Good Data Practices
Cyberseminar Series 4.0

Focusing on the interaction between research design and data decisions

VIReC
RESEARCHERS' GUIDE TO VA DATA

Previous Good Data Practices cyberseminar series archived on HSR&D website

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Health Services Research & Development

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VIReC Cyberseminar Archive

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- **Filter** by VIReC series
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***Filter* by VIReC Series:** VIReC Good Data Practices **filter**

Search VIReC archive: **search**

DATE	TITLE	VIReC SERIES	PRESENTERS
2015/09/24	Using REDCap: Data management in studies linking primary and secondary data	Good Data Practices	Deppen, Stephen
2015/09/22	Decisions, Decisions, Decisions: Selecting Methods and Tools for Data Analysis	Good Data Practices	Hynes, Denise
2015/09/17	Mind the Gap: Using administrative and claims data to answer your research question	Good Data Practices	Wagner, Todd
2015/09/15	Planning for Data: Early, Often and Ongoing	Good Data Practices	Krein, Sarah
2014/05/29	Reduce, Reuse, Recycle: Planning for Data Sharing	Good Data Practices	Kok, Linda
2014/05/22	Controlled Chaos: Tracking Decisions During an Evolving Analysis	Good Data Practices	Groeneveld, Peter
2014/05/15	"The Living Protocol" – Managing Documentation While Managing Data	Good Data Practices	Maciejewski, Matt
2014/05/08	The Best Laid Plans: Plan Well, Plan Early	Good Data Practices	Garvin, Jennifer
2013/09/13	Research Application.	Good Data Practices	Maciejewski, Matt
2013/09/11	Planning for Data Re-use	Good Data Practices	Kok, Linda
2013/09/10	Managing and Documenting Data Workflow	Good Data Practices	Hynes, Denise
2013/09/09	Early Data Planning for Research	Good Data Practices	Hynes, Denise

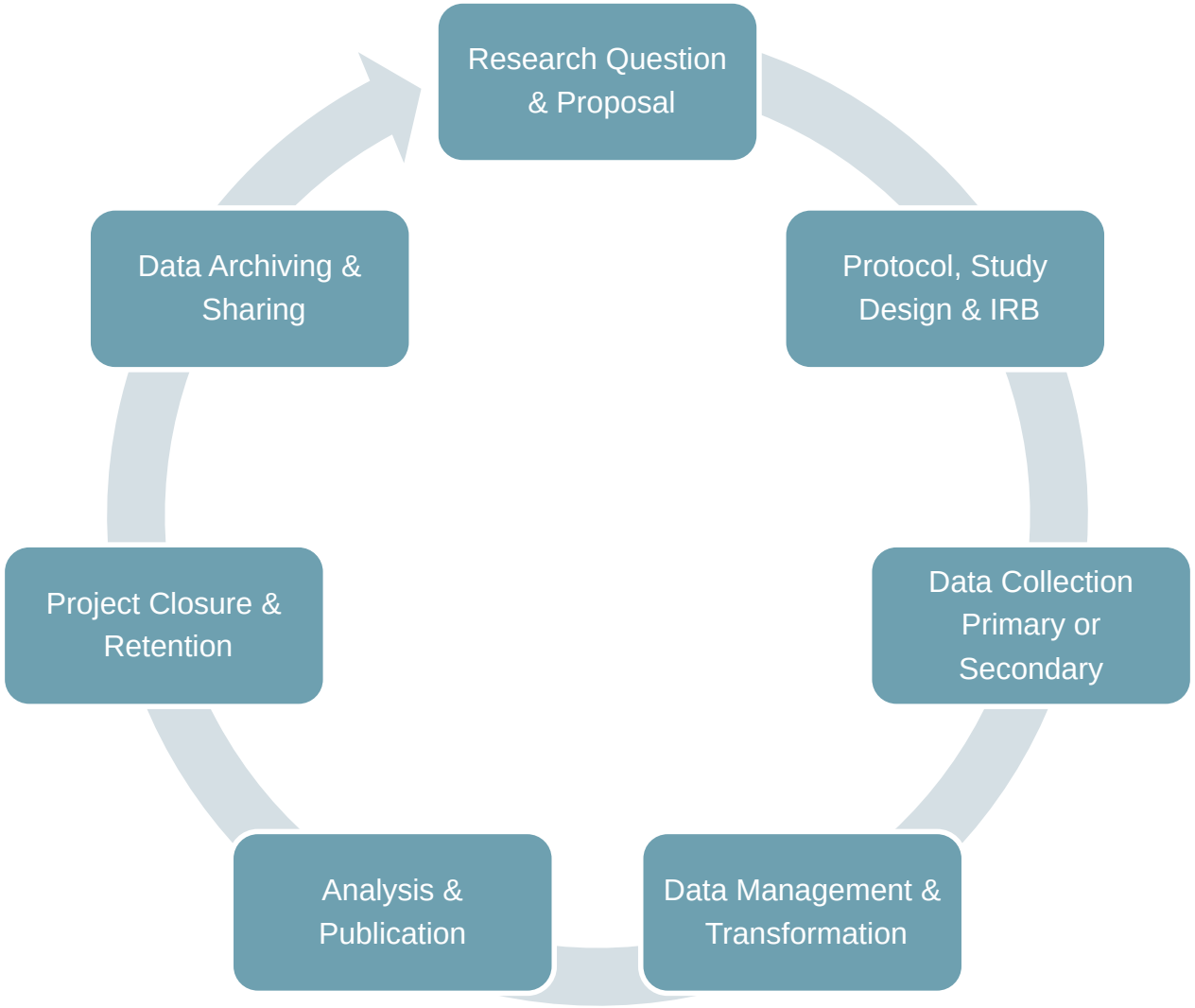
http://www.hsrd.research.va.gov/cyberseminars/catalog-archive-virec.cfm?

Good Data Practices Poll #1

Have you attended a Good Data Practice cyberseminar session before the current 2017 series?

- Yes
- No

Research Life Cycle



Examples of factors that influence data decisions

- Research question
- Study design
  - Objectives, aims, hypotheses
  - Independent and dependent variables
  - Planned manuscripts
- Available data
- Feasibility testing

Learning objectives of the Good Data Practices 4.0 series

Series' participants will

- Understand how previous research results and conceptual/decision models influence the development of the research question
- Learn how a research question can influence the choice of study design
- Understand ways in which research questions and study designs can affect decisions about data
- Become aware of potential data management and analysis challenges and ways they might be addressed
- Become familiar with potential limitations in VA data sources and examples of ways to address them

Visit our Education page for more information & registration links.
www.virec.research.va.gov

FY '17 Good Data Practice Cyberseminar Series

Tuesdays and Thursdays in February, 2017
1:00-2:00 PM (ET)

Date	Topic	Presenter
Tuesday, February 14, 2017	Incorporating Genomics in Routine Care for Veterans with Colon Cancer: Study Design and Data Decisions	Sara Knight
Thursday, February 16, 2017	Data Use and Data Decisions in a Mixed Methods Study about Hand Hygiene	Heather Reisinger
Tuesday, February 21, 2017	Data Decisions and Quantitative Analysis in a Study Investigating the Impact of Remote ICU Monitoring in VA Hospitals	Mary Vaughan-Sarrazin Amy O'Shea
Thursday, February 23, 2017	Capstone Discussion: The Influence of Research Design on Data Decisions	Discussant: Neil Jordan

VIReC
RESEARCHERS' GUIDE TO VA DATA

Poll #2: Your role as a data user

- What is your role in research and/or quality improvement?

a. Research investigator

b. Data manager

c. Project coordinator

d. Clinical Staff

e. Operations Staff

f. Other (please specify)

Poll #3: Your experience with VA data

How many years of experience do you have working with VA data?

- One year or less
- More than 1, less than 3 years
- At least 3, less than 7 years
- At least 7, less than 10 years
- 10 years or more

Good Data Practices Cyberseminar

Data Use and Data Decisions in a Mixed Methods Study about Hand Hygiene (HH)

Heather Schacht Reisinger, PhD

Associate Director for Research, Center for Comprehensive Access and Delivery Research and Evaluation, Iowa City VAHCS

Associate Professor, Internal Medicine, University of Iowa

February 16, 2017

Disclaimers

- The opinions expressed in this presentation are those of the author and do not necessarily reflect the views of the Department of Veterans Affairs.
- I’m a medical anthropologist.
- No financial disclosures or other disclaimers to report.

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- Nelson Chang
- Erin Balkenende
- Dan Suh
- Sue Bradley
- Sarah Krein
- Diana Sams
- Dan Morgan
- Lisa Pineles
- Shirley Goodman
- Kal Gupta
- Alex Rochman
- Makaila Decker
- Gio Baracco
- Carol Ramos
- Moraima Rodriguez
- Marvin Bittner
- Joseph Thurn
- Graeme Forrest
- Chris Pfeiffer
- Jwan Mohammadi
- Mike Rubin
- Jason Capron
- Amy Nelson
- Jose Cadena-Zuluaga
- Melissa Hibner

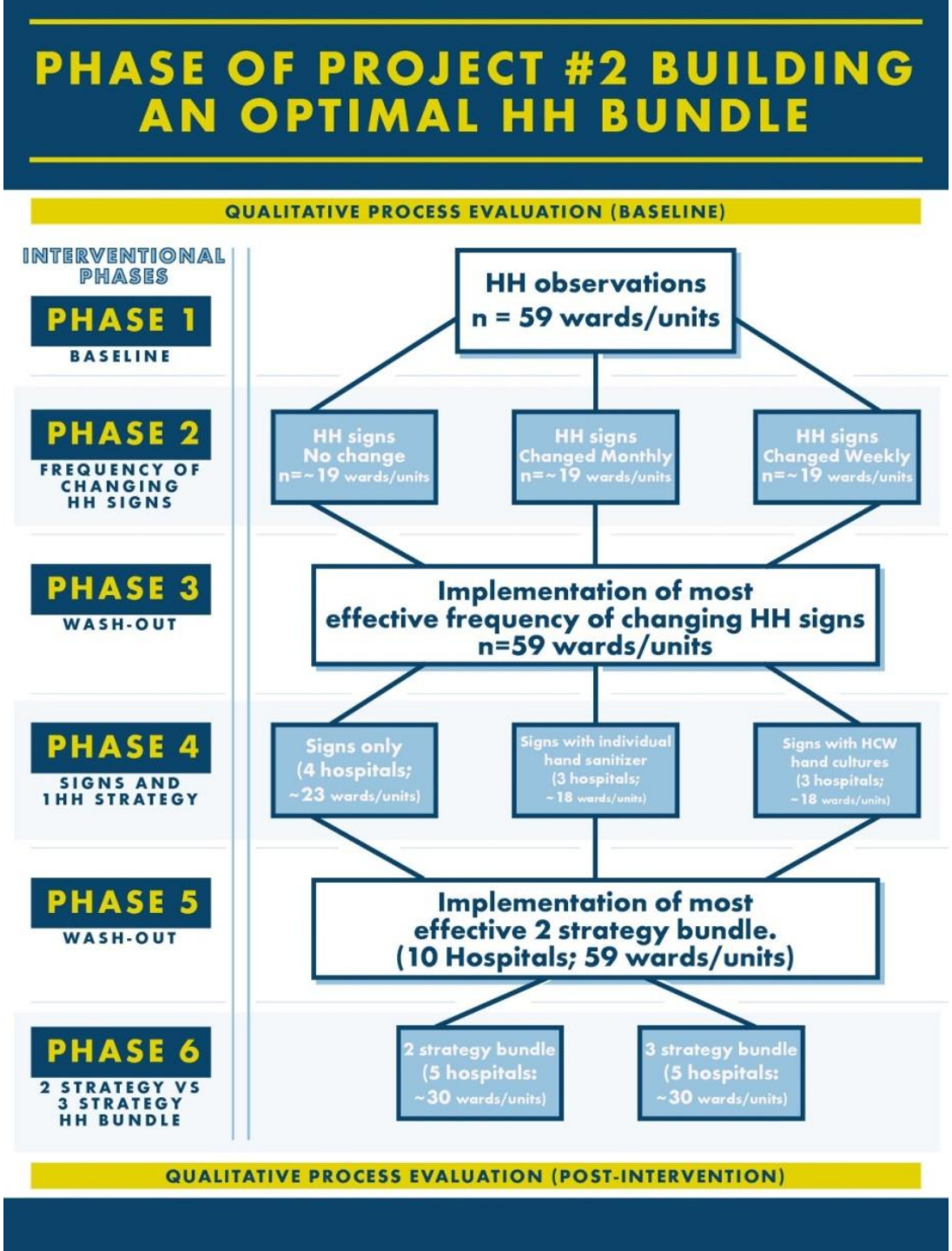
The objectives of this session are:

