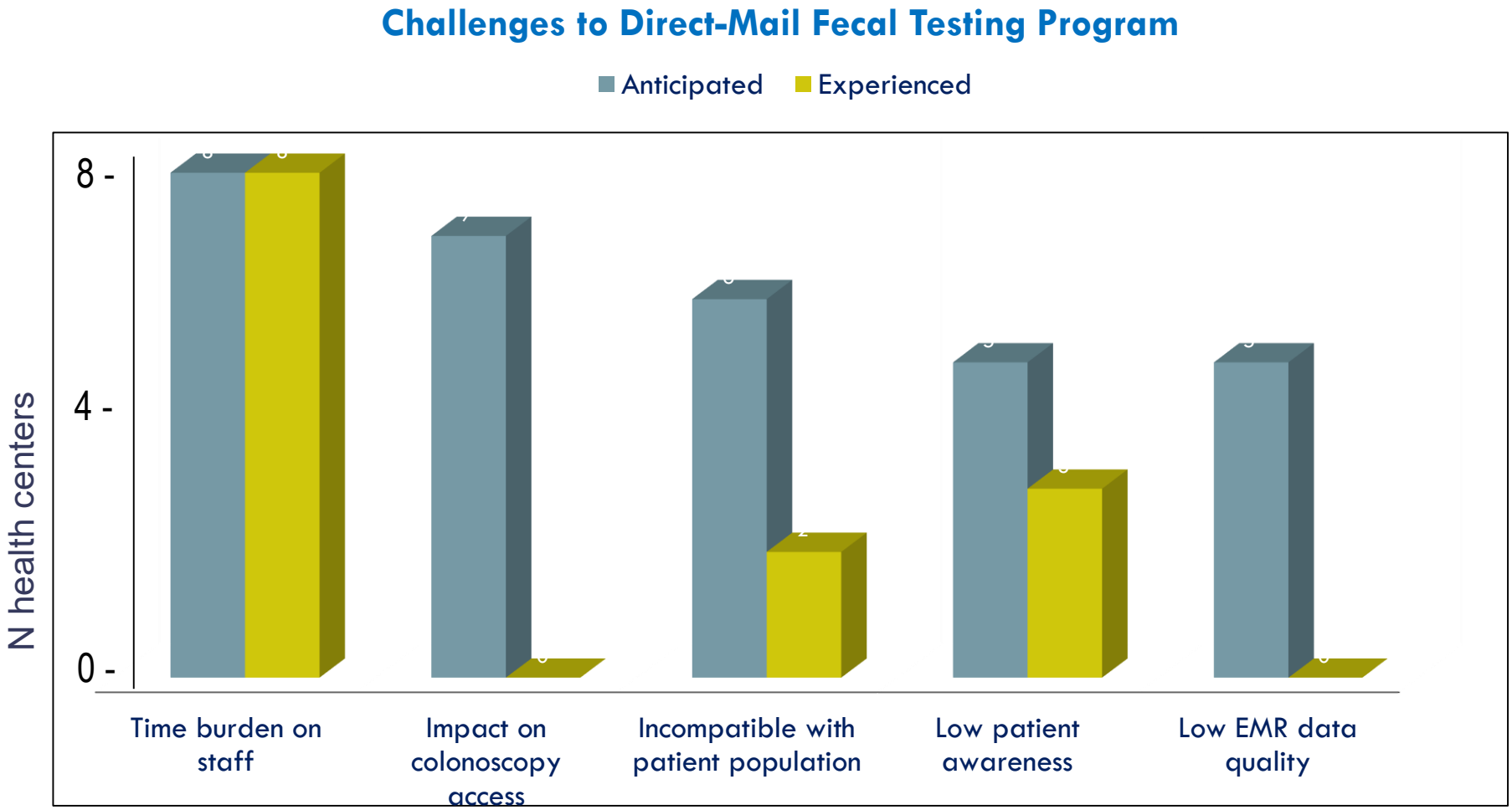
— Quality Improvement Manager

Topic 4

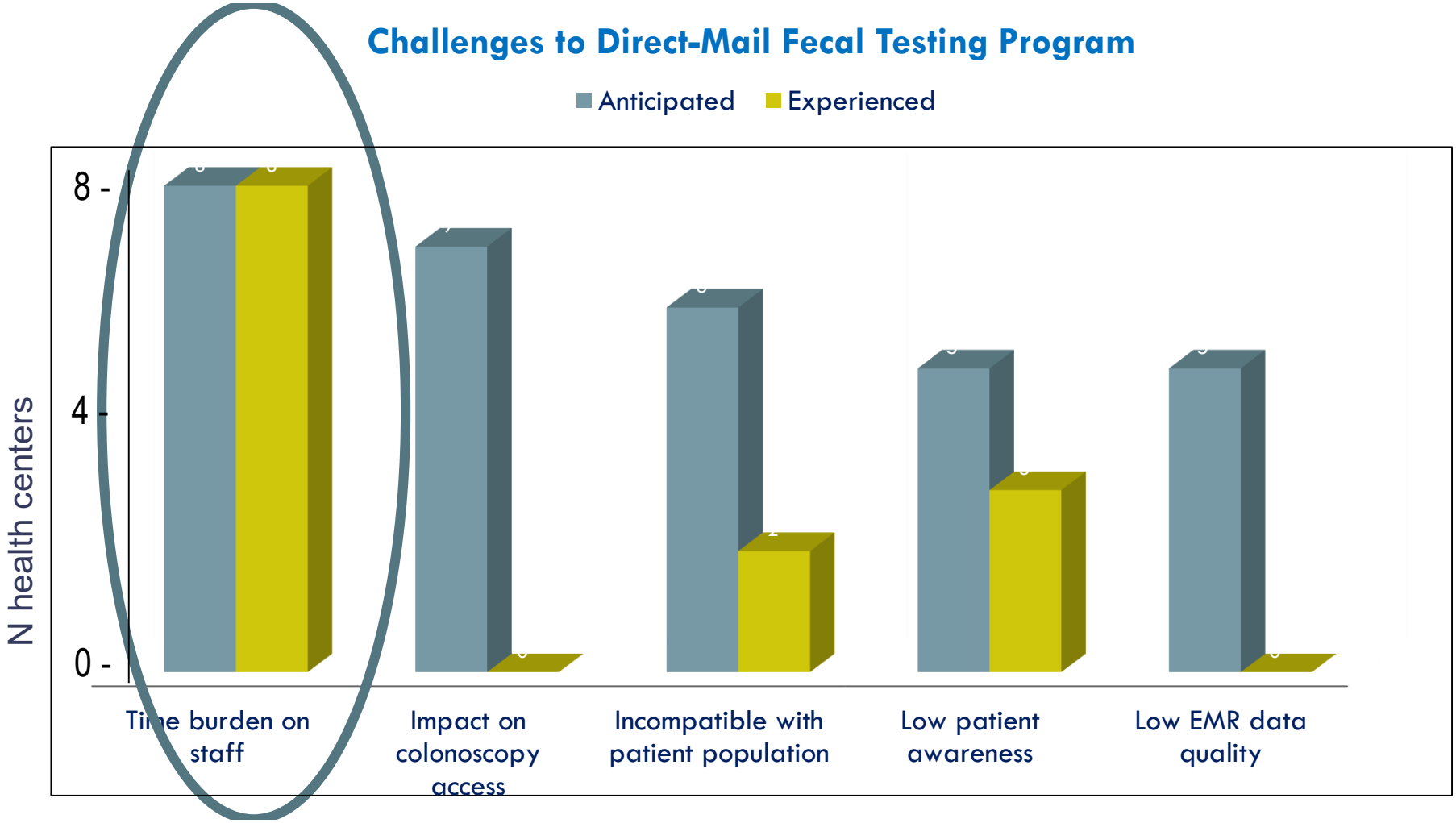
Partnerships for sustainability

- Partnership with Medicaid Health Plans
- Collaborative model for direct-mail program

