Protocol

Protocol for: Miller LG, McKinnell JA, Singh RD, et al. Decolonization in nursing homes to prevent infection and hospitalization. N Engl J Med. DOI: 10.1056/NEJMoa2215254

This trial protocol has been provided by the authors to give readers additional information about the work.

The Protect Nursing Home Trial
Protocol

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AHRQ

UNIVERSITY of CALIFORNIA IRVINE

LABioMed Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center

project PROTECT

PROTECTING NURSING HOME RESIDENTS FROM INFECTIONS AND READMISSIONS

Welcome

Project PROTECT is a two-arm cluster randomized trial involving 28 nursing homes in Southern California. Nursing homes will be randomized to either routine care or universal decolonization with chlorhexidine bathing/showering plus nasal decolonization with iodophor. The PROTECT Trial will assess the impact on hospitalization due to infection and antibiotic use. This trial is a joint collaboration between investigators at the University of California Irvine, LA BioMed/Harbor UCLA, and University of Massachusetts Amherst. This study is federally funded by the Agency for Healthcare Research and Quality.

Summary of Goals

Nursing homes frequently admit large numbers of residents harboring highly antibiotic-resistant bacteria known as multi-drug resistant organisms (MDROs). These MDROs can cause serious infections and outbreaks. Large clinical trials in hospitals have proven that removal of these bacteria from the skin and nares using antiseptic soaps and ointments (decolonization) can prevent MDROs and infections.

This trial will compare routine bathing care to body surface decolonization to not only achieve the known benefits of MDRO reduction, but to assess whether decolonization may also reduce antibiotic use and hospitalization due to infection.

Study Investigators

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PROTECTING NURSING HOME RESIDENTS FROM INFECTIONS AND READMISSIONS

University of California Irvine

Susan Huang, MD MPH (Lead)
Steven Tam, MD
Steven Park, MD PhD
Ellena Peterson, PhD
John Billimek, PhD
Connie McGuire, PhD

LA BioMed at Harbor UCLA

Loren Miller, MD MPH
James McKinnell, MD

University of Massachusetts Amherst

Ken Kleinman, ScD

Additional Steering Committee Members

Jocelyn Montgomery, RN PhN (CAHF)
Nancy Beecham, RN (CA NADONA)
Karl Steinberg, MD (AMDA)
Nimalie Stone, MD (SHEA/CDC)

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Routine Care Toolkit Binder

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SHEA AHRQ CDC
University of California Irvine
LABioMed Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center
CAHF amda NADONALTC

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Contact Information

Topic	Who to Contact	Contact Information
General Questions	Central Office Gabrielle Gussin, MS	[redacted] Email: [redacted]
Urgent Questions (Requires immediate reply)	Senior Field Supervisor* Raveena Singh, MA CCRP	[redacted]

* Will have access to lead investigators at all times

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Participant Information and Requirements:
What to Expect – *Routine Care*

Designating a Local Champion

Each participating facility will select an on-site collaborative champion. Key roles of the champion will include: joining coaching calls, ensuring continuation of routine bathing and showering of residents with your usual products as you are already doing, and serving as an overall liaison to the collaborative.

Participating in Scheduled Collaborative Coaching Calls

Coaching calls will be hosted by the Project PROTECT team to guide collaborative activities. The on-site champion (or a proxy) is expected to join these calls to relay their status to Project PROTECT staff and communicate updates to the facility.

Coaching calls will be of value to the Routine Care arm because the Project PROTECT investigators will host informational and best practice calls to provide important foundational information for all nursing homes.

Agree to Implement Assigned Activity

Your nursing home has been randomized to the routine care group. For all nursing homes in the routine care group, there will be no change in current practices for bathing or showering. Nursing homes randomized to the other group will implement a decolonization protocol involving chlorhexidine (CHG) bathing and nasal decolonization with iodophor.

What is the Value of the Routine Care Group?

Each group plays a critical role in assessing the impact of decolonization in nursing homes. A comparison group is vital to understanding whether the decolonization strategy is cost effective by reducing antibiotic use or hospitalization. Without a standard practice comparison group, it would not be possible to know whether changes were due to national trends that are happening in nursing home care or whether they are due to the decolonization strategy. If decolonization were effective, we would not want to conclude that it was not. Similarly, if decolonization is not effective, we would not want to conclude that it was. Having a routine care group (or control group) allows us to have increased certainty of the impact of decolonization.

Collect Baseline and End-Intervention Resident Swabs

To understand the impact of decolonization in reducing the overall burden of multi-drug resistant organisms (MDROs), samples will need to be collected from residents at participating facilities. Each facility will be asked to collect nose and skin swabs from 50 residents once before the intervention and once at the end of the intervention period. Project PROTECT coordinators will work closely with the on-site collaborative champions to schedule swabbing and provide detailed instructions on how to collect the swabs. All swabbing materials will be provided by Project PROTECT staff.

Maintain a Transfer Log and a Once Weekly Antibiotic Log

To evaluate the impact of decolonization on hospitalization due to infection and antibiotic usage, all participating facilities will be asked to maintain a transfer log and a once weekly antibiotic log. Project PROTECT coordinators will work closely with the study champion to complete data collection.

General Questions

[redacted]

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Frequently Asked Questions:
Group 1 – *Routine Care*

What is Project PROTECT?

PROTECT is a two-arm cluster randomized trial among nursing homes in Southern California. The goal is to evaluate whether a decolonization strategy can better protect residents from multi-drug resistant organisms (MDROs) and their associated infections and hospitalizations when compared to routine bathing and showering.

What is Routine Care?

Your nursing home is randomized to Routine Care. This means that you will continue routine bathing and showering of all residents with your usual products as you are already doing. There will be no change to your current practice. Please do **NOT** implement new campaigns or quality improvement initiatives that may change current bathing practices or compliance. Your nursing home will not implement routine chlorhexidine (CHG) bathing or nasal decolonization with iodophor. Participation in this group includes an agreement to **NOT** implement new quality improvement initiatives that involve CHG or iodophor.

Who is Coordinating Project PROTECT?

Infectious Diseases physicians from the University of California, Irvine (UCI) and LA Biomed at Harbor-UCLA are leading this project. These physician researchers have led several of the major trials that have proven that decolonization prevents infections in hospitals and in the post-discharge setting. There is also a scientific advisory board consisting of nursing home experts, geriatricians, public health experts, statisticians, infectious diseases physicians, and infection prevention experts from all over the country.

How Will My Participation in the Trial Help My Residents?

While we know decolonization reduces MDROs and infections, we do not know if the decolonization will reduce antibiotic use and hospital transfers in nursing home residents. This study will help provide important information about whether decolonization can be a cost-effective strategy for nursing homes.

How Can I Speak with a Coordinator or Investigator from Project PROTECT?

Please contact Project PROTECT study staff and investigators by calling [redacted] or emailing [redacted]

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Data Collection

The goal of Project PROTECT is to evaluate whether a decolonization strategy can better protect residents from multi-drug resistant organisms (MDROs) and their associated infections and hospitalizations when compared to routine bathing and showering. To understand the impact of decolonization, we will assess several outcomes:

Primary Outcome

- Transfers due to infection (% of discharges to a hospital due to infection)

Secondary Outcome

- All cause admissions (% of discharges to a hospital)

Other outcomes of interest include MDRO prevalence (MRSA, VRE, ESBL, CRE), antibiotic usage, and emergence of resistance (strain collection). Project PROTECT coordinators will work closely with the on-site study champions to collect data on measured outcomes. Additionally, data will be obtained from state and national datasets.

Maintaining a Hospital Transfer Log

For the outcome of reducing transfers to hospitals, participating nursing homes will be asked to record all transfers to the hospital or emergency department in a "Hospital Transfer Log." This log can be found in the "Transfer Tracking Log" binder kept at your facility.

For all resident transfers, you will be asked to specify on the log:

- First and Last Name*
- Date of Birth
- Room and Bed Number
- Transfer Date
- Hospital Name
- Primary reason for transfer
- ER/Admit status (ER only/Admitted)
- Was transfer due to infection? (Definitely Yes, Possibly, Definitely No)
- Regardless of transfer reason, was infection present? (Definitely Yes, Possibly, Definitely No)

Reason for transfer should include primary diagnosis and/or symptom(s). Examples include: confusion, shortness of breath, weakness, fever, cough, abnormal vital signs, etc.

* No identified data will be taken from the facility. First and last name will be kept on the log at the facility, and will not be removed from the facility. Only deidentified data and dates will be removed from facilities consistent with the Project PROTECT IRB approval for human subject protections.

Maintaining a Weekly Antibiotic Log

For the outcome of reducing antibiotic usage, participating nursing homes will be asked to complete a once-weekly "Antibiotic Log." This log can be found in the "Antibiotic Tracking Log" binder kept at your facility. The goal of this weekly assessment is to identify and record all residents on systemic (not topical) antibiotics and antifungals. This includes any antibiotic given orally or rectally, intravenously, or intra muscularly. For each assessment, the daily census should be recorded for calculating the proportion of residents on an antibiotic or antifungal at a given time.

For each antibiotic/antifungal prescribed, you will be asked to specify:

- First and Last Name*
- Date of Birth
- Room and Bed Number
- Medication Name
- Route (PO/IV/IM)
- Started at nursing home? (Yes/No, continued from Hospital)
- Reason for antibiotic (Pneumonia, UTI, Skin/Wound, Abdominal, Other (Specify), Unknown)

* No identified data will be taken from the facility. First and last name will be kept on the log at the facility, and will not be removed from the facility. Only deidentified data and dates will be removed from facilities consistent with the Project PROTECT IRB approval for human subject protections.

The assessment should be completed on the same day each week. Please omit ear drops, eye drops, and topical antibiotics.

Collect Baseline and End-Intervention Resident Swabs

For the outcome of reducing MDRO prevalence and emergence of resistance, participating nursing homes will be asked to support two point-prevalence swab cultures of residents. Each facility will be asked to collect nose and skin swabs from 50 residents once before the intervention and once at the end of the intervention period. All swabbing materials, logistics, laboratory transport, and laboratory processing will be provided by Project PROTECT staff.

Data Collection Questions?

[redacted]

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PROTECTING NURSING HOME RESIDENTS FROM INFECTIONS AND READMISSIONS

Protocol Training Module
Group 1: Routine Care

Project PROTECT Introduction

Your nursing home has agreed to participate in Project PROTECT, a federally funded randomized trial of nursing homes in Southern California. Project PROTECT is being conducted by infectious diseases physicians at the University of California Irvine, and Harbor-UCLA.

- From this training you will learn:
  - ✓ Why Project PROTECT is important
  - ✓ Which group your nursing home belongs to
  - ✓ The importance of routine care
  - ✓ How to contact study staff for additional information

- This training module will take approximately 10 minutes to complete

What is Project PROTECT?

- This trial is evaluating whether bathing with special antiseptic soap plus using nasal products to remove nose bacteria (universal decolonization) is better than routine bathing in nursing homes in reducing infection and antibiotic-resistant bacteria
- The goal is to:
  - Reduce transfers to hospitals due to infections
  - Reduce antibiotic use
  - Reduce multi-drug resistant organisms (MDROs)
- The 28 Southern California nursing homes participating in this trial will be randomized to one of the following groups:
  - **Group 1: Routine Care**
  - **Group 2: Universal Decolonization**
- Intervention begins **April 2017**

Group 1: Routine Care
Maintain Current Bathing/Showering

- Your nursing home has been randomized to **Group 1: Routine Care**
- This means you will continue routine bathing and showering of all residents with your **usual products** as you are already doing

Importance of the Routine Care Group

- Every new strategy needs to be compared to an existing strategy to know if it is better or not
- Strategies that are not better than current care, should not be adopted
- Nursing homes in the routine care group serve as the current gold standard to assess whether decolonization is helpful or not
- Remember, decolonization is labor-intensive and incurs cost, so we only want to implement if we are absolutely certain it is effective
- *Critical* to maintain current practices
- Do **NOT** adopt decolonization

It is Critical to Maintain Current Practices

Here is a scenario on the importance of maintaining current practices:

- Let's assume decolonization has a real effect. Group 1 (Routine Care) nursing homes add in some additional interventions that improve infection rates while Group 2 adopts Universal Decolonization. The trial shows no difference between Group 1 and Group 2 nursing homes and decolonization is deemed to be not-effective. No nursing homes adopt decolonization and an important and effective solution is lost.