1. Describe a mixed methods study combining qualitative evaluation and a cluster randomized control trial
   - Which research questions are best addressed using qualitative methods?
   - Which questions does a cluster randomized control trial answer?
   - Why combine the two?

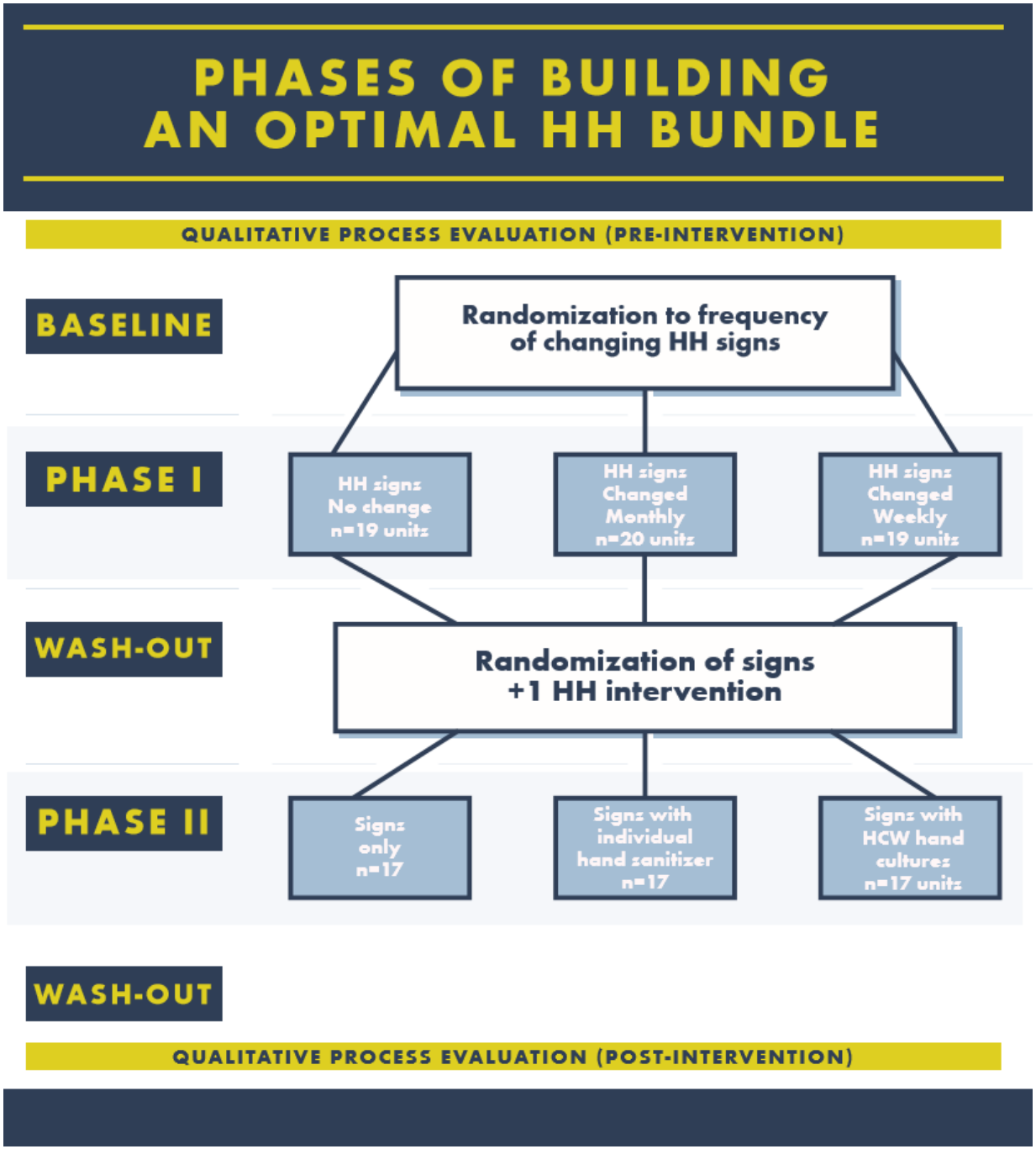
The objectives of this session are:

2. Review challenges, solutions, and lessons learned
   - Managing a multi-site, mixed methods study
   - Making good data decisions as a study evolves
3. Tell the story of…

How this…


PHASE OF PROJECT #2 BUILDING AN OPTIMAL HH BUNDLE
QUALITATIVE PROCESS EVALUATION (BASELINE)
INTERVENTIONAL PHASES
PHASE 1
BASELINE
HH observations n = 59 wards/units
PHASE 2
FREQUENCY OF CHANGING HH SIGNS
HH signs No change n=~19 wards/units
HH signs Changed Monthly n=~19 wards/units
HH signs Changed Weekly n=~19 wards/units
PHASE 3
WASH-OUT
Implementation of most effective frequency of changing HH signs n=59 wards/units
PHASE 4
SIGNS AND 1HH STRATEGY
Signs only (4 hospitals; ~23 wards/units)
Signs with individual hand sanitizer (3 hospitals; ~18 wards/units)
Signs with HCW hand cultures (3 hospitals; ~18 wards/units)
PHASE 5
WASH-OUT
Implementation of most effective 2 strategy bundle. (10 Hospitals; 59 wards/units)
PHASE 6
2 STRATEGY VS 3 STRATEGY HH BUNDLE
2 strategy bundle (5 hospitals: ~30 wards/units)
3 strategy bundle (5 hospitals: ~30 wards/units)
QUALITATIVE PROCESS EVALUATION (POST-INTERVENTION)

…became this.

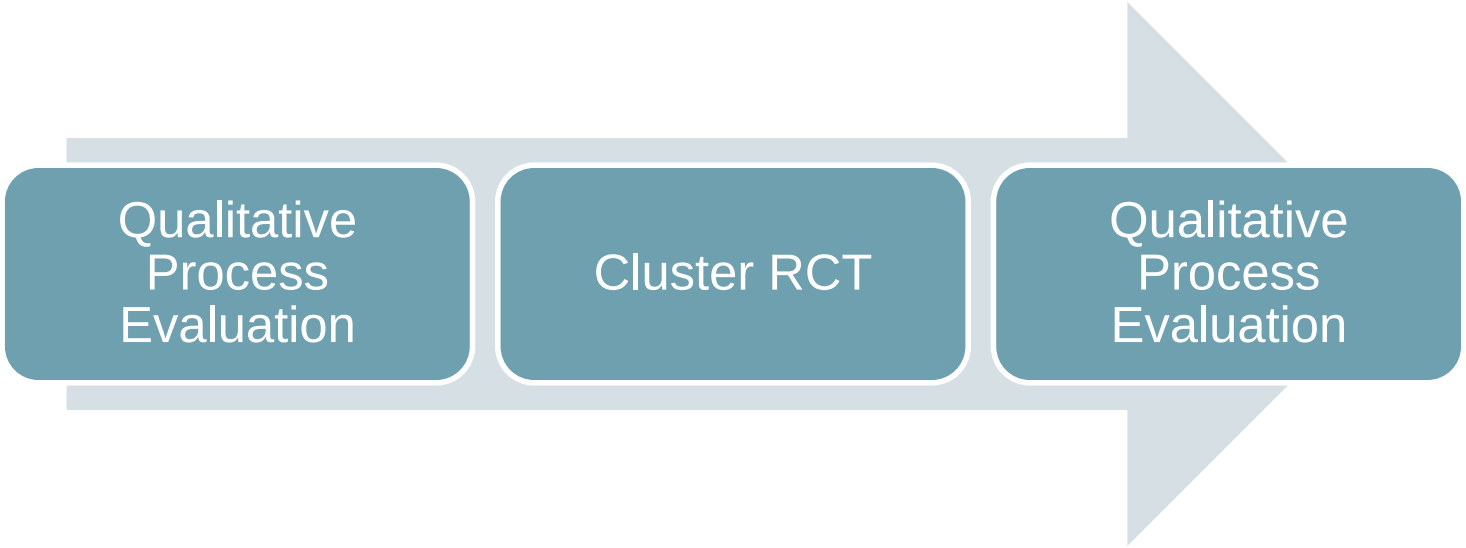

PHASES OF BUILDING AN OPTIMAL HH BUNDLE
QUALITATIVE PROCESS EVALUATION (PRE-INTERVENTION)
BASELINE
Randomization to frequency of changing HH signs
PHASE I
HH signs No change n=19 units
HH signs Changed Monthly n=20 units
HH signs Changed Weekly n=19 units
WASH-OUT
Randomization of signs +1 HH intervention
PHASE II
Signs only n=17
Signs with individual hand sanitizer n=17
Signs with HCW hand cultures n=17 units
WASH-OUT
QUALITATIVE PROCESS EVALUATION (POST-INTERVENTION)

Outline

- Background
- Qualitative design and methods
- Cluster randomized control trial
- Lessons learned

Background: Study Design and Aims

- Building an Optimal Hand Hygiene Bundle: A Mixed Methods Approach
  - Project #2 of the Advancing MRSA Infection Prevention CREATE
  - Sequential mixed methods study



Outline

- Background
- Qualitative design and methods
- Cluster randomized control trial
- Lessons learned

Aim 1 + Methods

- Identify combinations of hand hygiene intervention strategies that optimize hand hygiene compliance and that could form an evidence-based hand hygiene bundle for VHA implementation.

