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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Division of Infectious Diseases & Health Policy Research Institute
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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

Number of Units

- 1-2
- 3-4
- 5-6
- 7-8
- >8

Arm 1 Routine Care

Arm 2 Decolonization
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

- **Nov 2012 – Feb 2013**
  - Recruitment
  - Eligibility Surveys

- **Apr – Sept 2013**
  - IRB Ceding

- **Nov 2013**
  - Randomization

- **Mar 2014**
  - Arm 2 Site Training

- **Apr – May 2014**
  - Phase-in (Arm 2)

- **Jun 2014**
  - Intervention Start

- **Feb 2016**
  - End of Trial
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
  o Compatibility issues
  o Safety details
  o Making the case
• Alternative product questions

Universal ICU Decolonization: An Enhanced Protocol

Introduction and Welcome

This enhanced protocol is based on materials successfully used in the REDUCE MRSA Trial (Randomized Evaluation of Decolonization vs. Universal Clearance to Eliminate 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.
Universal ICU Decolonization Toolkit: An Enhanced Protocol

PREVENT HAIs
Healthcare-Associated Infections
Contents

Introduction and Welcome
Universal ICU Decolonization Protocol Overview
Scientific Rationale
References

Appendixes
Appendix A. Flow Chart for Implementing Universal Decolonization
Appendix B. Decisionmaking and Readiness for Implementation
Appendix C. Universal Decolonization in Adult ICUs Overview Statement
Appendix D. Universal ICU Decolonization Nursing Protocol
Appendix E. Training and Educational Materials
Appendix F. Chlorhexidine Bathing Skills Assessment
Appendix G. Safety and Adverse Events
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. Some of the most serious HAIs are those that involve the bloodstream. HAIs also prolong hospitalizations and lead to readmissions. 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.

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.

Among HAIs in 2009-2010, *S. aureus* was the most common cause of health care-associated infections. 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. 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.
Appendix A. Steps for Implementing Universal Decolonization

1. Assess the quality of the evidence and the need for intervention
2. Decision to adopt Universal ICU Decolonization per REDUCE MRSA Trial
3. Consider intervention scope across adult ICUs
4. Assess timing of intervention and elements of provided protocol
5. Garner institutional support from key stakeholders
6. Identify physician and nursing champions for each participating ICU
7. Finalize protocol and obtain committee approval
8. Set launch date, stock product, and address compatibility issues
9. Education and training
10. Assess adherence and impact
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**

- Neck, shoulders, and chest.
- Both arms and hands.
- Abdomen then groin and perineum.
- Right leg and foot.
- Left leg and foot.
- Back of neck, back, and then buttocks.

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

Universal ICU Decolonization Protocol
For CHG Bathing

BATHE WITH CHG USING FIRM MASSAGE TO REMOVE BACTERIA

BATH WITH CHG USING FIRM MASSAGE TO REMOVE BACTERIA

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

LINES AND TUBES:
- CHG to skin on lines, tubes & devices
- Bath with CHG right up to dressing
- OR to bathe over wound dressings
- After bathing, clean & disinfect

ONLY USE CHG CLOTHS BELOW THE JAWLINE

- Neck, Shoulders & Chest
- Both Arms & Hands
- Armpits, Thighs, & Perineum
- Right Legs & Feet
- Lift Legs & Foot
- Back of Neck, Back & Thighs

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

Please return completed form to the Unit Charge Nurse

Signature

Print Last Name: ___________________________  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

Evite las infecciones durante su hospitalización
DUCHAR diariamente con el jabón Chlorhexidine (CHG)

PATIENT

Prevent infections during your hospital stay
SHOWER daily with Chlorhexidine (CHG) soap

El PACIENTE

Evite las infecciones durante la hospitalización
Bañar diariamente con el jabón CHG

El Personal

Prevent infections during the hospital stay
BATH daily with Chlorhexidine (CHG) soap

STAFF

While in the hospital, bathe patients every day with a special antiseptic soap (CHG) to help remove germs and prevent infection.