By working together, all nursing homes in the PROTECT Trial will collectively learn the effect of the decolonization strategy

Competing Interventions

IMPORTANT

Participation in the routine care group includes an agreement to **NOT** implement new quality improvement initiatives that involve CHG or iodophor

Your key role is to maintain current processes for bathing and showering. Do *not* change current **basic** practices.

Special Circumstances

If a physician places an order to decolonize a resident with iodophor, chlorhexidine, or both, you should do the following:

1. Follow the physician orders

AND

2. Remind the physician that this nursing home is part of Project PROTECT. This nursing home has been randomized to the routine care arm which does not involve routine decolonization of residents.

Is Resident Consent Required?

No. The IRB has granted a waiver of consent.

This protocol has approved by the UC Irvine IRB and is in compliance with the Code of Federal Regulations (45 CFR part 46), to be implemented as a minimal risk project. Specifically, this project compares two Quality Improvement strategies**.** This improvement strategy has met all criteria for waiver of consent. A handout will be provided for all residents upon admission to the nursing home.

Thank You

This is a landmark trial to identify the best strategies for reducing infection, antibiotic use, hospitalization, and multi-drug resistant organisms (MDROs) in nursing homes.

Your role in the Routine Care group of this trial is critical to understand whether decolonization is or is not beneficial over current best practice.

Questions?

General Questions

[redacted]

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PROTECTING NURSING HOME RESIDENTS FROM INFECTIONS AND READMISSIONS

Group 1: Routine Care
Protocol Training Post-Test

Date: _____ **Title (*circle one*): CNA LVN RN OTHER: _____**

Name: _____ **Signature: _____**

1. **Your nursing home is participating in the PROTECT Project. Which group has your nursing home been randomized to?**
   A. Group 1: Routine Care
   B. Group 2: Universal Decolonization

2. **What is the purpose of the PROTECT Project?**
   A. To reduce multi-drug resistant organisms like MRSA and ESBL
   B. To protect residents from infection
   C. To reduce antibiotic usage
   D. All of the above

3. **As part of the routine care group, your nursing home is agreeing to all of the following except?**
   A. Continue current bathing and showering practices
   B. Maintain an antibiotic and transfer log
   C. Bathe all residents with chlorhexidine soap
   D. None of the above

4. **Participation in the routine care group includes an agreement to NOT implement new quality improvement initiatives that involve CHG or iodophor**
   A. True
   B. False

5. **When will the PROTECT Project intervention launch?**
   A. April 2017
   B. May 2017
   C. June 2017

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PROTECTING NURSING HOME RESIDENTS FROM INFECTIONS AND READMISSIONS

Group 2: Universal Decolonization Toolkit Binder

LA BioMed | School of Medicine University of California • Irvine | Harbor-UCLA Medical Center

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PROTECTING NURSING HOME RESIDENTS FROM INFECTIONS AND READMISSIONS

Welcome

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Summary of Goals

Nursing homes frequently admit large numbers of residents harboring highly antibiotic-resistant bacteria known as multi-drug resistant organisms (MDROs). These MDROs can cause serious infections and outbreaks. Large clinical trials in hospitals have proven that removal of these bacteria from the skin and nares using antiseptic soaps and ointments (decolonization) can prevent MDROs and infections.

This trial will compare routine bathing care to body surface decolonization to not only achieve the known benefits of MDRO reduction, but to assess whether decolonization may also reduce antibiotic use and hospitalization due to infection.

Study Investigators

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University of California Irvine

Susan Huang, MD MPH (Lead)
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PROTECTING NURSING HOME RESIDENTS FROM INFECTIONS AND READMISSIONS

Universal Decolonization Toolkit Binder

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PROTECTING NURSING HOME RESIDENTS FROM INFECTIONS AND READMISSIONS

Participant Information and Requirements: What to Expect – *Universal Decolonization*

Designating a Local Champion

Each participating facility will select an on-site collaborative champion. Key roles of the champion will include: joining coaching calls, scheduling a date for on-site training with Project PROTECT staff, ensuring implementation and compliance assessments of the protocol, and serving as an overall liaison to the collaborative.

Participating in Scheduled Collaborative Coaching Calls

Coaching calls will be hosted by the Project PROTECT team to guide collaborative activities. These webinars will be held twice a month during the early launch phase, then transition to once a month. The on-site champion (or a proxy) is expected to join these calls to relay their status to Project PROTECT staff and communicate updates to the facility.

Collect Baseline and End-Intervention Resident Swabs

To understand the impact of decolonization in reducing the overall burden of multi-drug resistant organisms (MDROs), samples will need to be collected from residents at participating facilities. Each facility will be asked to collect nose and skin swabs from 50 residents once before the intervention and once at the end of the intervention period. Project PROTECT coordinators will work closely with the on-site collaborative champions to schedule swabbing and provide detailed instructions on how to collect the swabs. All swabbing materials will be provided by Project PROTECT staff.

Maintain a Transfer Log and a Once Weekly Antibiotic Log

To evaluate the impact of decolonization on hospitalization due to infection and antibiotic usage, all participating facilities will be asked to maintain a transfer-to-hospital log and a once weekly antibiotic log. Project PROTECT coordinators will work closely with the study champion to complete data collection.

Hosting On-Site Decolonization Training

Project PROTECT staff will provide on-site training for chlorhexidine bathing and nasal decolonization for use on all adult residents. We will provide face-to-face instructional training materials and a short video. Training will be provided to front line nurses and nursing assistants. Project PROTECT coordinators will work with the on-site collaborative champion to schedule and organize the training.

Receive Contributed Product

While participating nursing homes would be responsible for the costs of labor to implement these interventions, Project PROTECT will defray costs with contributions for 2% CHG cloths for bathing, 4% liquid CHG for showering, and nasal iodophor. Project PROTECT staff will work with the local champion to receive these contributions.

Checking Products for Chlorhexidine Compatibility

Some commonly used skin care products in nursing homes such as lotions and barrier creams can inactivate chlorhexidine and prevent the antiseptic from protecting residents from infections. Project PROTECT staff will work with the local champion to help ensure that compatible skin care products are available as needed.

Monitoring Decolonization Compliance

Participating sites will be asked to conduct periodic compliance checks using a simple checklist to assess adoption of the decolonization protocol.

Using Non-Chlorine (Peroxide) Bleach for Laundry

The soap used in this decolonization intervention contains the antiseptic CHG, which if directly applied to cotton material, will cause brown staining when laundered with chlorine bleach. In order to prevent brown staining of linens and towels, all participating facilities in which laundry is performed on site, will need to switch to non-chlorine (peroxide) bleach.

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Nursing Protocol
Nasal Antiseptic (10% Povidone-Iodine)

Who should receive iodophor?

- Adult residents in nursing homes participating in the PROTECT Trial
- Use on admission twice daily for 5 days and then twice daily for 5 days according to the nursing home's every other week schedule until discharge
- Do not use if the resident has an allergy to iodine
- If a resident is readmitted to the nursing home, the protocol starts again, including the admission treatment

Excluded residents

- Known allergy to iodophor or iodine
- <18 years old

Who can administer iodophor?

- Only licensed nurses can administer iodophor

Protocol for Using Iodophor

1. Place resident's bed at 30 degrees, if tolerated
2. Have resident use a tissue to blow their nose or clean the nares and tip of nostril. Discard tissue.
3. Insert swab into one nostril and rotate for 30 seconds covering all surfaces. Apply in a circular manner to entire surface of inner nose at least 3 times. Discard swab.

4. Using a new swab, repeat step 3 on the other nostril
5. Do not blow nose. If solution drips, dab with tissue.
6. Do this twice a day for 5 days on admission, and then repeat every other week

Special Circumstances

- If nasal devices are in place (e.g. nasal intubation, NG tubes), swab iodophor around tubing, if possible
- If nasal packing is in place (e.g. recent surgery/trauma), do not apply to that nostril

Missed Doses

If one dose is missed, restart iodophor as soon as possible and go back to the regular schedule. Do *not* double up doses. If more than 1 day's worth of iodophor is missed, the resident will need to restart the 5 days of therapy.

Side Effects

Allergic reactions are rare, but can occur. If the resident experiences a reaction possibly related to the study product, contact the resident's treating physician for all clinical decisions on whether to stop the product or provide any medication to address a possible reaction. Complete a "Study Related Event" form located in your Toolkit binder and submit it to the nursing home's nursing director.

Do NOT sent protected health information to the PROTECT Team

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PROTECTING NURSING HOME RESIDENTS FROM INFECTIONS AND READMISSIONS

Nursing Protocol:
Chlorhexidine Bathing and Showering

Who should receive chlorhexidine?

- Adult residents in nursing homes participating in the PROTECT Trial
- If a pregnant or breastfeeding resident is admitted – please contact Project PROTECT staff before activating protocol

Excluded residents

- Known allergy to chlorhexidine (CHG)
- <18 years old

Who can administer CHG?

- Nurses, nursing assistants, and any other healthcare worker trained on giving a bath or shower

Protocol for Bed Bathing with 2% Chlorhexidine No-Rinse Bathing Cloths

- CHG bathing or shower to be provided on admission followed by bathing and showering per routine schedule
- Provide one-page CHG information sheet for residents to read prior to initial CHG cloth bath. These information sheets do not replace verbal instruction, but they save time and allow reinforcement of information already read.
- **Pre-Bath:** Clean all incontinence or gross soilage using a CHG compatible baby wipe or cloths with water. Do not use soap which can inactivate CHG. Ensure trash can nearby. Determine number of cloths needed.

- Cloths may be used at room temperature or warmed for comfort based upon resident preference. If warmth desired, do not remove cloths from warmer until resident is fully ready for bath.
- Just before bath, remove one set of warmed packets (3 packets in a set, 2 cloths per packet for a total of 6 cloths) of 2% CHG cloths from the warmer. Removed packet should have a "ready" light illuminated to confirm fully warmed. Do not remove if unsure if resident wants bath.
- For obese residents, additional cloths may be needed. Take extra single 2-cloth packets until the needed number is reached.
- Educate the resident that the CHG cloths work better than soap and water in removing bacteria from the skin and that the cloths serve as their protective bath.
- If the resident wishes to self bathe, provide verbal instructions, and assist with hard to reach areas. Refer to "Resident Talking Points" in your Toolkit binder for example verbal instructions for residents as well as how to encourage bathing. **Self-bathers will need assistance with cleansing of any wounds and devices.**
- Regardless of resident size, use ALL of the 6 cloths for bathing the following body areas. **Both sides of the cloth should be used**.
- Ensure that cloths are applied to skin by firm massage to ensure binding of CHG to skin proteins, which allows it to continue to kill germs for a minimum of 24 hours.
    - Cloth 1: Face, neck, and chest. **Avoid eyes and ears.**
    - Cloth 2: Both shoulders, arms, and hands
    - Cloth 3: Abdomen and *then* groin/perineum
    - Cloth 4: Right leg and foot
    - Cloth 5: Left leg and foot
    - Cloth 6: Back of neck, back and *then* buttocks
- Once opened, cloths should be kept on the blue insulator for warmth until used. **Do not place cloths directly onto sheets** as this will produce a brown stain when combined with bleach in the laundry. This will not be an issue as you switch to non-chlorine bleach.