Cluster-randomized controlled trial that will sequentially test three individual hand hygiene interventions to identify an optimal combination of interventions to increase hand hygiene compliance.

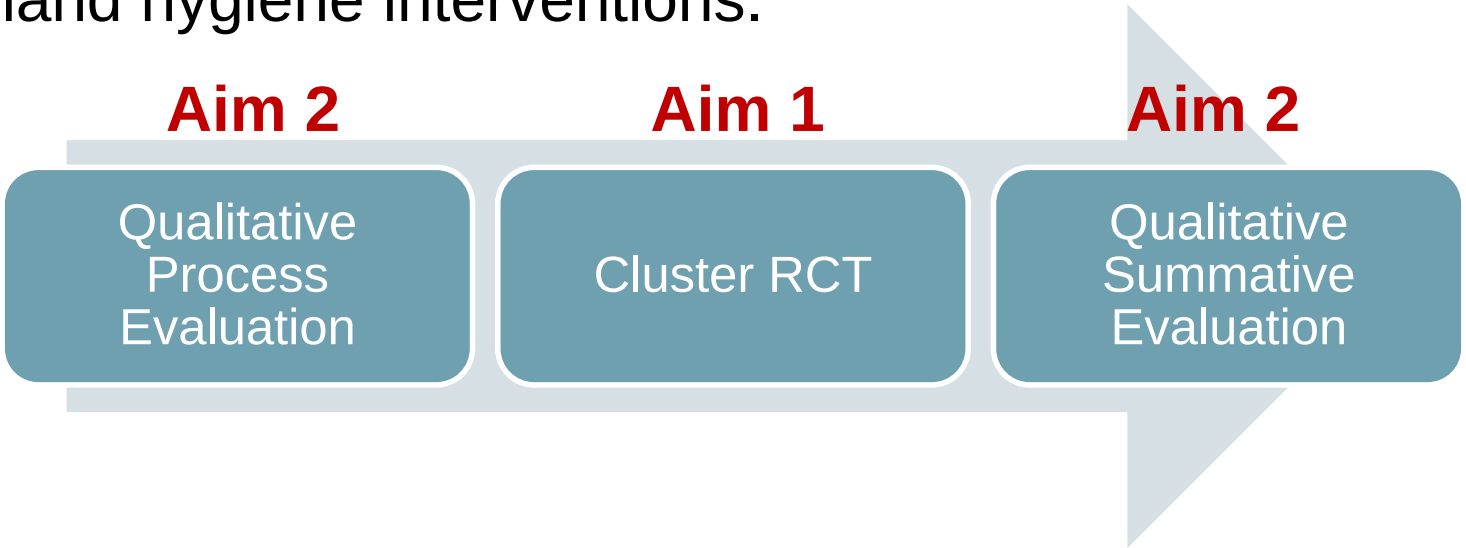
Aim 2 + Methods

- Identify institutional, organizational, ward/ICU, and individual level facilitators and barriers to implementing hand hygiene interventions.

Qualitative evaluation to examine barriers and facilitators to the interventions and develop contextual insight for implementing and scaling-up the intervention.

Sequencing Specific Aims and Methods

1. Identify combinations of hand hygiene intervention strategies that optimize hand hygiene compliance and that could form an evidence-based hand hygiene bundle for VHA implementation.
2. Identify institutional, organizational, ward/ICU, and individual level facilitators and barriers to implementing hand hygiene interventions.



Outline

- Background
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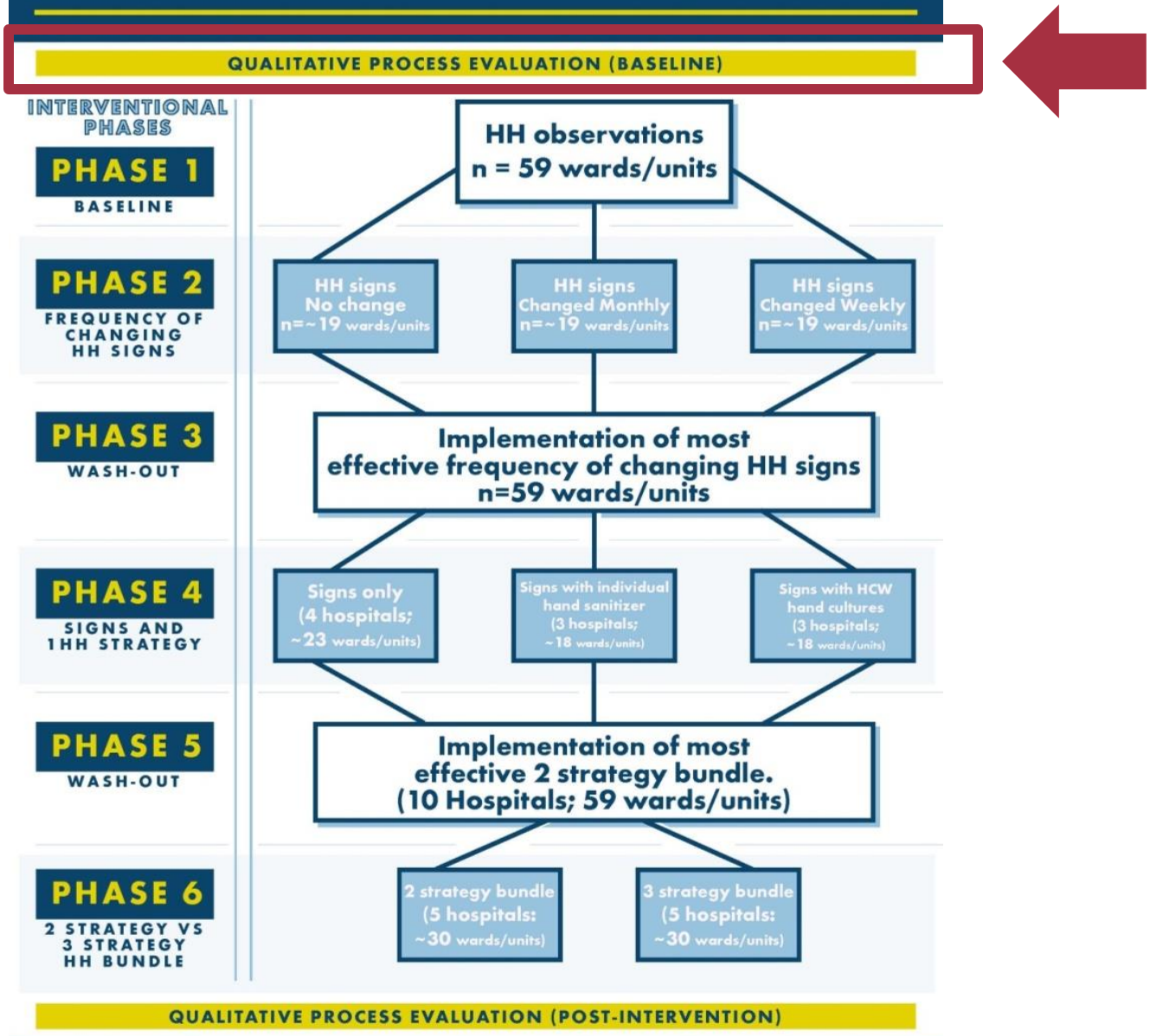
PHASE OF PROJECT #2 BUILDING AN OPTIMAL HH BUNDLE



Baseline Qualitative Evaluation

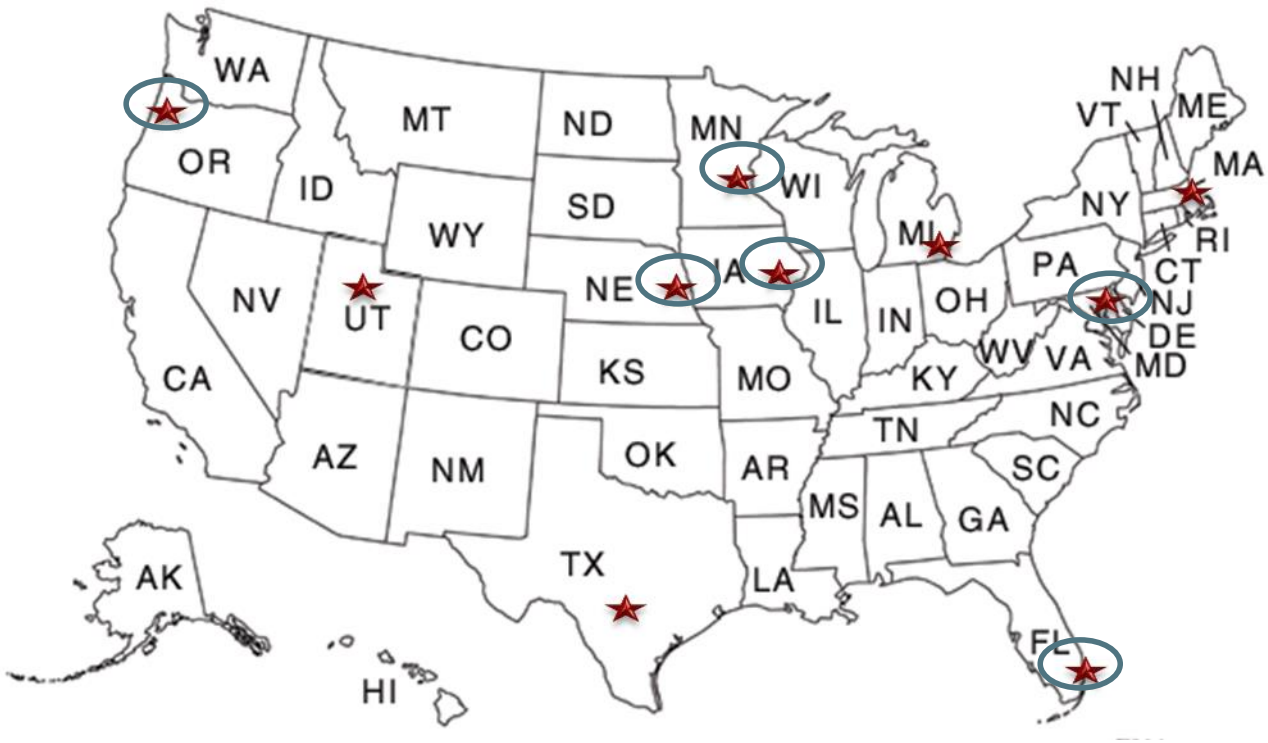
Six Site Visits:

- Interviews with Infection Control Team
- Interviews with staff most involved with HH program
- Focus groups with two wards/units per site
- Observations of current HH policies and practices

Four Phone "Visits":

- Interviews with Infection Control Team
- Interviews with staff most involved with HH program

Baseline Qualitative Evaluation



Site Observations

Baltimore, MD
Iowa City, IA
Miami, FL
Minneapolis, MN
Omaha, NE
Portland, OR

Phone Interviews Only

Ann Arbor, MI
Boston, MA
Salt Lake City, UT
San Antonio, TX

Collecting and Transforming Data

- Audio recordings → Over 40 Transcripts
- Field notes → Integrated Word document (6 sites)
- HH policy (all 10 sites)
- HH observation form (all 10 sites)
- Other documents staff thought we should have to understand their HH program (e.g., HH compliance reports, training materials for observers, etc.)