6 cloths should be applied as below:

1. Encourage CHG shower or bath
2. Your enthusiasm is the greatest predictor of patients wanting to use CHG
3. Encourage bathing every day. Starting on admission is ideal, before IV, lines, urinary catheters, and procedure/surgery.
4. Patients need direction on how to apply correctly and thoroughly
5. Help clean 6 inches of lines, drains, tubes
6. CHG is better than soap and water in removing germs and works for 24 hours
7. CHG is safe to use on surface wounds, rash es and burns and removes germs
8. Allow to air dry for best effect

Clean all skin areas with special attention to:
- Neck
- All skin folds
- Skin around all devices (tub/tube/drain)
- Wounds unless deep or large
- Armpits, groin, between fingers/feet

Protect your patients every day
1. Rinse body with warm water
2. Wash hair and face with CHG
3. Turn off the water and lather washcloth with plenty of CHG soap
4. Lather and massage soap in all areas
5. Leave soap for 2 minutes before rinsing

Daily Staff Huddle Reminders for CHG Bathing:
- Cleaning Wounds and Devices
  - Do not forget wounds and devices! Cleaning them prevents surface bacteria from diving into the body and causing infection
  - Clean ALL devices on the body: lines, tubes, drains
  - Clean ALL wounds unless packed
  - Patients don't feel comfortable cleaning their wounds and devices, staff HAVE TO HELP clean them
  - For showering patients, staff should take a single 2-pack of CHG and clean their wounds and devices for them after the shower

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

For Liquid CHG:
- Apply CHG soap to all body areas out of the water
- Keep on for at least 2 minutes before rinsing
- Use the provided mesh cloth or sponge to lather
Quarterly Staff and Patient Compliance Assessments

CHG Cloth Observation Checklist
Please complete for THREE different staff per unit

CHG Cloth Self-Bathing Patient Survey
Please complete for THREE different patients per unit

CHG Cloth Bathing Observation Form

Patient CHG Cloth Self-Bathing Survey
• “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
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)

Legend
- Level I-II
- Level III
- Level IV-V
Background: Trauma Care System Patient, Provider & Setting Level Heterogeneity
Co-morbidity: PTSD, Depression, Suicidal Ideation, TBI & Alcohol and Drug Use Problems Among Randomly Selected Trauma Surgery Inpatients (N=878)
Preparing for the Trial: Up-front Incorporation of Implementation Science Frameworks

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

- Single Site Alcohol Trials & Harborview Implements
- ACS/COT Green Book Initial Alcohol Requirement
- Multisite Alcohol RCT & Single Site PTSD RCT
- NIH ACS/COT Alcohol & PTSD Policy Summit
- ACS/COT Gold Book Universal Alcohol Requirement & PTSD Guidelines
- PCORI RCT
- PCORI ACS/COT Policy Summit
- UH3 Multisite PTSD RCT
- NIH ACS/COT PTSD & Comorbidity Policy Summit

Years:
- 2000
- 2006
- 2011
- 2014
- 2016
- 2020
Alcohol Universal Screening & Intervention at Level I & II trauma centers
American College of Surgeons Policy Partnership Builds Practice Change Momentum Into Trial Design & Roll-out
PTSD & Comorbidity

PTSD and depression screening & intervention best practice guideline recommendation
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

Patients & Front-Line Providers

Implementation Team
Front-line MD, RN, PhD, & MSW Clinicians/Researchers, Mixed Methods Expert Consultant

National Policy Change Agents

Clinical Services Research
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)

Evidence-based Interventions for Alcohol Problems in Trauma Centers
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
Aligning policies, priorities, and partnerships for colon cancer screening...
# Presentation outline

<table>
<thead>
<tr>
<th>Background on STOP CRC</th>
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<tbody>
<tr>
<td>Aligning policy to raise CRC screening as a priority</td>
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<tr>
<td>Applying familiar improvement approaches</td>
</tr>
<tr>
<td>Partnerships for sustainability</td>
</tr>
<tr>
<td>Summary and wrap-up</td>
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</tbody>
</table>
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.
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