- After use on assigned part of body, use a clean part of the cloth to **clean devices on that part of the body within 6 inches of the resident,** including central lines, urinary catheters, drains, G-tube/J-tubes, rectal tubes, chest tubes.
- **Wipe over non-gauze dressings.** This will help remove bacteria where devices penetrate the skin. CHG is safe on devices and can be used over occlusive and semi-occlusive dressings.
- Allow to dry naturally. **Do not wipe off.**
- CHG cloths have moisturizers. If additional moisturizer or lotion is needed, only use lotions that are compatible with CHG (Refer to the "CHG Compatibility List" in the Toolkit binder)
- Do not place CHG cloths directly on bedding as contact with bleach during the washing process can leave brown stain. Once CHG is applied to the skin, it binds skin proteins and will not rub off onto bedding.
- Dispose of CHG cloths in trash. Do not flush in commode.
- **Post-Bath**
    - **Incontinence episodes:** Remove soiled incontinence using CHG-compatible baby wipes, disposable cloths, or towels. If necessary, rinse off the affected area with water. Then, reapply CHG using a single packet of 2-cloths. Single packs should be kept in a row in the warmer for easy availability. **Use these additional packets as needed during the day.**
    - If barrier protection is needed, be sure to use CHG-compatible barrier protection products **after CHG is applied**. (Refer to "CHG Compatibility Sheet" in your Toolkit binder).

Protocol for Showering with 4% Liquid Chlorhexidine

- Provide one-page instruction sheet for residents on CHG showering to read prior to beginning shower ("Resident CHG Shower Instructions"). Residents will be more likely to read the instructions in their spare time.
- Provide resident with a dedicated mesh sponge to use and re-use during nursing home stay. The mesh sponge may be replaced every 2 weeks.
- Educate the resident that CHG works better than soap and water in removing bacteria from the skin and that **other soaps should be avoided**
- If the resident is self-showering, provide the resident with the following verbal instructions:
    - Use liquid CHG as shampoo in addition to body cleansing
    - Wet skin with water. Turn off water or stand out of water stream.
    - Put CHG onto wet mesh sponge and rub sponge until it is foamy
    - Firmly massage soapy sponge all over skin in the same order as CHG cloth instructions. **Reapply CHG generously to keep sponge full of foamy lather.**
    - **For best results, leave soapy lather on skin for 2 minutes.** 2 minutes is about the time it takes to soap up all body areas and then do it again before rinsing.
- Dry well with towel after rinsing
- If devices or wounds were wrapped for showering, unwrap these areas and use a CHG cloth to clean over device dressings, the 6 inches of all tubes/lines/drains closest to the resident, and all wounds that are not packed.
- CHG should be encouraged for hair, face, and body use. However, if residents insist on using personal shampoo or face products, instruct them to use their personal products first, rinse well, and keep personal bathing products off of the body because regular soaps and shampoos prevent CHG from working well. Only CHG should be used on the mesh sponge.

IMPORTANT REMINDERS for CHG Cloth Bathing and Showering

a. Do not use regular soap with CHG. Many soaps inactivate chlorhexidine. CHG works better than soap and water in deeply cleansing the skin.

b. Ensure thorough cleaning, with special attention to commonly soiled areas such as the neck, skin folds, and perineal areas. CHG is safe to use on perineal areas, including external mucosa.

c. For candidal rashes, note that CHG is active against candida. However, be sure that the CHG is dry between body folds. Fan the area with the blue insulator to aid drying. If not completely dry, rashes may worsen.

d. CHG is safe for superficial wounds, including stage 1 and 2 decubitus ulcers, superficial burns, as well as rashes and abrasions. These areas are at high risk for infection and CHG kills germs and helps prevent infections. Do not use on large or deep wounds, (e.g. packed wounds)

e. Use CHG for all bathing purposes, including full-body bathing, cleaning after incontinence clean up, or any other reasons for additional cleaning. This includes the face; however avoid contact with eyes and ears.

f. If moisturizer is needed, provide resident with CHG-compatible lotion

g. Allergic reactions are rare, but can occur. If your resident experiences a reaction possibly related to the study product, contact the resident's treating physician for all clinical decisions on whether to stop the product or provide any medication to address a possible reaction. Complete a "Study Related Event" form located in your Toolkit binder and submit it to the nursing home's nursing director.

h. Maintain facility policies for covering devices, including dressings to prevent water penetration and introduction of water borne bacteria.

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PROTECTING NURSING HOME RESIDENTS FROM INFECTIONS AND READMISSIONS

Frequently Asked Questions and Do's and Don'ts

This section includes:

- Project PROTECT Frequently Asked Questions
- Chlorhexidine Bathing Frequently Asked Questions for Providers
- Nasal Iodophor Frequently Asked Questions
- Wound Care Frequently Asked Questions
- Decolonization Do's and Don'ts

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PROTECTING NURSING HOME RESIDENTS FROM INFECTIONS AND READMISSIONS

Frequently Asked Questions:
Group 2 – *Universal Decolonization*

What is Project PROTECT?

PROTECT is a two-arm cluster randomized trial among nursing homes in Southern California. The goal is to evaluate whether a decolonization strategy can better protect residents from multi-drug resistant organisms (MDROs) and their associated infections and hospitalizations when compared to routine bathing and showering.

What is Universal Decolonization?

Your nursing home is randomized to Universal Decolonization. Decolonization is the removal of germs on the body such as Methicillin-Resistant *Staphylococcus aureus* (MRSA) and other highly antibiotic-resistant bacteria known as multi-drug resistant organisms (MDROs) through the use of special soaps and topical products. While body bacteria normally do not cause problems in healthy people, they are more likely to cause infection during hospitalizations or nursing home stays. To prevent infection, we will be applying topical antiseptic products to a resident's nose and skin. The goal is to reduce a resident's chances of developing a future infection and to prevent antibiotic use and hospitalization.

Has Decolonization Been Proven to Reduce Infections?

Yes, decolonization with topical antiseptics and nasal ointments to reduce bacteria has been proven in several trials to reduce MDROs and bloodstream infections in ICUs. While we know decolonization is one strategy to reduce MDROs, we are interested in assessing if it reduces antibiotic use and hospitalization due to infection in nursing home residents.

Who is Coordinating Project PROTECT?

Infectious Diseases physicians from the University of California, Irvine (UCI) and LA Biomed at Harbor-UCLA are leading this project. These physician researchers have led several of the major trials that have proven that decolonization prevents infections in hospitals and in the post-discharge setting. There is also a scientific advisory board consisting of nursing home experts, geriatricians, public health experts, statisticians, infectious diseases physicians, and infection prevention experts from all over the country.

What Is My Commitment and How Will It Impact My Working Life?

Your nursing home has committed to this project from April 2017 to December 2018. The focus will be on implementing the decolonization protocol to ensure that it is done well on a routine basis. Training materials will include a toolkit binder, training modules, and on-site training. We will also be checking in with you regularly to ensure that we give your residents the best chance of being protected from infection.

Are the Products Safe?

All treatments used in this study – chlorhexidine bathing liquid and cloths, and nasal povidone-iodine – have been approved by the United States Food and Drug Administration (FDA) for use in adults. Since they are all topical, their safety profile is excellent. However, all medicines and products can cause allergies and side effects. Please see section on Product Safety for more information.

How Do I Use the Products and How Often?

Decolonization starts on admission and continues throughout the nursing home stay. See the protocol tabs for detailed directions on how to bathe or shower with chlorhexidine and how to apply the nasal iodophor.

What If I Forget to Bathe My Residents with Chlorhexidine (CHG) or Give the Nasal Antiseptic?

If you forgot to bathe with CHG, give a chlorhexidine bath as soon as you are able. For the nasal iodophor, it depends on how many times you forgot. If you only forgot one day's worth of treatment, you should give the treatment as soon as possible according to the originally planned schedule to **complete a total of 5 days (not including the day you missed).**

If you skipped more than one day's worth of iodophor treatment, you will need to restart the 5 days of therapy. Remember it is important to make sure you use both products at the same time.

How Do I Report a Side Effect?

A side effect is a new medical problem that seems to be caused by one of the study treatments. Contact the resident's treating physician for all clinical decisions on whether to stop the product or provide any medication to address a possible reaction. Side effects and questions about side effects **should be reported** to Project PROTECT study staff by contacting them at: [redacted] during office hours (8am-5pm), Monday through Friday. A Project PROTECT study supervisor can be reached anytime, including after hours or on weekends for **urgent issues that cannot wait until business hours** by calling [redacted].

What If I Run out of Antiseptic Product?

We will be monitoring your supplies weekly to ensure adequate supplies. However, if you run out of product, please contact Project PROTECT study staff at [redacted]. We will make sure you have enough for all your trial needs.

How Will My Participation in the Trial Help My Residents?

While we know decolonization reduces MDROs and infections, we do not know if the decolonization will reduce antibiotic use and hospital transfers in nursing home residents. This study will help provide important information about whether decolonization can reduce these events.

Who Should I Contact If I Have Any Immediate Concerns About the Administration of CHG or Nasal Iodophor?

Please contact the Nursing Supervisor at your nursing home. If there is a potential side effect that needs treatment, contact the treating physician.

How Can I Speak with a Coordinator or Investigator from Project PROTECT?

Please contact Project PROTECT study staff and investigators by calling [redacted] or emailing [redacted].

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PROTECTING NURSING HOME RESIDENTS FROM INFECTIONS AND READMISSIONS

Frequently Asked Questions
Chlorhexidine for Bathing

What is chlorhexidine (CHG) and how safe is it?

CHG is an antiseptic agent that helps to reduce the amount of germs on your skin, including antibiotic-resistant germs such as MRSA. CHG is FDA approved for this purpose and its safety profile is excellent.

What if my resident refuses a bath?

Similar to any medical care or routine practice, residents can refuse any therapy. However, as you know, it is not routine practice to ask residents whether they want to refuse each component of usual standard of care (e.g. admission orders, type of bathing or shampoo product…). If, in the course of usual explanation of the bathing process, the resident does not wish to have this done, it is their right to refuse.

Encourage the resident several times before accepting a decline. If they are tired, check back later (give them a time point, half hour, etc.). Remind the resident that the bath is short and only takes 5-10 minutes and the bath will protect them from germs. Providing the one-page instructional handout can help the resident understand the value of the bath and save nursing staff time.

Some of the residents can perform their own bath or shower. What should be used, and can the resident bathe themselves?

If the resident wishes to self bathe, provide the resident with the 1-page "Shower with CHG Soap" or "Bathe with CHG Cloths" resident handouts found in your Toolkit binder. Having the resident read the instructions will save you time later because the resident will become familiar with the bathing process. Then, prior to bathing, verbally repeat the cloth bathing or showering instructions to ensure proper application. Remind the resident that if the bathing is not performed correctly, they may not receive the protective benefits.

If the resident wishes to perform a bed bath, remember to show the resident how to open the packages since they are difficult to open from the ends. Remind them to massage the CHG onto their skin and over non-absorbent dressings. Help them to clean hard to reach areas and to clean the 6 inches of any tube, drain, or line closest to the body. If the resident is able to step into the shower, 4% CHG liquid soap along with a mesh sponge for application should be provided. Again, help them clean hard to reach areas and parts of tubes, drains, and lines nearest the body.

What if my resident would like to use their own shampoo, conditioner, or face wash?

Remind the resident that regular soap and shampoo can inactivate CHG and prevent it from working. If your resident insists on using their own shampoo or face wash, instruct them to use these first and try to keep the shampoo and face wash off the body so CHG will work as body soap.

Is it okay for my residents to shave and use deodorant?

Even though shaving cream and deodorant may inactive CHG, we understand that residents will want to shave and use deodorant. If shaving is performed, ensure that shaving cream only contacts body area that is being shaved.