NOTE: Transcripts and field notes were uploaded to MAXQDA, a qualitative data management software program.

Participants

	Semi-Structured Interview Participants
Hospital Epidemiologists	10
Infection Preventionists	15
MRDO Coordinators	7
Other (e.g., Quality, Patient Safety)	7
Total	39

	Focus Group Participants
Nursing Staff	53
Medical	3
Environmental Services	3
Administrative	4
Other	5
Blank	1
Total	69

Interdisciplinary Team-based Analysis Process

Phase I:

Large “Chunk” Coding

Phase II:
Subcoding/Analysis

Phase III:

Manuscript Development

Phase I: Coding

- Each team member read 3 transcripts and noted structure of interviews, themes, and items of interest
- Met and drafted preliminary codebook
- Coded another transcript independently based on preliminary codebook, review transcript coding as a team, and revised codebook as necessary
- Continued team coding process throughout Phase I (48.8%)
- After codebook solidified, pairs of coders coded a subset of transcripts (51.2%)

Phase II and III: Subcoding, Analysis and Manuscript

EXAMPLE:

- Codes: “HH strategies” and “HH monitoring”
- Manuscript Theme: Hand Hygiene Programs
- Additional Data: Site HH data collection forms and HH policies
- Analysis: Database and subcoding process (described in Phase I)

Example:

Descriptive Analysis of Hand Hygiene Programs

HH Monitoring Process (n=10)

Who manages the program?	**Infection Control Team**	**6**
	Quality/Patient Safety	**4**
Who conducts observations?	**Infection Control Team**	**4**
	Quality/Patient Safety	**2**
	Champions	**7**
	Other	**2**
How is data collected?	**Paper/Pencil**	**9**
	iScrub	**1**
Who enters data?	**Infection Control Team**	**5**
	Quality/Patient Safety	**3**
	Champions	**1**
	Automated	**1**
Who reports data to leadership?	**Infection Control Team**	**10**

HH Monitoring Data Collection Forms (n=10)

Time marker on form	Monthly	6
	Specific Date	4
	Shift	5
	Specific Time	2
Identity of observer		6
Types of people observed	Nursing	10
	Medical	10
	Lab draw	7
HH Opportunities	Entry/Exit	6
	WHO 5 Moments	2
	Unique Combination	2
Method		4
Isolation precautions and PPE		3
Reasons for noncompliance		3

FY15 STVHCS Hand Hygiene Observation and Contributing Factors Form

Month of Observations: _____ Data Collected by: _____ Unit/Dept/Clinic: _____

Instructions: (1) Use a separate row for EACH entry or exit; (2) When there is a deficiency, indicate any observable factors that could have contributed; (3) Emergency situations are EXCLUDED from this monitoring

Observation # (at least 10 required monthly)	Date of Observation (example: 8/3)	Shift: Day, Evening, or Night	NRS = Nurse (RN & LVN) NA = Nursing Assistant MD = Physician (includes DO, DDS, DC) Mid-levels = NPs, CRNAs, and PAs PT/OT = Physical or Occupational Therapist Diet = Dietary Technician Lab = Lab Technician HSK = Housekeeper C = Chaplain Other = Identify in Comments (column K)	Entry or Exit? (Choose only ONE)		Staff performed appropriate hand hygiene?	If "NO" please continue	Hand Sanitizer dispenser issues (e.g., location, empty, broken, etc)?	Hands full?	Frequent entry and exit?	Admission or discharge process?	Improper use of gloves?	Comments
	A	B	C	D	E		F	G	H	I	J	K
1		D E N	NRS NA MD Mid PT Diet Lab HSK C Other	EN EX	Y N		Y N	Y N	Y N	Y N	Y N	
2		D E N	NRS NA MD Mid PT Diet Lab HSK C Other	EN EX	Y N		Y N	Y N	Y N	Y N	Y N	
3		D E N	NRS NA MD Mid PT Diet Lab HSK C Other	EN EX	Y N		Y N	Y N	Y N	Y N	Y N	
4		D E N	NRS NA MD Mid PT Diet Lab HSK C Other	EN EX	Y N		Y N	Y N	Y N	Y N	Y N	
5		D E N	NRS NA MD Mid PT Diet Lab HSK C Other	EN EX	Y N		Y N	Y N	Y N	Y N	Y N	
6		D E N	NRS NA MD Mid PT Diet Lab HSK C Other	EN EX	Y N		Y N	Y N	Y N	Y N	Y N	
7		D E N	NRS NA MD Mid PT Diet Lab HSK C Other	EN EX	Y N		Y N	Y N	Y N	Y N	Y N	
8		D E N	NRS NA MD Mid PT Diet Lab HSK C Other	EN EX	Y N		Y N	Y N	Y N	Y N	Y N	
9		D E N	NRS NA MD Mid PT Diet Lab HSK C Other	EN EX	Y N		Y N	Y N	Y N	Y N	Y N	
10		D E N	NRS NA MD Mid PT Diet Lab HSK C Other	EN EX	Y N		Y N	Y N	Y N	Y N	Y N	

10/2013 cmw
Revised 1/2014

NM will scan and email to Michelle Willingham by the COB of the 5th of the following month.
If scanning is unavailable, please fax to Michelle in Infection Control at 617-5291. *Thank you.*

Language to Describe Observers

Nurse 1: Well, they used to have people come along and look at you. You know?

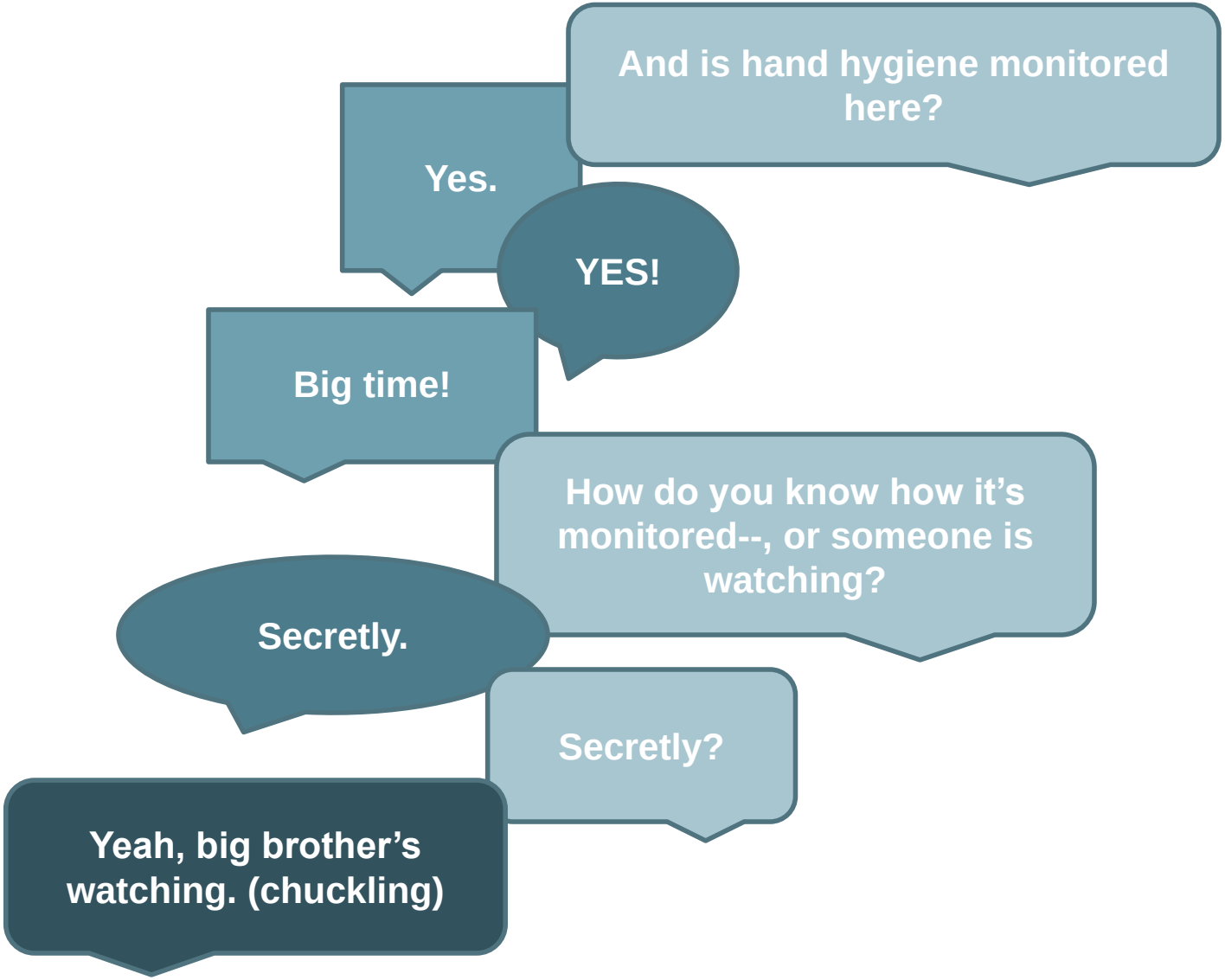
Interviewer: They had observers?

Nurse 2: The secret, secret shoppers. I have--, not seen [lately].

Interviewer: (overlapping) Secret shoppers?

Nurse 1: We just call ‘em spies. (laughter)

Language to Describe Observers



Language to Describe Observers

So you have to wash your hands in the room and then you come out and there's a hand washing Nazi there, they catch you and say you didn't wash your hands, because they don't see you wash your hands (chuckles)

So who's the hand washing Nazi?

Infectious disease control.

So they're very present?

Mmm. Not very, but enough. We don't see 'em every day. It's--, it's sporadic 'cause you know they go to different wards.

Outline

- Background
- Qualitative design and methods
- Cluster randomized control trial
- Lessons learned

Aim 1 + Methods

- Identify combinations of hand hygiene intervention strategies that optimize hand hygiene compliance and that could form an evidence-based hand hygiene bundle for VHA implementation.

Cluster-randomized controlled trial that will sequentially test three individual hand hygiene interventions to identify an optimal combination of interventions to increase hand hygiene compliance.

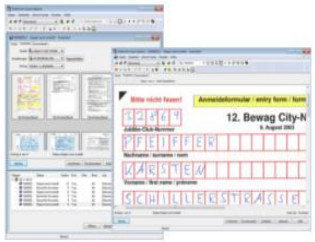
Primary Outcome: HH Compliance

HH observations collected by trained observers at each of the sites

- Process:
  - Observer stands outside patient room
  - Observes HCW HH behaviors for 15 minutes
  - Records behaviors on a structured observation template
  - Moves onto another ward/unit
  - Observes another patient room (records on a new form)
  - 10 hours per week of observation (40 observation forms)
  - Note: If HCWs ask why they are on the unit, reply with cover story about studying patient flow in and out of rooms.