Primary challenge to sustainability

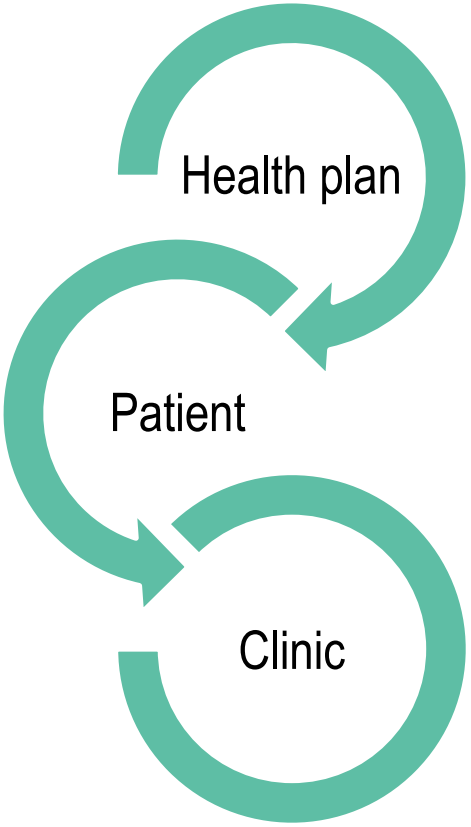


Primary challenge to sustainability



Cost-sharing for FIT mail-out: BENEFIT

- Overall goal is to improve CRC screening rates using direct-mail FIT approach;
- 4-year project specifically involving Medicaid Health Plans (for Medicaid and dual-eligible enrollees): Care Oregon in Oregon
- Led by Gloria Coronado (KPCHR), Beverly Green (Group Health) and Laura Mae Baldwin (UW). Funded by the Centers for Disease Control