What if my resident has an incontinence episode or needs freshening up throughout the day?

CHG cloths should be used for all bathing purposes, including full-body bathing, cleaning after soiling, or any other reasons for additional cleaning such as freshening up. Do not use soap to cleanse incontinent residents because soap can inactivate CHG. First remove urine/stool with usual incontinence wipes or cloths and water. Next, clean with CHG and allow to air dry. Finally, apply CHG compatible barrier protection over the area. Repeat as often as needed throughout the day.

My resident reports that their skin feels sticky after the bath.

The sticky feeling is due to the moisturizing ingredients in the CHG cloths and it will go away as it dries. The cloths contain aloe vera.

Is it safe to use on the perineum?

Yes, CHG is safe to use on the perineum and external mucosa.

Is CHG safe to use on lines, tubes, and drains?

Yes, it is very important to clean lines, tubes, and drains in addition to the skin surrounding these devices in order to prevent infection. The 6 inches of any tube, drain, or line nearest the body should be cleaned. Non-absorbable (non-gauze) dressings should also be wiped over with the CHG cloth after the skin is cleaned.

Should gloves be worn or changed during bathing with CHG cloths?

Yes. Although it is safe to handle the CHG cloths with bare skin, gloves should be worn for bathing residents. If gloves become soiled, they should be changed.

I am having trouble with applying bandages after bathing my residents with CHG. Does CHG weaken bandage adhesive?

If you are having trouble reapplying a bandage after bathing a resident with CHG, it's usually because not enough time has elapsed to allow for drying. After bathing a resident, please allow the CHG to dry for about 5 minutes. This should provide ample time for the CHG to absorb and not affect the bandage adhesive. If

you cannot wait the full 5 minutes and if the resident's skin still feels tacky, it will prevent the bandage from sticking properly.

Are there special instructions for large or obese residents?

In order to be effective in removing germs, it is important that CHG cloths are applied with a firm massage on all skin areas (gently massaged onto wounds). This is particularly important in skin folds of large or obese residents since dirt, sweat, and germs can accumulate there. Make sure that after the CHG cloth is applied, the skin fold areas are allowed to fully dry. Lift skin folds to clean by firmly massaging the entire skin with the CHG cloth. Sometimes placing rolled towels to prop open skin folds may help with the application or drying process. Use as many CHG cloths as necessary.

What are the most commonly missed bathing practices that we can enforce with our staff?

1. Cleaning lines, drains, and tubes closest to the body as well as cleaning over non-absorbable dressings
2. Ensure cloths are applied to skin with firm massage
3. Use the CHG wipes on superficial wounds/stage 1 & 2 decubitus ulcers

How should we dispose of the CHG cloths?

Used CHG cloths should be disposed of in the trash. The CHG cloths will clog the pipes. **Do not flush. Instruct residents NOT to place the wipes in the commode or toilet.**

Will long-term use of CHG cloths cause bacteria to become resistant?

This is always a possibility and the reason why we are collecting bacterial isolates from your nursing home to assess resistance to CHG over the course of the trial. Thus far, despite wide use, CHG resistance has rarely been reported in the U.S.

I think my resident may be having a reaction to the CHG cloths or CHG liquid soap. What should I do?

Similar to all quality improvement projects, any questions regarding issues related to the decolonization products should be directed to the resident's nurses and

treating physicians. Side effects and questions about side effects **should be reported** to Project PROTECT study staff by contacting them at: [redacted] during office hours (8am-5pm), Monday through Friday. A Project PROTECT study supervisor can be reached anytime, including after hours or on weekends for **urgent issues that cannot wait until business hours** by calling [redacted]. Severe allergic reactions to CHG are extremely rare.

However, if you think a resident may be developing a severe allergic reaction (including hives, severe itching, difficulty breathing, tightness in the chest, swelling of the mouth, face, lips, or tongue), stop the decolonization drug and **immediately** call 911.

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PROTECTING NURSING HOME RESIDENTS FROM INFECTIONS AND READMISSIONS

Frequently Asked Questions
Wound Care

The majority of our nurses and certified nursing assistants (CNAs) feel comfortable using chlorhexidine (CHG) cloths on superficial wounds, but some do not. How would you suggest easing their concerns?

Remind all nursing staff that CHG cloths are safe to use on superficial wounds and stage 1 & 2 decubitus ulcers. Using the buddy system, in which nursing staff who are comfortable using CHG on superficial wounds buddy up with staff who are less comfortable, can also help. You can also contact Project PROTECT staff to help answer additional questions.

Should I be concerned about CHG having a stinging effect on wounds?

Antiseptic over-the-counter products often contain alcohol and will sting when applied to wounds. In contrast, CHG cloths do not contain alcohol and will not sting. In fact, CHG cloths contain dimethicone and aloe vera which are moisturizers and actually have a soothing effect on the superficial wound area.

Will CHG be absorbed if I put it on a wound?

There is minimal to no systemic absorption when using CHG on a superficial wound. In addition, the CHG may be particularly important to get rid of bacteria in an open wound and prevent infection.

For what types of wounds is CHG safe?

CHG can be gently applied to any superficial wound, including stage 1 and 2 decubitus ulcers, friable skin/rash, and superficial burns. We do not recommend using CHG on large or deep open wounds. Skin near and surrounding any wound should always be cleaned well.

Can I use CHG cloths over a closed surgical incision?

Yes. CHG is beneficial and should be applied over a closed surgical incision to eradicate bacteria and the reduce risk of infection.

What if my resident has a wound vac?

CHG should be applied over any semi-permeable or occlusive dressing. This includes wound dressings that meet that criteria, as well as wound vacs. Apply over the dressing and to any tube within 6 inches of the body. CHG can also be applied over sutured or stapled wounds. If the dressing is permeable (for example, gauze), then use CHG up to the dressing.

How firmly should I apply CHG cloths to a wound?

It depends on whether the wound is over a bony prominence or not. If the wound is not over a bony prominence, then CHG should be applied with a firm massage to ensure adequate contact and anti-bacterial activity. However, if the wound is in the location of a bony prominence, a *gentle massaging motion* should be used to avoid causing additional soft tissue damage or extension of the wound due to pressure against the bone.

I am having trouble with applying bandages after bathing my residents with CHG. Does CHG weaken bandage adhesive?

If you are having trouble applying a bandage after bathing a resident with CHG, it's usually because not enough time has elapsed to allow for complete drying. After bathing a resident, allow the CHG to completely dry for about 5 minutes. When completely dry, CHG will not affect the bandage adhesive. If you are in a rush, fanning the CHG dry is acceptable, but do not wipe off or blot dry. If the resident's skin still feels tacky, it may prevent the bandage from sticking properly.

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PROTECTING NURSING HOME RESIDENTS FROM INFECTIONS AND READMISSIONS

Frequently Asked Questions
Nasal Iodophor

What is iodophor?

Iodophor is another name for "povidone-iodine," which is an over-the-counter antiseptic that is most known for its use in cleaning scrapes, cuts, and wounds and preventing infections. It is also FDA cleared for use in the nose.

What is the purpose of putting it in the nose?

Iodophor removes germs that commonly live in the nose, including methicillin-resistant *Staphylococcus aureus*, or MRSA. Many studies have shown that nursing home residents are much more likely to harbor MRSA than people in the community or patients in hospitals. In fact, recent data across many nursing homes in Southern California and elsewhere have shown that over 40% of nursing home residents harbor MRSA. Because having MRSA in the nose is a known risk factor for later infection, our nursing home has decided to adopt the use of iodophor for our residents to prevent transmission and infection.

Is decolonization a proven strategy?

Yes. Use of chlorhexidine baths and nasal decolonization has been proven in large clinical trials to reduce MRSA and other bacteria and prevent infection. This has been shown in hospital ICUs and in post-discharge nursing home settings.

How safe is iodophor?

Povidone-iodine is an over-the-counter antiseptic product. It has been used in healthcare for over 60 years. Nasal iodophor has been used in thousands and thousands of patients prior to surgery, in ICUs, and in nursing homes as a way to prevent MRSA and methicillin-sensitive *Staphylococcus aureus* (MSSA) infection. Side effects from iodophor are uncommon, mild and resolve with discontinuation. They may include nasal irritation, runny nose, and sneezing. As with any product, rare serious allergic reactions can occur.

Why are we giving iodophor instead of mupirocin?

Iodophor has many advantages over mupirocin. First, it is an antiseptic product, not an antibiotic. Second, there is evidence that it is better tolerated than mupirocin. Third, mupirocin resistance has been reported throughout the U.S. and is fairly common in many Southern California nursing homes.

What if the resident wants to blow their nose after application?

Residents should be told to blow their nose before the application to help clear the nasal area. They should be encouraged not to blow their nose immediately after application for best effects.

Is it okay to provide decolonization if my resident is not alert?

This routine decolonization regimen of chlorhexidine soap plus nasal iodophor has been approved as a standing nursing protocol which is covered in the resident's admission agreement as usual care. It is provided with an MD order. While residents are able to refuse, all residents who are unable to refuse will be provided this as our facility's standing nursing protocol consistent with the admission agreement.

If my resident refused the last iodophor dose, am I supposed to offer it again?

This protective regimen should be encouraged among residents. If a resident refused their medication, staff would try to encourage the resident to take it at a later time. Similarly, if a resident refused a bath, staff would try to encourage a bath at a later time. Staff need to assess whether the resident is refusing at this time (e.g. tired, in pain, irritable), or whether the resident is refusing all further doses and if the resident understands the reason and the value of the iodophor (e.g. to prevent infection due to MRSA and other bacteria).

My resident left our nursing home, but has been readmitted. Do they need to receive iodophor again?

Yes. Regardless of prior receipt, iodophor should be administered each time a resident is admitted to your nursing home to ensure residents are protected for their entire stay.

What if the resident develops a reaction?

Similar to all quality improvement interventions, if a problem arises, it should be brought to the attention of the treating nurse and physician, who will decide all necessary actions related to discontinuing product and ordering any medications to address the reaction.

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Decolonization Do's and Don'ts

DO
• Begin decolonization on admission to remove germs as soon as possible
• Use chlorhexidine (CHG) for all bathing/showering needs for all residents
• Use 2% no-rinse CHG cloths for bed baths *or* 4% rinse-off liquid CHG for showers
• Use CHG for regular bathing during resident's entire nursing home stay
• Massage CHG onto skin for best effect
• Use CHG on lines, tubes, drains, and over non-gauze dressings
• Use on superficial wounds and rashes to remove germs
• Use nasal iodophor treatment twice a day for a 5-day period every other week
• Report iodophor/CHG related events to treating physician and nursing director

DON'T
• Do NOT get CHG into eyes or ears
• Do NOT wipe off after applying CHG cloths. Let air dry.
• Do NOT flush CHG cloths. Place in trash.
• Do NOT continue protocol after discharge
• Do NOT use protocol on residents <18 years old
• Do NOT use iodophor and/or CHG on resident if resident is allergic

REFER TO NURSING PROTOCOL FOR STEP-BY-STEP INSTRUCTIONS

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PROTECTING NURSING HOME RESIDENTS FROM INFECTIONS AND READMISSIONS

Resident Talking Points

This section includes:

- Resident Talking Points on Chlorhexidine Bathing
- Resident Talking Points on Nasal Iodophor

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PROTECTING NURSING HOME RESIDENTS FROM INFECTIONS AND READMISSIONS

Resident Talking Points
Chlorhexidine Bathing

Residents may have questions regarding CHG bathing and nasal iodophor. Below are some suggested responses to common resident questions.

REMEMBER: Your **enthusiasm** and **encouragement** will be the greatest predictor of a resident's acceptance and support for this infection prevention protocol.

What are these cloths for?