HH Data Collection: TELEform

- TELEform used to collect data
- Completed TELEforms uploaded to a VA SharePoint
- Data manager uploads forms and reviews data
- What is TELEform?
  - A computerized data entry system that uses Optical Character Recognition (OCR) to read data collection forms
- Why use TELEform?
  - Accuracy
  - Quick and efficient data entry
  - Double data entry achieved with just one operator



TELEFORM®

Appendix A: CREATE Observation Data Collection Form

Site: ☐ ANN ☐ BAL ☐ BOS ☐ IOW ☐ MIA ☐ MIN ☐ OMA ☐ POR ☐ SAN ☐ SAL **Unit/Ward** ☐☐ **Room:** ☐ **Observer:** ☐☐☐

Date: ☐☐ / ☐☐ / ☐☐ **Start:** ☐☐ : ☐☐ ☐ AM ☐ PM **Stop:** ☐☐ : ☐☐ ☐ AM ☐ PM **# Beds:** ☐ **# Patients:** ☐

Month Day Year

Isolation: ☐ No ☐ Yes (IF YES:) **Isolation Type:** ☐ Contact ☐ Droplet ☐ Airborne ☐ Enteric ☐ Other

(If more than one form is required, all fields in this section must be EXACT on all associated forms for proper data linkage to occur)

No Activity: ☐ *(Check here if there is no activity. No observations should be completed below.)*

ENTRY						5 MOMENTS												EXIT		
						BEFORE						AFTER								
						pt contact			aseptic task			fluid exposure		pt contact		surroundings				
Time	HCW	HH/Mthd		Gloves	Gown	HH/Mthd		Gloves	HH/Mthd		Gloves	HH/Mthd		HH/Mthd		HH/Mthd		HH/Mthd		Time
☐☐ : ☐☐ ☐ AM ☐ PM	☐☐	☐ Y ☐ N ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ U	☐ Y ☐ N ☐ U	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ U	☐ S ☐ P ☐ W	☐☐ : ☐☐ ☐ AM ☐ PM
☐☐ : ☐☐ ☐ AM ☐ PM	☐☐	☐ Y ☐ N ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ U	☐ Y ☐ N ☐ U	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ U	☐ S ☐ P ☐ W	☐☐ : ☐☐ ☐ AM ☐ PM
☐☐ : ☐☐ ☐ AM ☐ PM	☐☐	☐ Y ☐ N ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ U	☐ Y ☐ N ☐ U	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ U	☐ S ☐ P ☐ W	☐☐ : ☐☐ ☐ AM ☐ PM
☐☐ : ☐☐ ☐ AM ☐ PM	☐☐	☐ Y ☐ N ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ U	☐ Y ☐ N ☐ U	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ U	☐ S ☐ P ☐ W	☐☐ : ☐☐ ☐ AM ☐ PM
☐☐ : ☐☐ ☐ AM ☐ PM	☐☐	☐ Y ☐ N ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ U	☐ Y ☐ N ☐ U	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ U	☐ S ☐ P ☐ W	☐☐ : ☐☐ ☐ AM ☐ PM

HH Opportunities:
Y = Yes
N = No
N/A = Not applicable/Didn't perform task
U = Unobserved/Didn't see

HH Method:
S = Soap and water
P = Pocket hand rub
W = Wall-mounted hand rub

HCW Type:---------------------------CLINICAL---------------------------
DT: Dietician/Nutritionist
IV: IV Team
MD: Physician
MS: Medical Student
NP: Nurse Practitioner/Physician Asst
NS: Nursing Student
PC: Patient Care Tech/Nursing Asst
PH: Pharmacist/Pharmacy Student
RD: Radiology Tech
RH: Rehab Services (PT/OT)
RN: Nurse (RN, LPN, BSN)
RT: Resp Therap
SW: Social Worker
UC: None of the above/ unknown clinical

NON-CLINICAL
CH: Chaplain
ES: Environ Services
FS: Food Service
PT: Patient Transporter
VI: Visitor
VO: Volunteer
UN: None of the above/ unknown non-clinical

Comments: ☐

REISINGER_CREATE_V2 *10/14/2014* 1435144620

Appendix A: CREATE Observation Data Collection Form

Site: ☐ ANN ☐ BAL ☐ BOS ☒ IOW ☐ MIA ☐ MIN ☐ OMA ☐ POR ☐ SAN ☐ SAL **Unit/Ward** 09 **Room:** 14 **Observer:** CLG

Date: 05 / 05 / 15 (Month / Day / Year) **Start:** 10 : 45 ☒ AM ☐ PM **Stop:** 11 : 00 ☒ AM ☐ PM **# Beds:** 1 **# Patients:** 1

Isolation: ☐ No ☐ Yes **(IF YES:) Isolation Type:** ☐ Contact ☐ Droplet ☐ Airborne ☒ Enteric ☐ Other

(If more than one form is required, all fields in this section must be EXACT on all associated forms for proper data linkage to occur)

No Activity: ☐ *(Check here if there is no activity. No observations should be completed below.)*

ENTRY						5 MOMENTS – BEFORE – pt contact			BEFORE – aseptic task			AFTER – fluid exposure		AFTER – pt contact		AFTER – surroundings		EXIT	
Time	HCW	HH/Mthd		Gloves	Gown	HH/Mthd		Gloves	HH/Mthd		Gloves	HH/Mthd		HH/Mthd		HH/Mthd		HH/Mthd	Time
: ☐ AM ☐ PM		☐ Y ☐ N ☒ U	☐ S ☐ P ☐ W	☐ Y ☒ N ☐ U	☐ Y ☒ N ☐ U	☐ Y ☒ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☒ N	☐ Y ☐ N ☒ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☒ N	☐ Y ☐ N ☒ N/A ☐ U	☐ S ☐ P ☐ W	☒ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☒ W	☐ Y ☒ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☒ Y ☐ N ☐ U	☐ S ☐ P ☒ W	10 : 50 ☒ AM ☐ PM
10 : 48 ☒ AM ☐ PM	ES	☐ Y ☒ N ☐ U	☐ S ☐ P ☐ W	☐ Y ☒ N ☐ U	☐ Y ☒ N ☐ U	☐ Y ☐ N ☒ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☒ N	☐ Y ☐ N ☒ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☒ N	☐ Y ☐ N ☒ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☒ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☒ N/A ☐ U	☐ S ☐ P ☐ W	☒ Y ☐ N ☐ U	☐ S ☐ P ☒ W	10 : 49 ☒ AM ☐ PM
10 : 53 ☒ AM ☐ PM	CH	☐ Y ☒ N ☐ U	☐ S ☐ P ☐ W	☐ Y ☒ N ☐ U	☐ Y ☒ N ☐ U	☐ Y ☐ N ☒ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☒ N	☐ Y ☐ N ☒ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☒ N	☐ Y ☐ N ☒ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☒ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☒ N/A ☐ U	☐ S ☐ P ☐ W	☒ Y ☐ N ☐ U	☐ S ☐ P ☒ W	10 : 54 ☒ AM ☐ PM
10 : 55 ☒ AM ☐ PM	CH	☒ Y ☐ N ☐ U	☐ S ☐ P ☒ W	☒ Y ☐ N ☐ U	☒ Y ☐ N ☐ U	☒ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☒ W	☒ Y ☐ N	☐ Y ☐ N ☒ N/A ☐ U	☐ S ☐ P ☐ W	☒ Y ☐ N	☐ Y ☐ N ☒ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☒ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☒ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☒ W	☒ Y ☐ N ☐ U	☐ S ☐ P ☒ W	11 : 00 ☒ AM ☐ PM
: ☐ AM ☐ PM		☐ Y ☐ N ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ U	☐ Y ☐ N ☐ U	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ N/A ☐ U	☐ S ☐ P ☐ W	☐ Y ☐ N ☐ U	☐ S ☐ P ☐ W	: ☐ AM ☐ PM

HH Opportunities:
Y = Yes
N = No
N/A = Not applicable/Didn't perform task
U = Unobserved/Didn't see

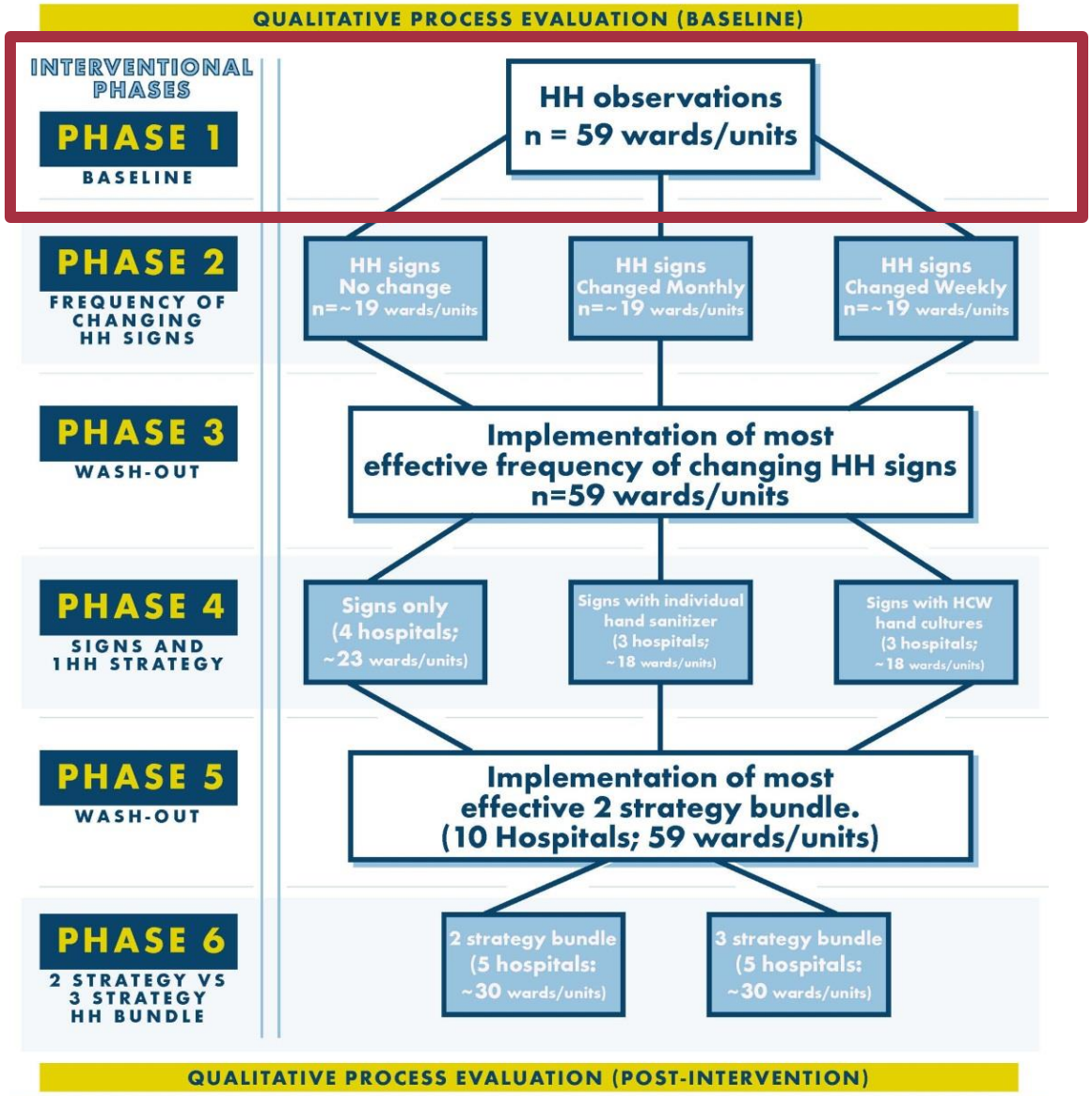
HH Method:
S = Soap and water
P = Pocket hand rub
W = Wall-mounted hand rub