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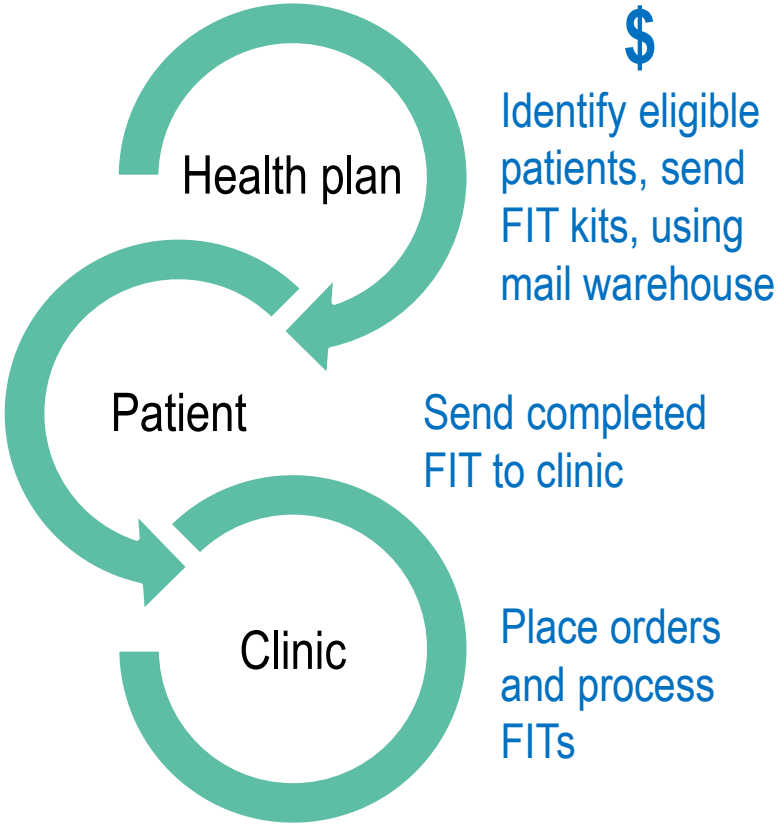
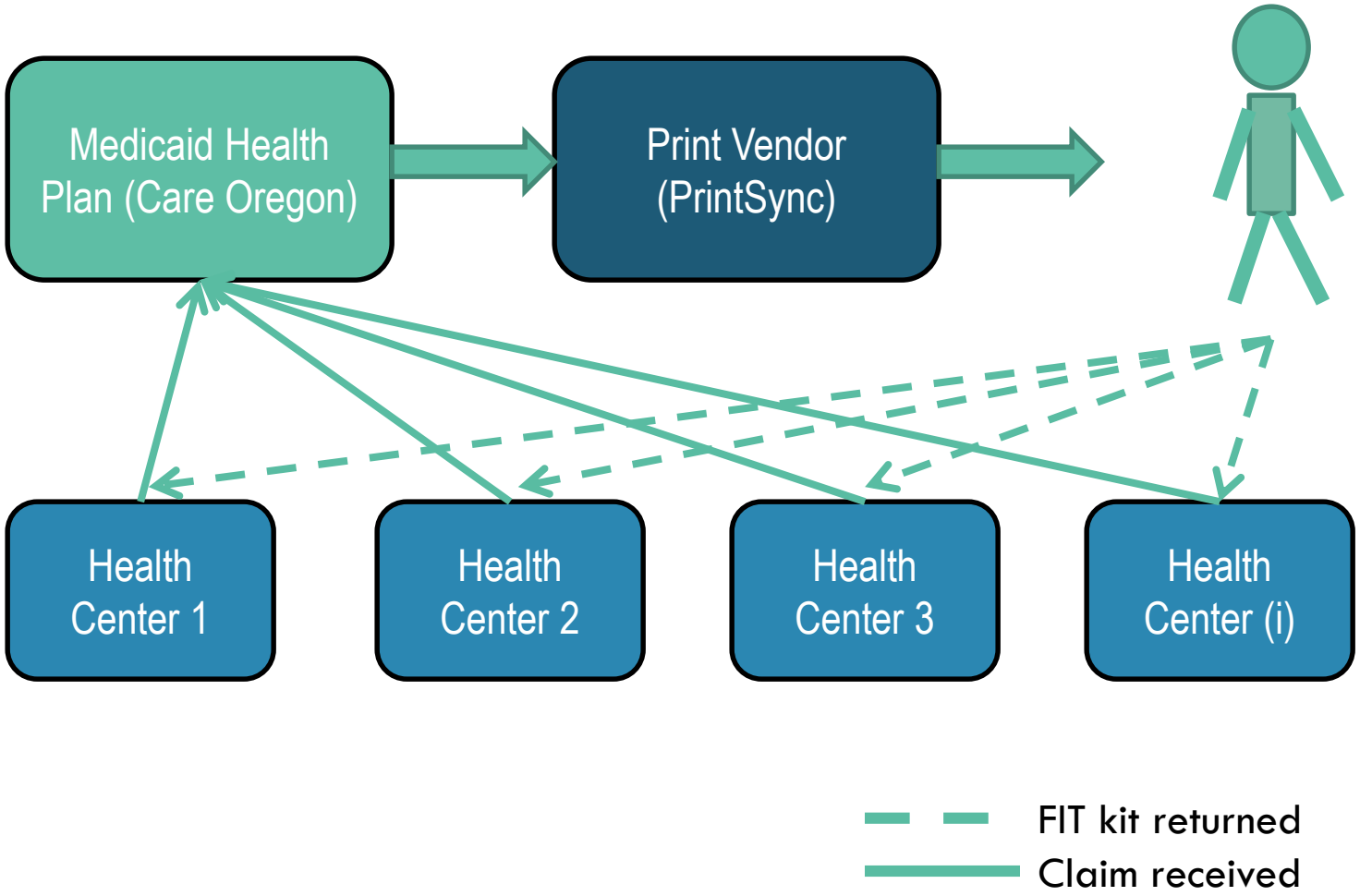


Partnership to share costs of direct-mail expenses



Topic 5

Summary and lessons learned

- National and local policy raised the priority of CRC screening, and identified new partners
- Implementation approach aligned with a familiar clinic approaches
- Partnerships hold promise for long-term sustainability.

Acknowledgments

Funding source: NIH Common Fund [UH2AT007782 and 4UH3CA188640-02] and Kaiser Permanente Community Benefit.

This work would not be possible without the dedication of staff at KP Center for Health Research, OCHIN, Care Oregon, and the STOP CRC Advisory Board.

A Few Designing for D&I Discussion Questions

- How should pragmatic trials ensure that interventions are designed to be implemented across various health systems?
- Are there key questions that should be integrated into trials to support designing for D&I?
- What lessons about designing for D&I have been learned through trials that have implications for future studies? (i.e. what might you do differently next time?)

Questions and Answers

Please submit questions for the panelists to:
PragClinTrialsWkshp@nih.gov