"This is your protective bath while you are staying at this nursing home. All residents here are provided this bath to prevent infection. This type of bathing uses a special soap called chlorhexidine which is deeply cleansing and works better than regular soap and water to remove germs and protect you from infection. It has been used on millions of patients in many hospitals and some nursing homes across the country to clean the skin and protect from germs."

How do you know it works better than soap?

"We are using the chlorhexidine soap because it has been proven to get rid of body germs and prevent infections in large clinical trials in U.S. hospitals. In those studies, antibiotic-resistant bacteria dropped by almost 40% and bloodstream infections dropped by 50%."

I don't feel as clean after bathing with the cloths.

"I know we usually think of baths as having soapy water, but while you still require medical care at this nursing home, these cloth baths work better than soap and water to remove germs from the skin. It is deeply cleansing and will protect you more than soap and water."

Why do these cloths leave my skin feeling sticky?

"I should have mentioned the brief sticky feeling before you started to use them. It's actually a good thing. The sticky feeling is due to the aloe vera in the cloths which moisturizes your skin while it cleans. The aloe is the sticky feeling that goes away after a few minutes and leaves your skin soft and moisturized."

Can I use my own soap and/or lotions along with this bath?

"No, other soaps and lotions may prevent this bath from working and may not protect you because they interfere with the germ-fighting ingredient in the soap. This bath works better than soap and water to protect you, so it is important that you only use the soap we give you during your stay."

I would prefer to use my own shampoo and face soap. Is this okay?

"Other soaps and shampoos may interfere with the CHG soap which works the best to remove germs from your body. We strongly encourage you to use the CHG while you are here. However, if you must use you your own shampoo or face soap, please use them first and try to keep the shampoo and face wash off of the body so CHG will work as body soap."

I am too tired and I don't feel like bathing.

"I understand you must be tired, but this bath is important to protect you from bacteria and germs. It will only take 5 to 10 minutes and will make you feel refreshed. I will help you. If you are too tired right now, I can come back later and check in with you."

I don't think I can bathe because I have an IV.

"Don't worry, we do this all the time. In fact, because you have lines, it's even more important to keep germs off the skin and prevent infection. We actually clean the lines after we clean your skin. I will help you with areas around the lines and any other hard to reach areas."

Can I wait to bathe tomorrow? I just arrived today.

"Your first day in a nursing home is the most important day to take a bath and protect you from germs before we begin your medical care here. Bathing takes only 5-10 minutes and will make you feel refreshed and clean."

I would prefer to perform my own bed bath.

"If you wish to bathe yourself, let me give you important instructions and a handout ("CHG Bathing for Residents"). Remember to read the instructions carefully, as the bath may not protect you if it is not done correctly. The CHG cloths have a special no-rinse soap that works better than soap and water to

remove germs that can cause infection. Massage the skin well with the cloths to remove skin germs. Don't rinse since the CHG continues to work for 24 hours to keep germs away. Don't forget to clean all skin areas, including the neck and skin folds. Most residents need some help. I can help you with any hard to reach areas as well as help you clean on and around your lines or drains."

Can I use the soap on wounds or skin rashes?

"Yes. In fact, cleaning skin wounds and rashes is particularly important since germs can get under the skin when there is a skin break. You should also use the cloth over plastic dressings and to clean 6 inches of any line, tube, or drain closest to your body. I will help you with that part of your bath."

The label for liquid CHG says it can be used for routine bathing (skin, wound, and general skin cleansing), but CHG cloths are labeled as preoperative. Is it okay to use the cloths for routine bathing?

"Yes, both CHG liquid and CHG cloths are safe to use for routine bathing. The cloths are labeled based upon the original studies performed by the manufacturer to market the product. Since then, many large clinical trials have now shown that routine CHG bathing reduces serious infections, even in critically ill residents. The manufacturer came to this nursing home to help train the staff on use of this product for routine bathing based upon these trials. In fact, 80% of US hospitals now use CHG as their soap for routine bathing of ICU patients. This type of routine bath has been used in hundreds of thousands of patients and is well-tolerated and safe. Our goal is to prevent infection and protect you while you are here."

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PROTECTING NURSING HOME RESIDENTS FROM INFECTIONS AND READMISSIONS

Resident Talking Points
Nasal Iodophor

Residents may have questions regarding nasal iodophor. Below are some suggested responses to common resident questions.

REMEMBER:

- Your **enthusiasm** and **encouragement** will be the greatest predictor of a resident's acceptance and support for the protocol.
- Exclude residents with known allergy to iodine.

A. How to introduce iodophor swabs to residents:

"Good morning Ms/Mr X, every other week, our nursing home provides all residents with iodophor swabs to remove bacteria from the front of the nose. Some bacteria that you may have heard of, like "MRSA," live in the front of the nose and can cause future infections. Studies have found that one-third to one-half of nursing home residents have MRSA so we want to protect all our residents from infection by giving this swab to get rid of those germs. Would that be okay?

Have you had this swab in your nose before? It's called iodophor, also known as povidone iodine. We use one swab in each nostril for about 30 seconds, or at least 3 times around slowly.

Our doctors are offering this to all residents Monday-Friday every other week. We give it twice a day. The goal is to protect all residents at the same time."

B. How to answer some possible questions from residents:

1. Will this make my nose brown?

"It is possible for iodophor to leave a brown tinge just on the outer edge of the nose, but we can use a tissue to dab that off if it bothers you."

2. Why does it need to be given twice a day?

"Iodophor needs to be given twice a day for 5 days because it takes multiple doses to help get rid of MRSA and other bacteria."

3. Why do we get to skip a week?

"After a 5 day course, most people's noses stay clear of bacteria for about a week, which is why we give a week off."

4. Why can't you screen residents to know who actually has MRSA and give it to just those who have it?

"There are several reasons why we give the iodophor swabs to all residents together. First, MRSA is contagious. Studies have shown that 30-50% of nursing home residents have MRSA, so it is important to treat everyone together. Second, screening swabs are not perfect and they only tell us if MRSA is in the nose at the time of the swab. Third, in addition to MRSA, the swabs help with other types of bacteria."

Prevent infections during each nursing home stay

BATHE or SHOWER with Chlorhexidine (CHG) soap

STAFF

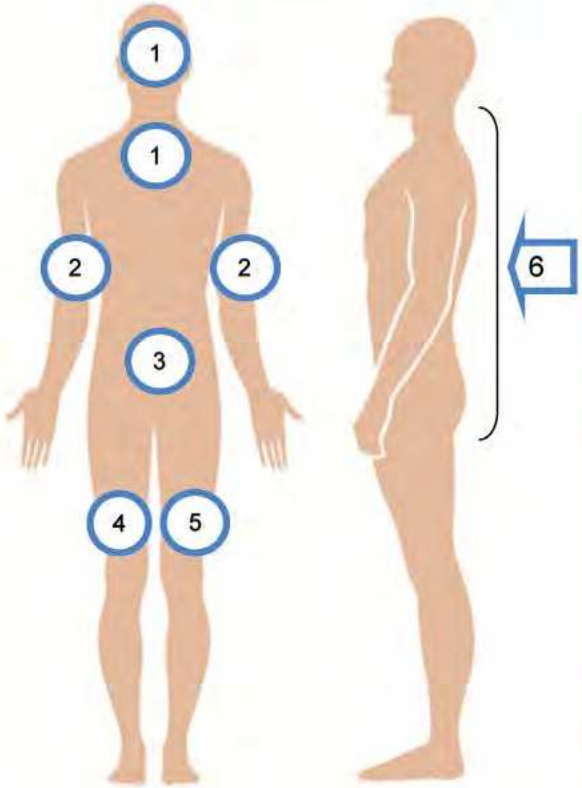
Bathe with CHG to remove germs and prevent infection

CHG works better than soap and water

CHG is a protective bath

CHG cloths are less drying than soap

Apply as shown below



Avoid eyes, mouth, & ear canals

REMINDERS

- **Your enthusiasm** helps residents understand why CHG is important
- Bathing on admission removes germs to protect the resident and nursing home
- CHG works for 24 hours to kill germs
- **Firmly massage** CHG onto skin
- Clean **6 inches** of lines, drains, tubes
- Safe on surface wounds, rashes, burns
- Use only CHG-compatible lotions
- If barrier protection needed, apply CHG then apply barrier protection

Clean all skin areas with attention to:

- Neck
- All skin folds
- Skin around all devices (line/tube/drain)
- Wounds unless deep or large
- Armpit, groin, between fingers/toes

SHOWERING with CHG soap

1. Rinse body with warm water
2. Wash hair and face with CHG
3. Avoid getting into eyes and ears
4. Turn off water and lather mesh sponge with plenty of CHG
5. Massage CHG onto all skin areas
5. Leave CHG on for **2 minutes** then rinse

BATHING with CHG cloths

1. Tell residents these cloths are their protective bath
2. Use all 6 cloths. More, if needed.
3. **Firmly massage** skin with cloth
4. Clean over semi-permeable dressings
5. Clean 6 inches of lines, tubes, and drains
6. Air dry. Do not wipe off.
7. Put used cloths in trash. **Do not flush.**

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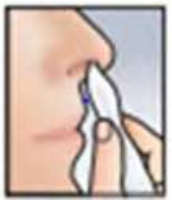
Prevent infections during nursing home stay

HOW TO APPLY Nasal 10% Povidone-Iodine (Iodophor)

STAFF

Apply nasal povidone-iodine antiseptic swabs to all residents *twice daily for 5 days every other week* to help remove germs and prevent infection

How to Use:



Clean nostrils (including tip) with tissues prior to application

Insert swab into one nostril and rotate for 30 seconds, or at least 3 times around slowly, covering all surfaces. Discard swab.

Repeat with 2nd swab in other nostril

Do NOT blow nose if solution drips. Gently wipe with a tissue.

Instructions

- Apply iodophor swabs **twice daily** for **5 days every other week**
- Clears bacteria that live in the nose that can cause infection, like *S. aureus* (including MRSA)
- 80% of *S. aureus* infections are caused by bacteria in the resident's own nose

Povidone-Iodine use in specific circumstances

- If nasal device in place (NG tube), swab around tubing if possible
- If nasal packing in place, do not apply to that nostril

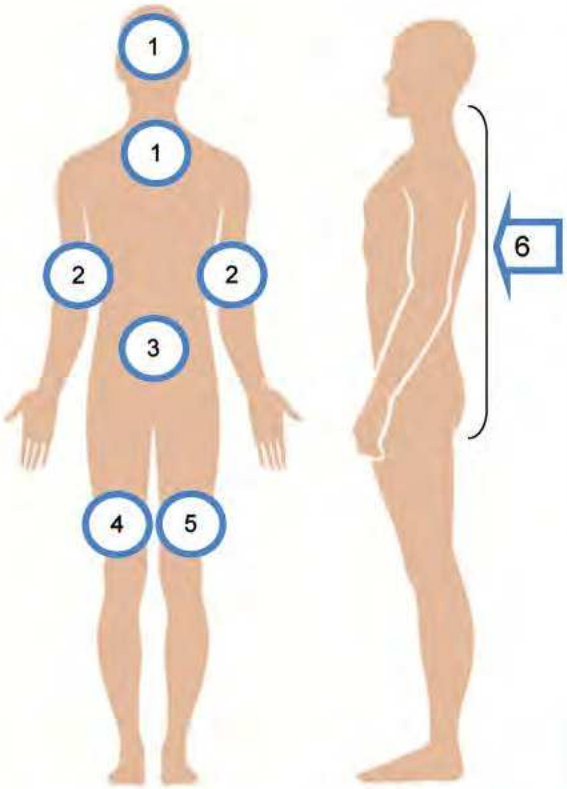
Prevent infections during your nursing home stay

BATHE with Chlorhexidine (CHG) Cloths

RESIDENT

During your stay, bathe *regularly* with a special antiseptic (CHG) which removes germs and prevents infection better than soap and water.