HCW Type: ----------CLINICAL----------
DT: Dietician/Nutritionist
IV: IV Team
MD: Physician
MS: Medical Student
NP: Nurse Practitioner/Physician Asst
NS: Nursing Student
PC: Patient Care Tech/Nursing Asst
PH: Pharmacist/Pharmacy Student
RD: Radiology Tech
RH: Rehab Services (PT/OT)
RN: Nurse (RN, LPN, BSN)
RT: Resp Therap
SW: Social Worker
UC: None of the above/ unknown clinical

NON-CLINICAL
CH: Chaplain
ES: Environ Services
FS: Food Service
PT: Patient Transporter
VI: Visitor
VO: Volunteer
UN: None of the above/ unknown non-clinical

Comments: RN in room on arrival [redacted] CG 5/5/15

PHASE OF PROJECT #2 BUILDING AN OPTIMAL HH BUNDLE



Poll #4: Hand Hygiene Compliance

- In a systematic analysis of over 75 hand hygiene studies, what was the average baseline compliance rate?
  - 92.3%
  - 78.7%
  - 38.7%
  - 15.6%

Phase 1: Baseline

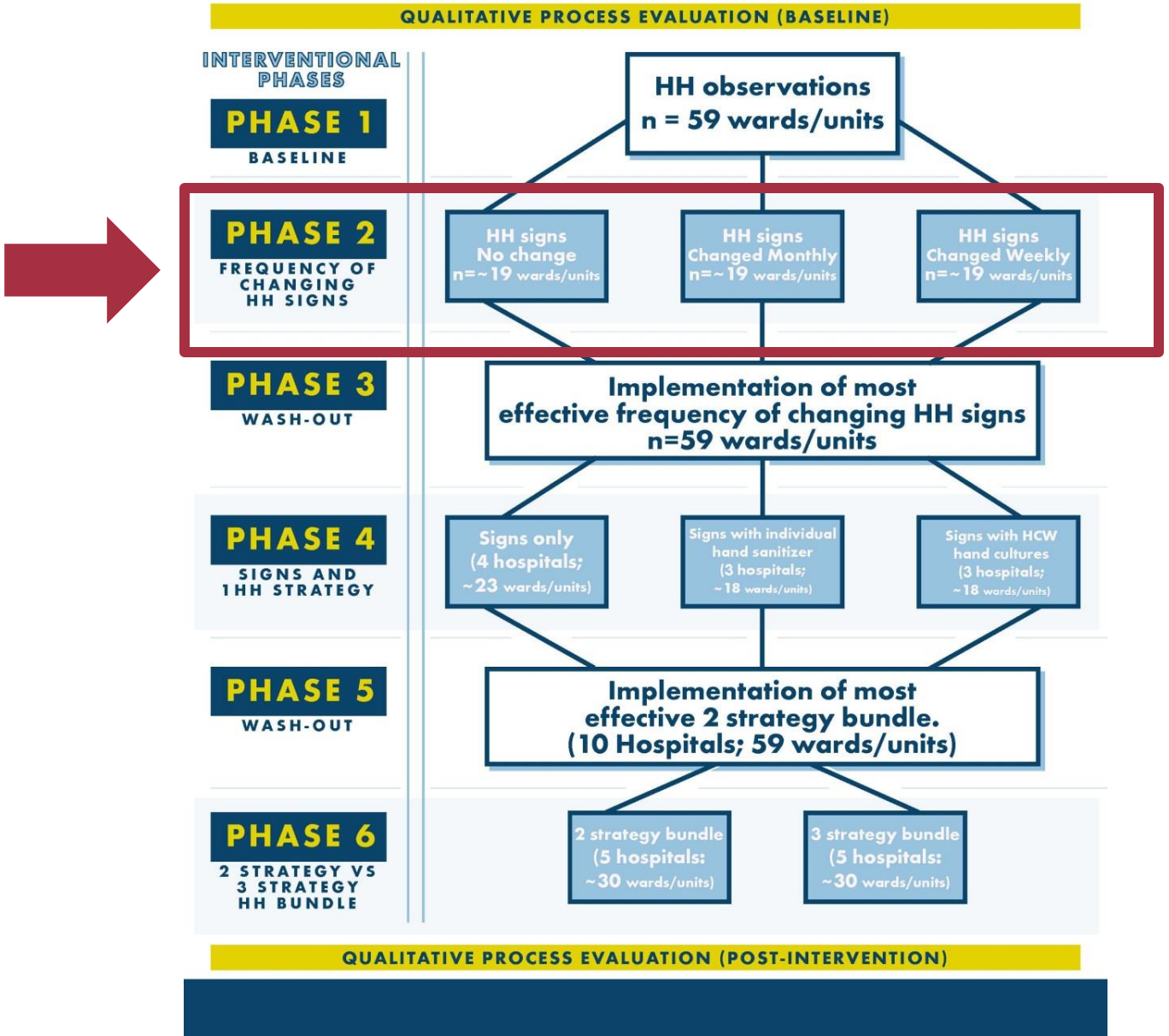
- Six months of data collection
- Collected baseline HH data for 59 wards/units at nine sites

19,554 Observations

9710 Entry
14% - 66%

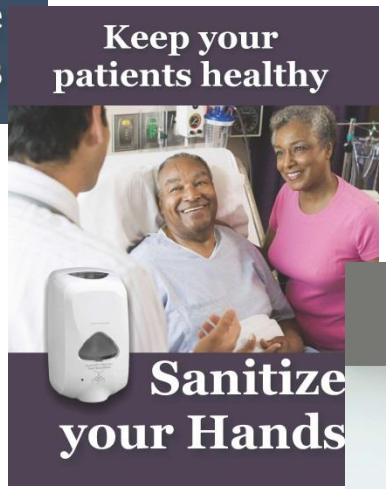
9844 Exit
36% - 69%

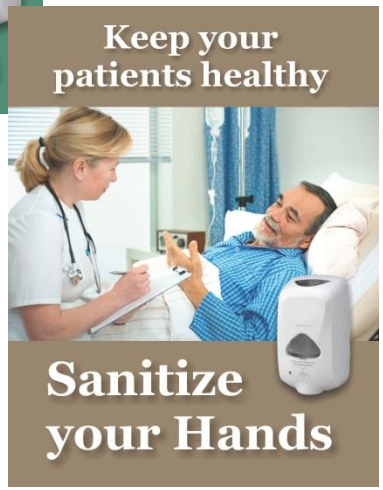
PHASE OF PROJECT #2 BUILDING AN OPTIMAL HH BUNDLE



Phase II: Signs

- Six month intervention period
- Frequency of changing point-of-use reminder signs
  - No change in signs
  - Change of signs monthly
  - Change of signs weekly
- Implemented as a cue to action, but to counter habituation





Signs

Keep your patients healthy
Sanitize your Hands
Keep your patients healthy
Sanitize your Hands
Keep your patients healthy
Sanitize your Hands
Keep your patients healthy
Sanitize your Hands
Keep your patients healthy
Sanitize your Hands
Keep your patients healthy
Sanitize your Hands

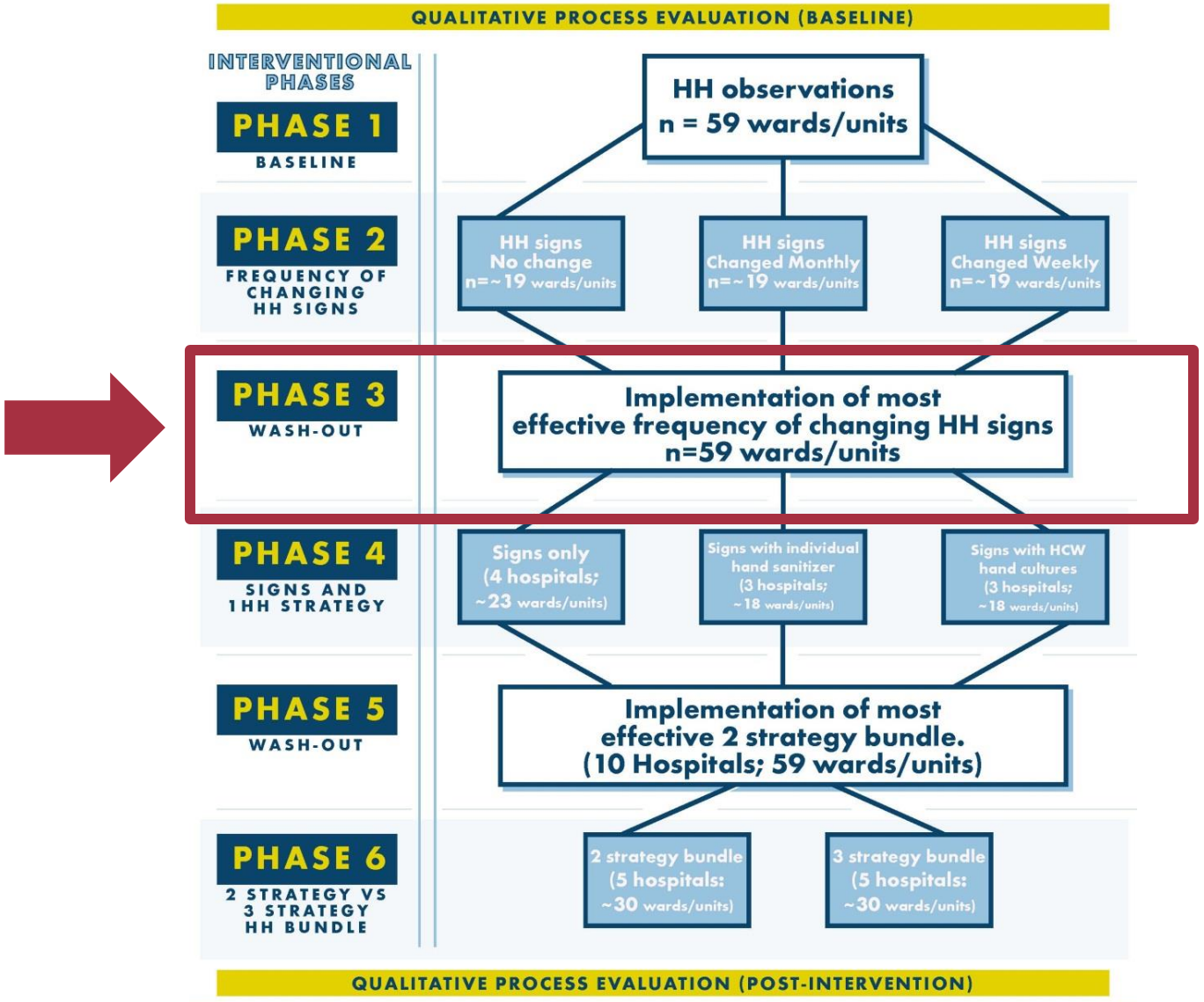
Block Randomization by Wards/Units

- Units ranked by compliance rate
- Randomized to one of three arms
  - No change in signs
  - Change of signs monthly
  - Change of signs weekly