<table>
<thead>
<tr>
<th>Location</th>
<th>Percentage</th>
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</thead>
<tbody>
<tr>
<td>National (NHIS) '15</td>
<td>62.4</td>
</tr>
<tr>
<td>National FQHC '15</td>
<td>38.3</td>
</tr>
<tr>
<td>Washington FQHC '15</td>
<td>41.6</td>
</tr>
<tr>
<td>Oregon FQHC '15</td>
<td>36.6</td>
</tr>
<tr>
<td>California FQHC '15</td>
<td>41.2</td>
</tr>
</tbody>
</table>

Source: National Health Interview Survey and Uniform Data Systems
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

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

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

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

Oregon Health Authority 2014
Oregon Medicaid CRC screening rates suboptimal and marked by pronounced health disparity

Percent of members who had recommended colorectal cancer screening, by race and ethnicity.
Bars show average rates. Gray lines represent confidence intervals.

- African American: 52.4%
- American Indian / Alaska Native: 56.1%
- Asian (non-Pacific Islander): 40.1%
- Hispanic: 28.3%
- Pacific Islander: 58.2%
- White: 53.3%

Medicaid total 2014: 49.8%

Oregon Health Authority 2015
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.
2014 Oregon passed legislation that requires insurance companies to treat 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 there is no financial barrier to follow-up colonoscopy for insured patients.
CRC screening rates in STOP CRC clinics
Applying familiar improvement approaches

- Using Plan Do Study Act Cycles
Process Improvement: Plan – Do – Study – Act

1. Plan
   - Plan the intervention

2. Do
   - Try the intervention on a small scale

3. Study
   - Study the results
   - Refine the intervention
   - Prepare for further implementation

4. Act
   - Plan the intervention
PDSA #2: Improving FIT sample collection

Improperly collected FIT tests: Plan-Do-Study-Act Cycle

<table>
<thead>
<tr>
<th>Month</th>
<th>N collection date missing</th>
<th>N improperly collected - other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov-14</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Dec-14</td>
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<tr>
<td>Jan-15</td>
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<td>13</td>
</tr>
<tr>
<td>Nov-15</td>
<td>14</td>
<td>11</td>
</tr>
<tr>
<td>Dec-15</td>
<td>12</td>
<td>12</td>
</tr>
</tbody>
</table>

Source: 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 1 different 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

Multnomah County Health Department

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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 hacerlo usted. Si recibe este análisis si tiene entre 50 y 74 años de edad y no ha tenido una colonoscopia en los últimos 9 años.

Aquí está su análisis Insure Fit. Haga lo en casa y devuélvalo. El examen verá la salud de su colon para ver si hay sangre en su popú. Conocer estas señales de advertencia temprano le dará la mejor posibilidad de un tratamiento exitoso.

Para el análisis:
- Empiece con un escobillón limpio y vacíe sin productos de limpieza en la agua. Jale la palanca de agua una vez antes de empezar.
- Use 2 muestras de popú 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

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Уважаемый(ая) 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 вашу жизнь. Вы можете получить данный тест, если ваш возраст от 50 до 74 лет, и за последние 9 лет вы не проходили колоноскопию.

Ваш тест 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 ранних 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. Убедитесь, что вода в унитазе не содержит никаких чистящих средств.
- Используйте 2 образца кала. 1 для отнесения к каждому образцу.
- Оставьте на 24 часа на проведение каждого теста.
- В течение следующих 3 дней после окончания теста вышлите его результаты в опломленном конверте.

Если у вас есть какие-либо вопросы, пожалуйста, свяжитесь с нами по телефону 503-988-5558.

Спасибо!

Marty Grasmeder, MD
Медицинский директор

Multnomah County Health Department

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
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

Challenges to Direct-Mail Fecal Testing Program

- Time burden on staff
- Impact on colonoscopy access
- Incompatible with patient population
- Low patient awareness
- Low EMR data quality

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Primary challenge to sustainability

Challenges to Direct-Mail Fecal Testing Program

- Time burden on staff
- Impact on colonoscopy access
- Incompatible with patient population
- Low patient awareness
- Low EMR data quality

N health centers

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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
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
Partnership to share costs of direct-mail expenses

Medicaid Health Plan (Care Oregon) -> Print Vendor (PrintSync) -> Health Center 1, Health Center 2, Health Center 3, Health Center (i)

- FIT kit returned
- Claim received
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