Each packet has 6 cloths to be used on all skin areas as shown below:



Avoid eyes, mouth, & ear canals

Take a CHG Bed Bath

BATHING with CHG cloths

1. Use CHG cloths for bed bathing. Starting on your admission day works best to remove germs.
2. These no-rinse cloths are your protective bath. The CHG continues to get rid of germs for 24 hours.
3. Use all 6 cloths. More, if needed.
4. **Firmly massage** on all skin areas to ensure deep cleaning of skin
5. Clean over non-gauze dressings
6. **Your nursing assistant will clean wounds and parts of lines, tubes, and drains nearest the body**
7. Throw away in trash. **Do not flush.**

Protect Yourself

Important Points and Reminders

- CHG is proven to work better than soap and water to get rid of germs
- CHG cloths have aloe and are good for your skin. CHG is less drying than soap.
- **Do not rinse.** Once massaged onto skin, CHG works to kill germs for at least 24 hours
- **Be thorough. Ask for help for hard to reach areas, backside, around devices.**
- CHG is safe on rashes and wounds that are not very large or deep
- **Clean lines, drains, tubes 6 inches from the body.** Ask for help, if needed.

Clean all skin areas with attention to:

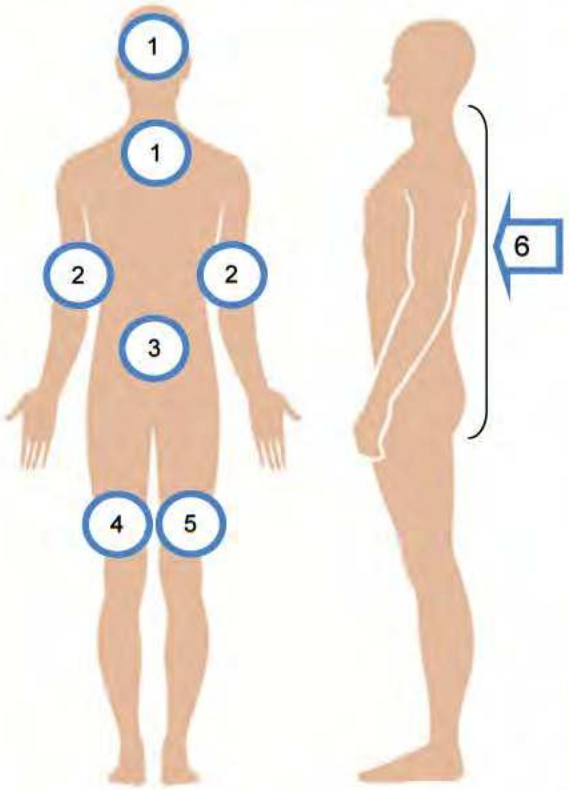
- Neck
- All skin folds
- Skin around all devices (tubes/drains)
- Wounds and open skin
- Armpits, groin, between fingers/toes

Prevent infections during your nursing home stay

SHOWER with Chlorhexidine (CHG) Soap

RESIDENT

During your stay, shower *regularly* with a special antiseptic soap (CHG) which removes germs and prevents infection better than soap and water



Avoid eyes, mouth, & ear canals

*Regular soap and shampoo prevent CHG from working well. If you must use your own shampoo or face wash, use them first and try to keep the shampoo and face wash off the body so CHG will work as body soap.

Take a CHG Shower

Showering with CHG soap

1. CHG will be provided in showers to wash your hair, face, and body
2. Begin with hair and face, rinse
3. **Use a mesh sponge.** It helps CHG lather well.
4. Apply generous amount of CHG to sponge and rub until foamy
5. **Apply CHG with water off** or stand out of water stream
6. Firmly massage onto all skin areas. Reapply CHG to keep cloth foamy.
7. **Ask for help for hard-to-reach areas**
8. For best effect, leave soapy lather on skin for 2 minutes. Rinse body well.

After showering with CHG soap

1. Rinse mesh sponge and hang to dry
2. Ask nurse to help clean lines, tubes, drains, or wounds that were covered for showering with **CHG cloths**
3. If needed, ask your nurse for CHG-compatible lotions to moisturize

Protect Yourself

Reminders

- CHG is proven to work better than regular soap to get rid of germs
- Once massaged onto skin, CHG works to kill germs for at least 24 hours
- **Use CHG regularly. Starting on the admission day works best** to remove germs
- Be thorough. Ask for help to reach hard-to-reach areas, including backside, around devices, on wounds
- CHG is safe on rashes, burns, and wounds that are not large or deep

Clean all skin areas with attention to:

- Neck
- All skin folds
- Skin around all devices (tubes/drains)
- Wounds and open skin
- Armpit, groin, between fingers/toes

Nursing Home Name: _____ Date: _____

STAFF Skills Assessment:
CHG Cloth Observation Checklist

Individual Giving CHG Bath

Please indicate who performed the CHG bath.

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

Observed CHG Bathing Practices

Please check the appropriate response for each observation.

☐ Y ☐ N Resident received CHG cloth bathing handout
☐ Y ☐ N Resident told that bath is a no rinse cloth that provides protection from germs
☐ Y ☐ N Provided rationale to the resident 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
☐ 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 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. How many cloths were used for the bath? (1 cloth set = 3 cloth packs with 2 cloths each, 1 single cloth pack = 2 cloths)

_____

2. If more than 1 cloth set (6 cloths) was used, provide reason.

_____

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

_____

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

_____

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

_____

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

_____

Nursing Home Name: _____ Date: _____

RESIDENT Self-Bathing Skills Assessment:

CHG Cloth

Please record resident responses after the resident 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 or lotions while in this nursing home?**
   ☐ Y ☐ N

6. **Were you told to bathe with the cloths while in this nursing home?**
   ☐ 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

Nursing Home Name: _____ Date: _____

RESIDENT Self-Bathing Skills Assessment:

CHG Showering

Please record resident responses after the resident showered with CHG liquid.

Questions

1. **Were you provided a handout with instructions on how to apply the CHG liquid in the shower?**
   ☐ Y ☐ N

2. **Were you told that CHG kills germs better than regular soap and water?**
   ☐ Y ☐ N

3. **Did you soap up twice with CHG before rinsing?**
   ☐ Y ☐ N

4. **Were you told NOT to use other bathing soaps or lotions while in this nursing home?**
   ☐ Y ☐ N

5. **Were you told to bathe or shower with CHG while in this nursing home?**
   ☐ Y ☐ N

6. **Did you or an assistant clean your lines, tubes, and/or drains with a CHG cloth after showering?**
   ☐ Y ☐ N ☐ N/A

7. **Did you or an assistant clean your wounds with a CHG cloth after showering?**
   ☐ Y ☐ N ☐ N/A

project PROTECT

PROTECTING NURSING HOME RESIDENTS FROM INFECTIONS AND READMISSIONS

Data Collection

The goal of Project PROTECT is to evaluate whether a decolonization strategy can better protect residents from multi-drug resistant organisms (MDROs) and their associated infections and hospitalizations when compared to routine bathing and showering. To understand the impact of decolonization, we will assess several outcomes:

Primary Outcome

- Transfers due to infection (% of discharges to a hospital due to infection)

Secondary Outcome

- All cause admissions (% of discharges to a hospital)

Other outcomes of interest include MDRO prevalence (MRSA, VRE, ESBL, CRE), antibiotic usage, and emergence of resistance (strain collection). Project PROTECT coordinators will work closely with the on-site study champions to collect data on measured outcomes. Additionally, data will be obtained from state and national datasets.

Maintaining a Hospital Transfer Log

For the outcome of reducing transfers to hospitals, participating nursing homes will be asked to record all transfers to the hospital or emergency department in a "Hospital Transfer Log." This log can be found in the "Transfer Tracking Log" binder kept at your facility.

For all resident transfers, you will be asked to specify on the log:

- First and Last Name*
- Date of Birth
- Room and Bed Number
- Transfer Date
- Hospital Name
- Primary reason for transfer
- ER/Admit status (ER only/Admitted)
- Was transfer due to infection? (Definitely Yes, Possibly, Definitely No)
- Regardless of transfer reason, was infection present? (Definitely Yes, Possibly, Definitely No)

Reason for transfer should include primary diagnosis and/or symptom(s). Examples include: confusion, shortness of breath, weakness, fever, cough, abnormal vital signs, etc.

* No identified data will be taken from the facility. First and last name will be kept on the log at the facility, and will not be removed from the facility. Only deidentified data and dates will be removed from facilities consistent with the Project PROTECT IRB approval for human subject protections.

Maintaining a Weekly Antibiotic Log

For the outcome of reducing antibiotic usage, participating nursing homes will be asked to complete a once-weekly "Antibiotic Log." This log can be found in the "Antibiotic Tracking Log" binder kept at your facility. The goal of this weekly assessment is to identify and record all residents on systemic (not topical) antibiotics and antifungals. This includes any antibiotic given orally or rectally, intravenously, or intra muscularly. For each assessment, the daily census should be recorded for calculating the proportion of residents on an antibiotic or antifungal at a given time.

For each antibiotic/antifungal prescribed, you will be asked to specify:

- First and Last Name*
- Date of Birth
- Room and Bed Number
- Medication Name
- Route (PO/IV/IM)
- Started at nursing home? (Yes/No, continued from Hospital)
- Reason for antibiotic (Pneumonia, UTI, Skin/Wound, Abdominal, Other (Specify), Unknown)

* No identified data will be taken from the facility. First and last name will be kept on the log at the facility, and will not be removed from the facility. Only deidentified data and dates will be removed from facilities consistent with the Project PROTECT IRB approval for human subject protections.

The assessment should be completed on the same day each week. Please omit ear drops, eye drops, and topical antibiotics.

Collect Baseline and End-Intervention Resident Swabs

For the outcome of reducing MDRO prevalence and emergence of resistance, participating nursing homes will be asked to support two point-prevalence swab cultures of residents. Each facility will be asked to collect nose and skin swabs from 50 residents once before the intervention and once at the end of the intervention period. All swabbing materials, logistics, laboratory transport, and laboratory processing will be provided by Project PROTECT staff.

project PROTECT

PROTECTING NURSING HOME RESIDENTS FROM INFECTIONS AND READMISSIONS

Just in Time Training

This section includes:

- "Just in Time Training" handout

Note: All frontline staff and new hires are required to complete the PROTECT Training Module and post-test located in the "Nursing Home Decolonization Training Module" binder.

project PROTECT

Just in Time Training

What is the purpose of this project?

Project PROTECT is evaluating the use of antiseptic soaps and nasal products to remove bacteria that can cause infection. This method of "decolonizing" residents uses chlorhexidine baths and nasal povidone-iodine, both of which have been used in healthcare for over 60 years to get rid of body germs and prevent infection. We are evaluating whether decolonization can reduce hospitalization and antibiotic use in nursing home residents.

Decolonization Protocol

1. **Chlorhexidine**
   - Use 2% no-rinse chlorhexidine (CHG) cloths or 4% rinse-off liquid CHG for showers on admission, and for all subsequent routine bathing needs
   - The skin at highest risk for infection is skin that is cut, broken, or punctured. CHG is safe for rashes and wounds that are not packed or deep. Use CHG on and over all devices.
   - Decolonization stops when discharged or transferred
   - If readmitted, protocol begins again
2. **Iodophor Nasal Treatment**
   - For licensed nurses only: Use nasal iodophor twice daily for 5 days on admission and then repeat every other week
3. **How to Bathe with CHG Cloths**
   - At first, pair with a "buddy" who can teach you
   - Bathing poster is posted in each room
   - Review attached 1-page staff education
   - To save time, give 1-page bath/shower resident instructions handout to residents a few hours before bath
   - Apply CHG to skin with **firm massage**
   - Avoid eyes and ears
   - **Let air dry. Do not wipe off.**
   - Do NOT flush cloths
   - Do NOT use soap (can inactivate CHG)
   - For incontinence, clean with incontinence wipes (water if needed), cleanse with CHG cloth, then use CHG-compatible barrier product

Have you had your bath today?