The Challenges Begin

- Delay starting the intervention period
  - Didn’t plan for time to analyze full 6 months of baseline data (e.g., create a clean dataset) and time to work with statistician to create the block randomization (~2 month delay)
  - Piloted signs at 3 VA sites; implementing it at 9 was a different story (~1 month)
- Down to 8 sites and 51 units
- Statistician raises concerns about power calculations after reviewing real data

PHASE OF PROJECT #2 BUILDING AN OPTIMAL HH BUNDLE



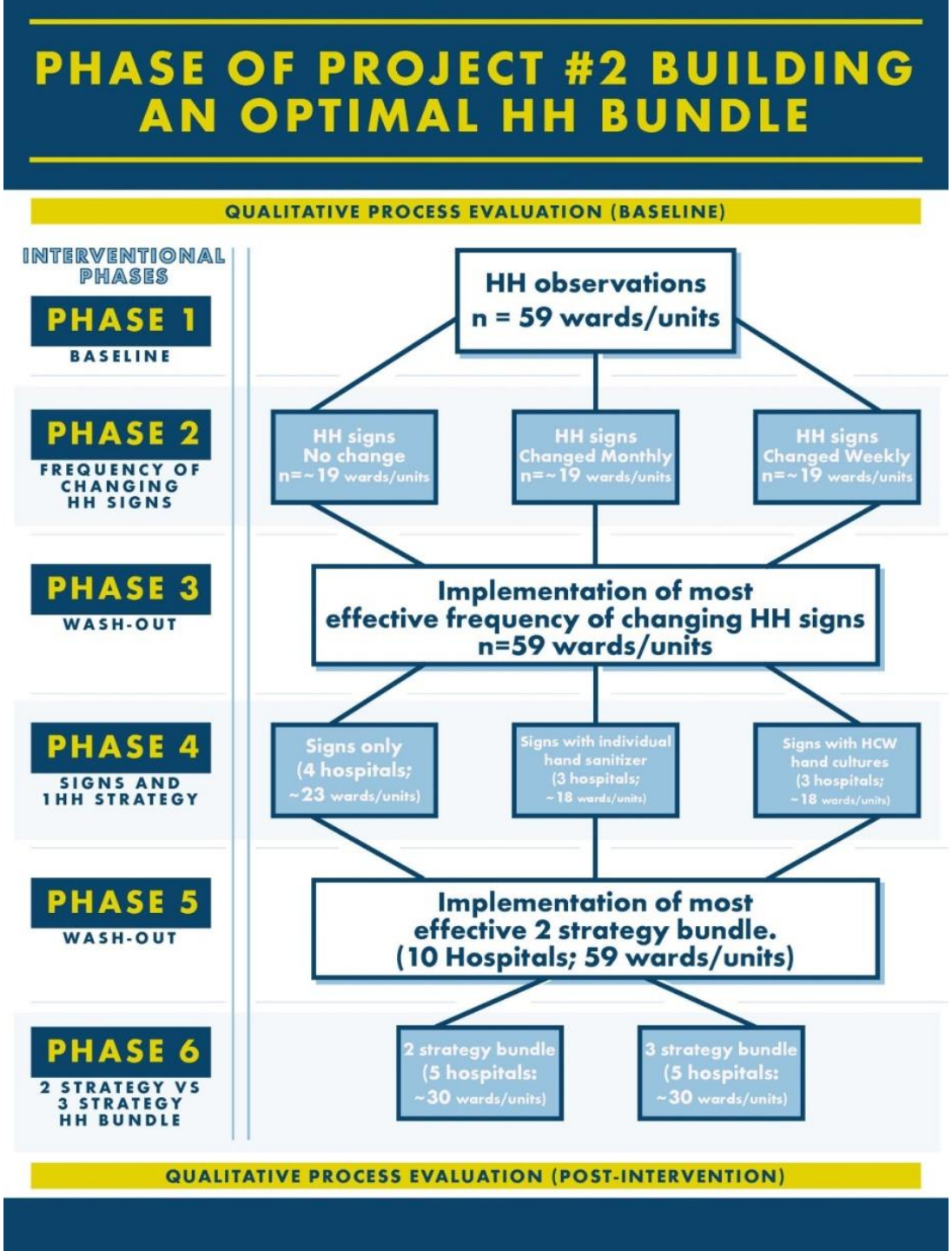
Phase III: Wash-Out

- Qualitative interviews conducted over the phone with the Infection Control Team to elicit feedback on implementing the intervention
- Signs changed based on the frequency determined most effectiveness in Phase II

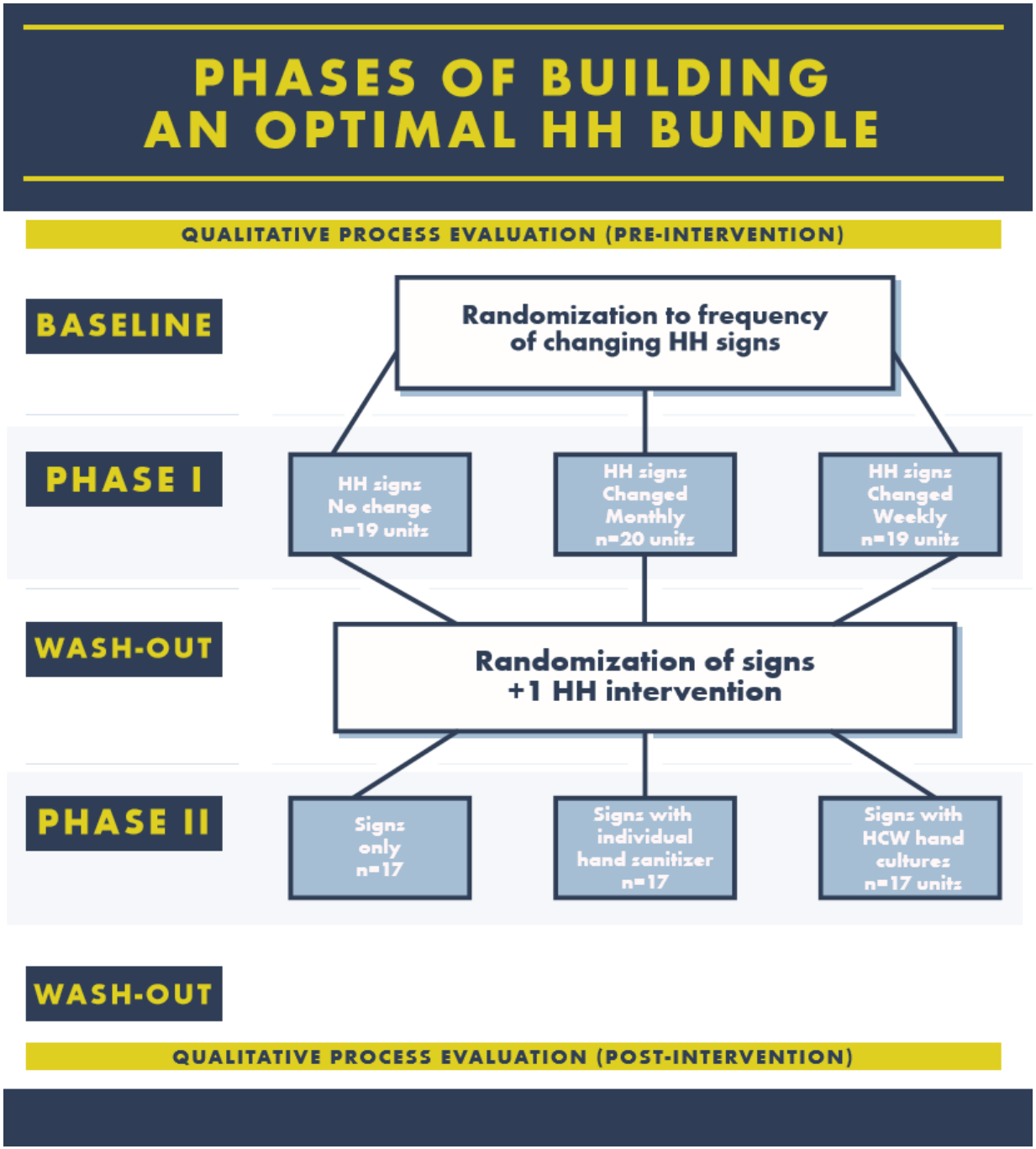
More Challenges (and Solutions)

- Effectiveness of changing signs is not clear cut
  - Decided not to change signs during wash-out period
- Shortened wash-out period to make up for delays in implementing the first intervention phase
- Analysis of problems with power calculations
  - Extend the Phase IV intervention period

When this…

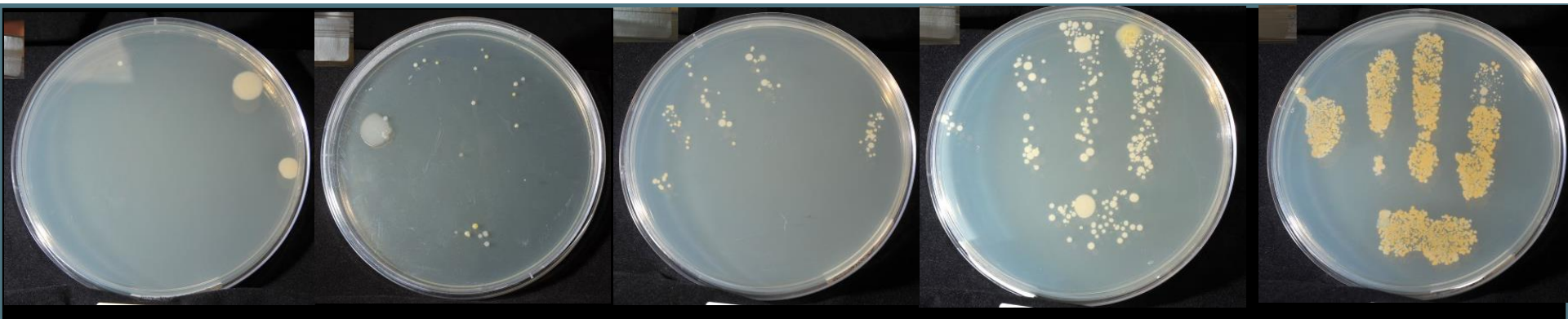

PHASE OF PROJECT #2 BUILDING AN OPTIMAL HH BUNDLE
QUALITATIVE PROCESS EVALUATION (BASELINE)
INTERVENTIONAL PHASES
PHASE 1
BASELINE
HH observations n = 59 wards/units
PHASE 2
FREQUENCY OF CHANGING HH SIGNS
HH signs No change n=~19 wards/units
HH signs Changed Monthly n=~19 wards/units
HH signs Changed Weekly n=~19 wards/units
PHASE 3
WASH-OUT
Implementation of most effective frequency of changing HH signs n=59 wards/units
PHASE 4
SIGNS AND 1HH STRATEGY
Signs only (4 hospitals; ~23 wards/units)
Signs with individual hand sanitizer (3 hospitals; ~18 wards/units)
Signs with HCW hand cultures (3 hospitals; ~18 wards/units)
PHASE 5
WASH-OUT
Implementation of most effective 2 strategy bundle. (10 Hospitals; 59 wards/units)
PHASE 6
2 STRATEGY VS 3 STRATEGY HH BUNDLE
2 strategy bundle (5 hospitals: ~30 wards/units)
3 strategy bundle (5 hospitals: ~30 wards/units)
QUALITATIVE PROCESS EVALUATION (POST-INTERVENTION)

…became this.