_____ **Please return completed form to the Nursing Director**

Signature

_____ _____ _____/_____/_____

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

project PROTECT

PROTECTING NURSING HOME RESIDENTS FROM INFECTIONS AND READMISSIONS

Safety and Side Effects

Your nursing home will be using nasal iodophor and chlorhexidine gluconate (CHG) products during this study to reduce bacteria that can cause infection. Both products have excellent safety profiles.

Both iodophor and CHG are only used topically, and are not absorbed into the bloodstream during use. In addition, these FDA-cleared products have been used in healthcare for a very long time and are considered safe for use in adults. Both are found over-the-counter, and have been used in healthcare for over 60 years.

Most people have no side effects when using iodophor or CHG. However, as with any medication, side effects may occur. With topically applied products like iodophor and CHG, the most common side effects are irritation at the site of application.

Chlorhexidine Gluconate (CHG)

Millions of patients have used CHG for bathing. It is currently used for:

- Central line and surgical skin prep
- Surgical pre-operative bathing
- Wound cleansing and irrigation
- Daily bathing in intensive care units

Local Side Effects Are Estimated to Happen in 1-3% of Patients

- Skin irritation
- Rash
- Redness of the skin

Povidone-Iodine Nasal Swab (Iodophor)

True allergy to iodine (the active ingredient in iodophor) does not exist since iodine is needed by the body. However, reactions can occur to the other ingredients. Side effects, although uncommon include:

- Mild discomfort
- Irritation

Severe Allergic Reactions

In **extremely rare** circumstances, severe allergic reactions can occur. **Such serious reactions are so rare that it cannot even be accurately reported.**

However, if you believe a resident may be developing a severe allergic reaction (including hives, severe itching, difficulty breathing, tightness in the chest, swelling of the mouth, face, lips, or tongue), stop the study drug, **immediately** call 911, and notify the treating physician.

A PROTECT Project senior supervisor can be reached anytime, including after hours or on weekends for urgent issues that cannot wait until business hours by calling [redacted]

For all side effects, please contact the treating physician for all resident care needs. Complete a "Study Related Event" form and submit it to the nursing home's nursing director. For general information, call [redacted] or email us at [redacted]

STUDY-RELATED EVENT SUBMISSION FORM

Please use this form to report all study related events.
For clinical decisions related to possible study related events, please contact the treating physician.

Please complete all fields before faxing

******DO *NOT* INCLUDE ANY RESIDENT IDENTIFIERS ON THIS FORM******

Fax completed form(s) to [redacted]
or email to [redacted]
Questions? Contact [redacted]

Facility name: _____

Please provide contact information below:

Name of individual staff member completing this form: _____
First Name Last Name

Phone: (_____) _____ - _____

Section I: General Information

Date of First Symptom Onset: ____/____/_____ Date Symptom Resolved: ____/____/_____

Please fill out <u>one</u> form per study related event.

Resident Gender: M F

Please choose the option that best describes the event:

☐ Skin/mucosa related, *continue to* ***Section II: Skin Related Events***

☐ Non-skin related, *please provide a brief description of the event. You may be contacted for more information.*

_____

_____

_____

Section II: Skin Related Events

Please indicate the study agent that you feel is related to the event:
☐ Chlorhexidine (CHG) ☐ Iodophor

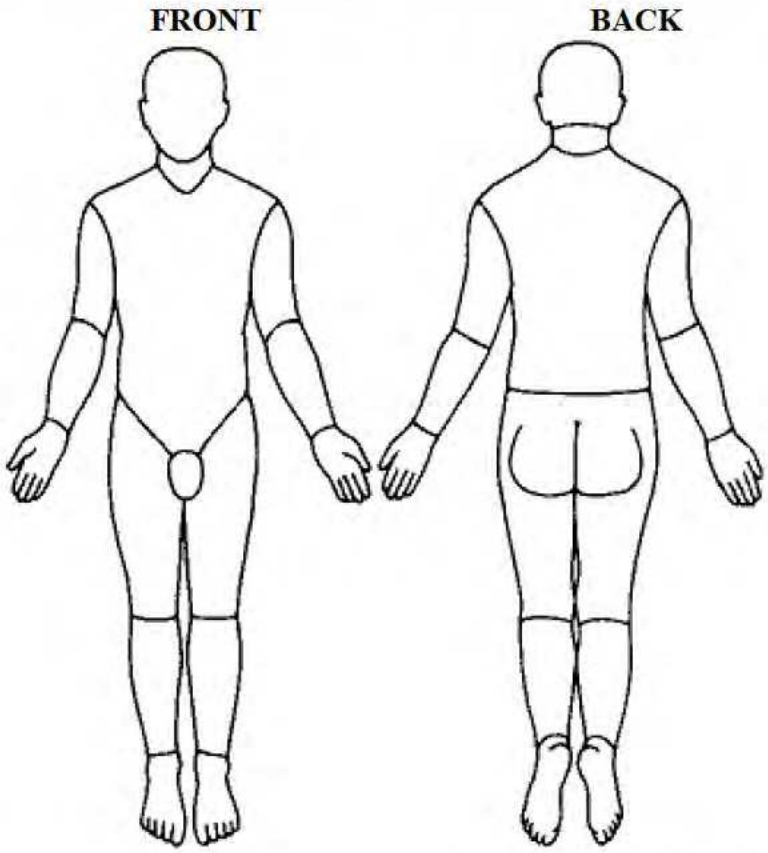
If you checked chlorhexidine, please indicate the CHG product that was used:
☐ Liquid CHG (4%) ☐ CHG 2% Cloths

Corrective Action Taken (Check all that apply):
☐ Study Drug Discontinued ☐ Topical cream/lotion applied ☐ None
☐ Oral/IV Benadryl given ☐ Oral/IV steroids given ☐ Other (*please specify below*)

STUDY-RELATED EVENT SUBMISSION FORM

Please shade the parts of the body, to scale.

ONLY INDICATE RASHES BELIEVED TO BE RELATED TO A STUDY DRUG EFFECT:



Erythema (Redness)
- ☐ None
- ☐ Mild (spotty or diffuse)
- ☐ Moderate, uniform redness
- ☐ Intense redness

Scaling
- ☐ None
- ☐ Mild, "dry skin" scale
- ☐ Moderate scaling
- ☐ Desquamation/sloughing

Blistering
- ☐ None
- ☐ Papules only
- ☐ Localized blisters
- ☐ Extensive blisters or bullae

Is the face involved? ☐ Yes ☐ No

In your opinion, how certain are you that this event is related to the trial agent (study drug) above?
- ☐ Definitely related
- ☐ Possibly related
- ☐ Unlikely to be related

Is it possible that another medication/product could have produced this reaction?
- ☐ Yes ☐ No

Have any other drug(s) been discontinued?
- ☐ Yes ☐ No

If yes, please specify: _____

Please fax completed form to [redacted] at [redacted] ATTN: [redacted]
Remember: DO NOT include any resident identifiers on this form.

Keeping germs away

Have you had your bath today?

Every resident, every day

Shower Instructions

We are pleased to provide you with a special soap, chlorhexidine (CHG), which has been proven to work better than soap and water to remove germs from your skin and protect you from infection.

1. Use liquid **chlorhexidine (CHG)** for all areas of the body
2. Use CHG as shampoo. **Avoid eyes and ears**. Rinse well.
3. Next, clean face with CHG. Rinse.
4. Apply generous amount of CHG to mesh sponge. **Rub until foamy.**
   - Wet skin with water
   - Turn water off or stand out of water stream
   - **FIRMLY MASSAGE** soapy sponge onto all skin from head to toe
   - Reapply CHG generously to the sponge to keep sponge foamy
     - ✓ Neck and chest
     - ✓ Both shoulders, arms and hands
     - ✓ Abdomen, hip and groin
     - ✓ Both legs and feet
     - ✓ Back of neck, genitals and buttocks last
   - **For best results, leave soapy lather on skin for 2 minutes. 2 minutes is about the time it takes to soap up all body areas and then do it again before rinsing**
5. **Don't forget to clean your neck, armpits, and skin folds well, including under the breast. Clean between fingers and toes too.**
6. Rinse body well
7. Rinse sponge and hang to dry
8. Ask nurse to help clean lines, tubes, drains, or wounds that were covered for showering with CHG cloths
9. If needed, ask your nurse for CHG-compatible lotion to moisturize

CHG continues to work for 24 hours to keep germs off your body. If you must use your own shampoo and face products, please use them before the CHG soap. Please try to keep them off the body as regular soap and shampoo prevents CHG from working as well.

project PROTECT

PROTECTING NURSING HOME RESIDENTS FROM INFECTIONS AND READMISSIONS

Contact Information

Topic	Who to Contact	Contact Information
General Questions	Central Office [redacted]	[redacted] Email: [redacted]
Study Supplies	Central Office [redacted]	[redacted] Email: [redacted]
Urgent Questions (Requires immediate reply)	Senior Field Supervisor* [redacted]	[redacted]
Study related events Questions Reporting	Central Office [redacted] Fax Study Related Event Form	[redacted] Email: [redacted]

* Will have access to lead investigators at all times

Protect Trial:

Protecting Nursing Homes from Infections and Hospitalization

Statistical Analysis Plan

Ken Kleinman, ScD

February 4, 2015

PROTECT Trial Design Characteristics and Outcomes

Study Design	Cluster-randomized controlled clinical trial
Study Population	Residents of 28 Southern California nursing homes serving adults (≥18 years old)
Exclusions	Facilities routinely using decolonization; dedicated dementia or psychiatric units. Age <18y.
Unit of Randomization **Arm 1 (N=14)** **Arm 2 (N=14)**	Nursing homes Routine bathing practice per established protocols Use of chlorhexidine for all showering/bathing, nasal mupirocin x 5 days for MRSA carriers
Baseline	Routine bathing with soap and water 3x/week; no nasal decolonization
Intervention	Body decolonization: 3 daily CHG baths on admission, then 3x/week CHG bathing Nasal decolonization: Nasal iodophor twice daily for 5 days every other week
Study Period	**18-Month Baseline Period** (Retrospective Data): Sept 2015-February 2017 **Training and Phase In Period**: March-June 2017 (not included in analysis) **18-Month Intervention Period:** July 2017-December 2018
Primary Outcome	Infectious admissions (% of transfers to a hospital that are due to infection)
Secondary Outcomes	All-cause admissions (% of discharged residents transferred to a hospital for any reason) Antibiotic usage (average antibiotic days per resident) Prevalence of MDRO colonization (MRSA, VRE, ESBL, CRE) *

* Outcome of an aim distinct from the trial aim in original grant. Has distinct design, methods, collection, analysis.

Randomization

The unit of randomization will be the nursing home, with all residents within a nursing home assigned to the same arm. Cluster randomization is the only feasible randomization method when an intervention must be applied (or is typically applied) to an entire group, such as a quality improvement initiative. It is also the only method for evaluating interventions for which individuals are linked, e.g., by shared exposure to contagious illness, as occurs in nursing homes. Cluster randomization also has the advantage of studying interventions under conditions of actual use, of minimizing disruption to normal practice, and of allowing the use of health system resources for ensuring compliance with the intended treatment.

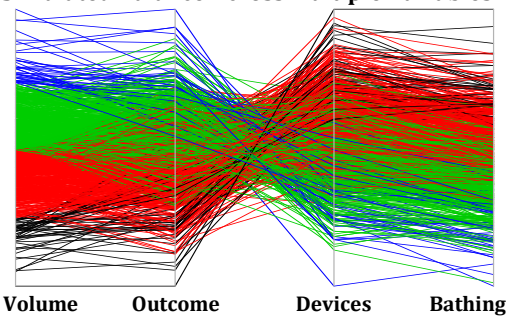
In cluster-randomized trials, the relatively smaller number of randomized units means that simple randomization may not ensure balance of key variables by chance alone. The existence of *a priori* data allows us to improve balance through stratification. One way is to establish pairs with similar covariate profiles in which one member per pair is assigned to each arm. There is no "best" method of making pairs. One approach we used in

a prior trial[145] is to calculate the Mahalanobis distance between facilities across all available key variables and choose the pairings with the minimum average within-pair distance. In this approach, we standardize the variables and then multiply by values calibrated to reflect any difference in their importance with respect to balance.

To select the best pairing scheme, we will compare this distance method to other pair construction schemes, using graphical methods to compare the balance between the arms under each scheme. For example, if two variables had to be balanced, we could tentatively divide the sample into two groups under a pair construction scheme and then generate a scatterplot showing the between-arm absolute value of the mean difference for one variable on the x-axis and the second on the y-axis for each possible result of the randomization. We would then divide the groups again under the same scheme, and find another point on the scatterplot. Repeating many times would show the typical distribution of balance under a scheme. Comparing the resulting scatterplots from each scheme can reveal the relative risks of imbalance and benefits for balance accruing to each scheme. One scheme may result in close balance on one key characteristic and very variable balance on the other, while a competing scheme may have good median balance on both characteristics, but a long tail implying a few bad-luck assignments with poor balance.

We aim to balance facility case mix based upon population age, wounds, comorbidities, and functional status scores, as well as infection prevention activities assessed by survey. To assess balance, we will use a parallel coordinates plot, a multivariate plot method. A simulation (**Figure)** shows a potential result of a single pair construction method using baseline values of volume, outcome, device use, and bathing frequency. Each blue, red, green, or black line shows the mean difference between arms for all four variables for one realized randomization under the scheme. The results show that a few randomizations, in blue, are relatively imbalanced on volume and outcome but are balanced on device use and bathing, while a few others, in black, have the reverse pattern. The green and red realizations are approximately equally balanced across these variables. If we considered it more important to balance on volume and outcome, this would not be an ideal scheme, as medium or poor balance is common.

Figure. Parallel Coordinates Plot Showing Simulated Balance Across Multiple Variables



Statistical Analysis

All outcomes will be assessed similarly. Here, we use the example of the primary outcome: the probability a transfer to a hospital is for an infectious diagnosis. Main trial results will be based on as-randomized, unadjusted analyses using logistics regression models. Clustering within nursing home will be accounted for using random effects, which are added model terms that allow unique baseline rates for each nursing home, and are necessary to account for clustered randomization. Model terms will include individual-level data on arm, nursing home, outcome events, trial period (baseline vs. intervention) and an interaction term between trial period and arm. Trial success will be determined by the significance of the interaction term, which assesses whether the difference in log odds between the baseline and intervention period differs significantly between the two arms. We can write a simple version of the model symbolically as:

$$logit(\Pr[R_{ij}]) = \log\left(\frac{\Pr[R_{ij}]}{1-\Pr[R_{ij}]}\right) = \beta_0 + \beta_1 Arm_{ij} + \beta_2 Period_{ij} + \beta_3 Arm_{ij} * Period_{ij} + b_i$$

where i is a nursing home, j is a resident within the nursing home, and R_{ij}=1 if the transfer has an infection diagnosis and 0 if not. Arm and $Period$ are indicator variables and are = 0 for patients in a nursing home in the control arm or baseline period and 1 if in the intervention arm or period, respectively. The random effect,b_i, allows for different readmission rates at each nursing home, and accounts for the clustering within a given nursing home. The ultimate effect of the intervention is assessed by β_3. If it is negative with p-value < .05 (or 95% CI excluding 0), then we can conclude that the intervention reduces the risk of infectious transfer.

Subsequent analyses will include as-treated and covariate-adjusted models. Adjusted models will account for individual age, gender, comorbidities (by diagnostic codes), and functional status scores. All analyses will use current versions of SAS (9.4), SAS/STAT (13.2, SAS Institute, Cary NC) and/or R (3.1.2).

Power

We assessed power via resampling methods. We used preliminary data on outcomes adjusted to an 18-month baseline and intervention period. First, each nursing home was randomly assigned to a study arm. Then, individuals were sampled with replacement from within each nursing home to simulate "baseline" period data. Individuals were sampled again to simulate the "follow-up" period data. For nursing homes assigned to intervention arm, observed readmissions among the sampled follow-up individuals were removed at a given probability to reflect the effect of the intervention. Finally, the analysis planned for the trial was conducted on the resampled "baseline" and "follow-up" data. In this case, the planned analysis is a generalized linear mixed model logistic regression with main effects for period and arm, with the study effect assessed via their interaction, as described above. To estimate power, we repeated this process 200 times. The proportion of times that the null hypothesis of no interaction effect was rejected, with alpha = .05, provided the estimated power. In contrast to analytic approaches to power, we also needed to find confidence limits on the estimate, which we did using exact methods. For cluster-randomized trials, this approach has the advantage that it does not require guessing the value of the intra-class correlation coefficient, or, importantly, its variability. In addition, this approach does not require an assumption of constant cluster size.

For our primary outcome, preliminary data showed that 21.3% of hospital transfers from nursing homes were due to infection. For the probability of transfer due to infection, we assessed the power for a relative reduction of 15%, from 21.3% to 18.1%. Power was estimated at 89% (95% CI [83%, 93%]). For our key secondary outcome of the probability of transfer to a hospital among discharges, our preliminary data showed that 37.8% of discharges were associated with admission to hospitals across the nursing homes. For this outcome, we estimated the power for a relative reduction of 8%, from 37.8% to 34.8%, to be 99.5% (95% CI [97%, 99.9%]). Even at a relative reduction of 5%, we have 74% power (95% CI [67%, 80%]). These effect sizes are meaningful because there is tremendous

national interest in reducing preventable readmissions, of which infections are a major cause. Reductions in overall readmissions of 1-3% are lauded as sizeable in the CMS Hospital Readmissions Program which fined 2,225 hospitals in its first year, with each fraction of a percent resulting in substantial lost revenue. The second year of this program saw a reduction of 0.6% in all cause readmissions. In summary, our power assessment demonstrates adequate power to detect plausible and meaningful effects of the proposed trial.

Protect Trial:

Protecting Nursing Homes from Infections and Hospitalization

Statistical Analysis Plan

Ken Kleinman, ScD

August 10, 2019

Study Conditions and Period

Participating nursing homes (28) were randomized to

- **Arm 1 – Routine Care**
  Nursing homes in this group arm did not change their bathing materials, timing, schedule, or other aspects of bathing regimen.
- **Arm 2 – Universal Decolonization**
  Nursing homes in this group used chlorhexidine soap or wipes for admission bathing and then for all resident bathing. They did not otherwise change their bathing materials, timing, schedule, or other aspects of bathing regimen. In addition, nasal iodophor was administered twice daily Monday through Friday, every other week.

Study Periods

- 18-month baseline period: September 2015-February 2017
- Phase-in period: March-June 2017 (not included in analysis)
- 18-month intervention period: July 2017-December 2018

Note that the baseline period occurred before the beginning of trial activities, including randomization. Data collection for primary and secondary trial outcomes used electronic sources and could not have been affected by randomization status.

Trial Outcomes

Trial Outcomes	Explanation
Primary outcome: Hospital transfer due to infection, among hospital transfers	If the resident was transferred from the nursing home to a hospital, was the transfer made because the patient had an infection?
Secondary outcome: Hospital transfer, among transfers	If the resident was transferred from the nursing home, were they transferred to a hospital?

Other outcomes are found in the below table. At the time of the study conception, these were planned for secondary manuscript submissions.

Other Outcomes	Explanation
Multidrug-resistant organism (MDRO) colonization	Was a resident colonized with a multidrug-resistant organisms (MDROs): (MRSA, VRE, ESBL, CRE)
Hospital transfer due to infection, among hospital transfers in Long Stay and Short Stay Subsets	As in above table, but with analyses stratified by length of stay.
Hospital transfer, among transfers in Long Stay and Short Stay Subsets	As in above table, but with analyses stratified by length of stay.
Emergency Department Transfer due to Infection; overall and in Long Stay and Short Stay Subsets	Probability that a resident is sent to the emergency department for an infection, overall and stratified by length of stay.

Statistical Analysis

Main trial results will be based on as-randomized, unadjusted analyses using generalized linear mixed models logistic regression. All outcomes will be assessed similarly. Here, we use the example of the primary outcome: transfer to a hospital for an infectious diagnosis. Clustering within nursing home will be accounted for using random effects, which are added model terms that allow unique baseline rates for each nursing home, and are used to account for clustered randomization.[207-208] Model terms will include individual-level data on arm, nursing home, outcome events, trial period (baseline vs. intervention) and an interaction term between trial period and arm. Trial results will be assessed through the interaction term, which measures the difference in log odds between the baseline and intervention period between the two arms. We can write a simple version of the model symbolically as:

$$logit\left(\Pr[R_{ij}]\right) = \log\left(\frac{\Pr[R_{ij}]}{1-\Pr[R_{ij}]}\right) = \beta_0 + \beta_1 Arm_{ij} + \beta_2 Period_{ij} + \beta_3 Arm_{ij} * Period_{ij} + b_i$$

where i is a nursing home, j is a resident within the nursing home, and R_{ij}=1 if the transfer has an infection diagnosis and 0 if not. Arm and $Period$ are indicator variables and are = 0 for patients in a nursing home in the control arm or baseline period and 1 if in the intervention arm or period, respectively. The random effect, b_i, allows for different readmission rates at each nursing home, and accounts for the clustering within a given nursing home. The ultimate effect of the intervention is assessed by β_3. If it is negative with p-value < .05 (or 95% CI excluding 0), then we can conclude that the intervention reduces the risk of infectious transfer.

Subsequent analyses will include as-treated and covariate-adjusted models. Adjusted models will account for individual age, gender, comorbidities (by diagnostic codes), and functional status scores. All analyses will use current versions of SAS (9.4), SAS/STAT (13.2, SAS Institute, Cary NC) and/or R (3.1.2).

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The Protect Nursing Home Trial
Statistical Plan Amendments

Date	Statistical Plan Amendments
2/4/2015	Original
8/20/2018	• Defined 'other' outcomes for secondary publications. Previously, clinicaltrials.gov listed both secondary outcomes for the primary manuscript and outcomes for secondary manuscripts under the same heading. After the ability to separate the two under "other outcomes," we clarified additional outcomes that were not trial outcomes. o Multidrug-resistant organism (MDRO) colonization (separate aim from the trial in original grant; distinct design, methods, collection, analysis) o Hospital transfer due to infection, in Long Stay and Short Stay Subsets o Hospital transfer for any reason, in Long Stay and Short Stay Subsets o Emergency Department visits due to Infection; overall and in Long Stay and Short Stay Subsets
6/19/2019	• Removed secondary outcome (antibiotic usage) o We had proposed to use the CMS Minimum Data Set (MDS) to assess this and other trial outcomes. At the time of the grant proposal, antibiotic usage was a newly-added variable. We assumed that this variable would increase in usage and accuracy with time. However, even five years after the variable was added, expert opinion from the creators of the MDS dataset, was that antibiotic data capture in MDS was poor and insufficient for analysis. Thus, the steering committee removed this as an outcome and filed a change with clinicaltrials.gov at that time. We note that MDS data is released 18 months following completion of a calendar year. This decision was made prior to receipt of any intervention data (2017-2018 MDS data) for the trial and prior to any data cleaning or analysis.
8/10/2019	• Updated layout, no change in content or meaning • Removed randomization details from statistical plan