PHASES OF BUILDING AN OPTIMAL HH BUNDLE
QUALITATIVE PROCESS EVALUATION (PRE-INTERVENTION)
BASELINE
Randomization to frequency of changing HH signs
PHASE I
HH signs No change n=19 units
HH signs Changed Monthly n=20 units
HH signs Changed Weekly n=19 units
WASH-OUT
Randomization of signs +1 HH intervention
PHASE II
Signs only n=17
Signs with individual hand sanitizer n=17
Signs with HCW hand cultures n=17 units
WASH-OUT
QUALITATIVE PROCESS EVALUATION (POST-INTERVENTION)

Phase IV: Signs Plus One

- Point-of-use reminder signs remained the same throughout Phase IV
- Randomization of sites to three conditions
  - Signs only
  - Signs plus individual hand sanitizer dispensers
  - Signs plus HCW hand cultures



PHASE OF PROJECT #2 BUILDING AN OPTIMAL HH BUNDLE

QUALITATIVE PROCESS EVALUATION (BASELINE)

INTERVENTIONAL PHASES

PHASE 1 BASELINE

HH observations
n = 59 wards/units

PHASE 2 FREQUENCY OF CHANGING HH SIGNS

HH signs No change n=~19 wards/units

HH signs Changed Monthly n=~19 wards/units

HH signs Changed Weekly n=~19 wards/units

PHASE 3 WASH-OUT

Implementation of most effective frequency of changing HH signs n=59 wards/units

PHASE 4 SIGNS AND 1HH STRATEGY

Signs only (4 hospitals; n=3 wards/units)

Signs with individual hand sanitizer (3 hospitals; ~18 wards/units)

Signs with HCW hand cultures (3 hospitals; ~18 wards/units)

QUALITATIVE PROCESS EVALUATION (POST-INTERVENTION)

PHASES OF BUILDING AN OPTIMAL HH BUNDLE

QUALITATIVE PROCESS EVALUATION (PRE-INTERVENTION)

BASELINE

Randomization to frequency of changing HH signs

PHASE I

HH signs No change n=19 units

HH signs Changed Monthly n=20 units

HH signs Changed Weekly n=19 units

WASH-OUT

Randomization of signs +1 HH intervention

PHASE II

Signs only n=17

Signs with individual hand sanitizer n=17

Signs with HCW hand cultures n=17 units

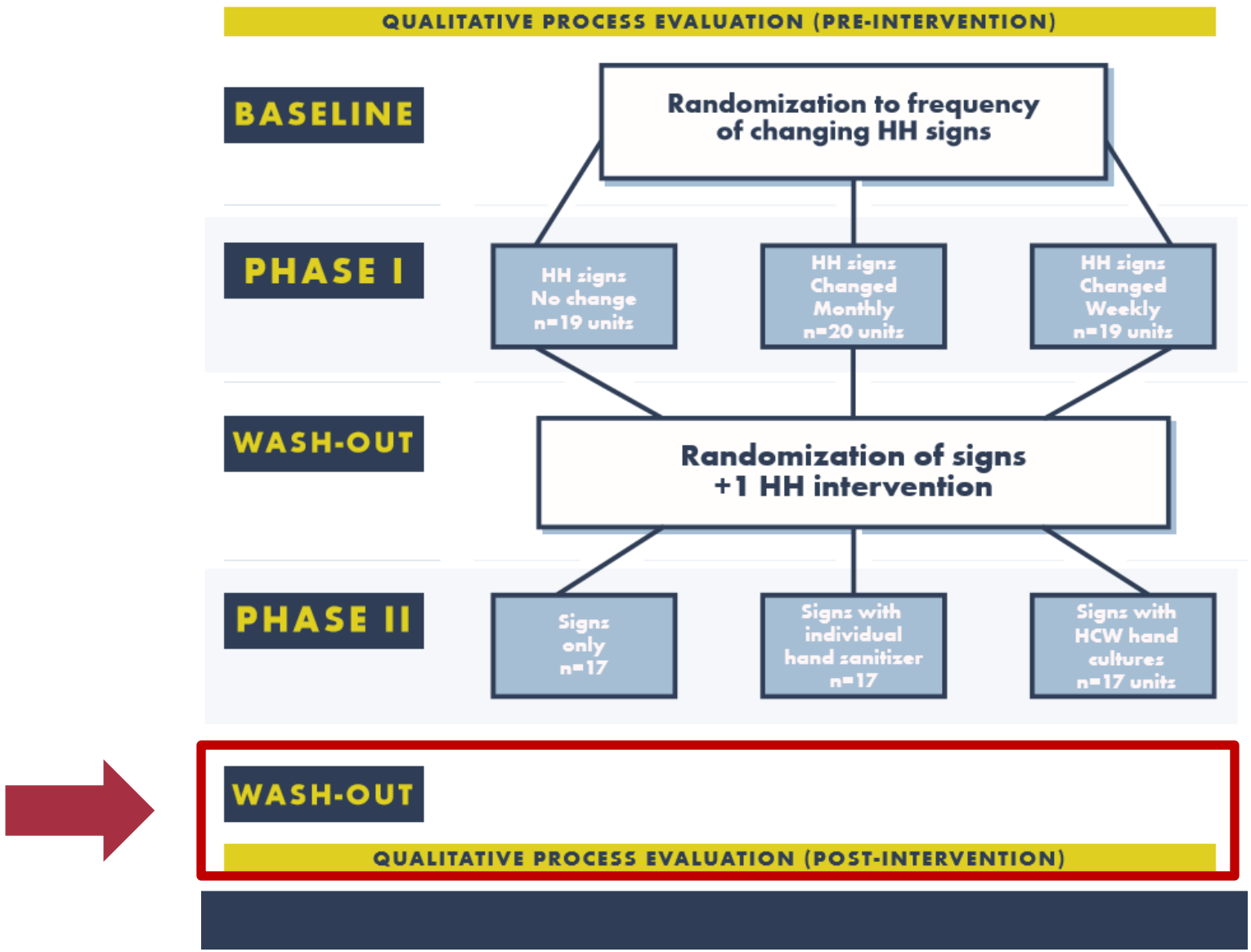
WASH-OUT

QUALITATIVE PROCESS EVALUATION (POST-INTERVENTION)

Challenges (and Solutions?)

- Extension of second intervention phase led to additional barriers
  - Individual hand sanitizers were not being used
  - Initial interest in HCW culture plates waned substantially (number of HCW plates obtained declined over time)
- More challenges with power?
  - Data still being analyzed

PHASES OF BUILDING AN OPTIMAL HH BUNDLE



Final Washout Period and Summative Evaluation

- Collecting final 3 months of HH observation data without interventions
- In the midst of a post-intervention qualitative evaluation
  - 4 site visits (2 sites dropped out of study)
  - 4 sites will participate in phone interviews only
- Plans for integrating qualitative findings and primary outcome data (HH observations) are underway
  - Several barriers to the interventions identified
  - Possible correlation between organizational issues (qualitative process evaluation) and baseline HH compliance rates

Outline

- Background
- Qualitative design and methods
- Cluster randomized control trial
- Lessons learned

Lessons Learned

Study Design

- The more sites you add, the more challenges you'll overcome.
- Plan time for randomization analysis.
- Plan some flex time into your study design.

Power Calculations

- Power calculations are never straightforward.
- Real data reveals false assumptions!

Interventions

- Larger trials reveal problems with scaling up an intervention.
- Tracking implementation issues is important for possible scale up.

Study Teams

- Be prepared for HR issues and attrition…

  because they impact data collection.

Have fun!

Thank you!

Resources

Quick links for VA data resources

Quick Guide: Resources for Using VA Data
http://vaww.virec.research.va.gov/Toolkit/QG-Resources-for-Using-VA-Data.pdf (VA Intranet)

VIReC: http://vaww.virec.research.va.gov/Index.htm (VA Intranet)

VIReC Cyberseminars: http://www.virec.research.va.gov/Resources/Cyberseminars.asp

VHA Data Portal: http://vaww.vhadataportal.med.va.gov/Home.aspx (VA Intranet)

VINCI: http://vaww.vinci.med.va.gov/vincicentral/ (VA Intranet)

Health Economics Resource Center (HERC): http://vaww.herc.research.va.gov (VA Intranet)

CDW: https://vaww.cdw.va.gov/Pages/CDWHome.aspx (VA Intranet)

Archived cyberseminar: What can the HSR&D Resource Centers do for you?
http://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/video_archive.cfm?SessionID=101

VIReC Options for Specific Questions

HSRData Listserv

- Community knowledge sharing
- ~1,200 VA data users
- Researchers, operations, data stewards, managers
- Subscribe by visiting http://vaww.virec.research.va.gov/Support/HSRData-L.htm (VA Intranet)

HelpDesk

- Individualized support

virec@va.gov

(708) 202-2413

FY '17 Good Data Practice Cyberseminar Series

Tuesdays and Thursdays in February, 2017
1:00-2:00 PM (ET)

Date	Topic	Presenter
Tuesday, February 14, 2017	Incorporating Genomics in Routine Care for Veterans with Colon Cancer: Study Design and Data Decisions	Sara Knight
Thursday, February 16, 2017	Data Use and Data Decisions in a Mixed Methods Study about Hand Hygiene	Heather Reisinger
Tuesday, February 21, 2017	Data Decisions and Quantitative Analysis in a Study Investigating the Impact of Remote ICU Monitoring in VA Hospitals	Mary Vaughan-Sarrazin Amy O'Shea
Thursday, February 23, 2017	Capstone Discussion: The Influence of Research Design on Data Decisions	Discussant: Neil Jordan

Visit our Education page for more information & registration links.
www.virec.research.va.gov

VIReC
RESEARCHERS' GUIDE TO VA DATA

Thank you!

- Questions?

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