



**IMPLEMENTATION OF CHLORHEXIDINE BATHING TO REDUCE
HEALTHCARE-ASSOCIATED INFECTIONS – THE ICARE STUDY
&**

**HUMAN FACTORS ENGINEERING TO PREVENT RESISTANT ORGANISMS: VA
PATIENT SAFETY CENTER OF INQUIRY: HERO PROJECT**

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**Observation of the Chlorhexidine Bathing Procedure
Training Manual**

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1 Introduction

Assessment of workflow and practices in infection control is often performed with direct observation in a clinical area over time, e.g., hand washing practices during the process of patient care. (Boyce, 2008; WHO 2009) The overall purpose of direct observation in this study is to understand the process of daily chlorhexidine gluconate (CHG) bathing.

The objective of this training manual is to provide researchers or quality improvement officers with instructions to consistently and effectively conduct observations of the CHG bathing process using one of two data collection tools. One tool will be used when CHG foam soap is used (Form A, Appendix A) while the other tool will be used when CHG impregnated wipes are used (Form B, Appendix C). One form shall be used per bath per patient.

This manual focuses on observing the CHG bathing process performed by healthcare workers (HCWs) in any unit. All observers shall thoroughly read the manual and complete orientation prior to beginning data collection. Effectively conducting direct observation in a healthcare environment is a challenging undertaking and requires a significant amount of training.

1.1 Direct observation in healthcare settings

Direct observation is an effective method for collecting real-time, naturalistic behavioral information about a specific job or process (Bisantz & Drury, 2005). This methodology has limitations, including: 1) the observer may not always fully understand the tasks being performed, 2) physical barriers or busy work environments can interfere with and not allow the observer to gain an appropriate perspective and 3) the presence of the observer may influence the way the worker carries out his tasks. The worker may become self-conscious of his/her work, spend more time on certain tasks or attempt to perform the activity being observed better than usual. This latter phenomenon is referred to as the Hawthorne effect (Parsons, H. M, 1974); the effect of the observer on the observed. The presence of the observer may disrupt the typical workflow (e.g., the movement and communication of the HCWs as they perform their work). Careful monitoring of one's observational procedures can help address these limitations.

HCWs are often moving in the course of their work. To effectively observe the process, the observer must follow the HCW and find an appropriate location to observe details of the work being performed. The observer should be close enough to the HCW in order to see details such as what type of supplies are being collected and how, and the order in which, the HCW is progressing through the CHG bathing process. However, it is also very important that the observer minimize the intrusiveness of the observation. The observer should be in a position that does not interfere with the workflow and should show respect for patient and family privacy. Keeping an appropriate distance enables a more natural work environment for the study participant, which in turn provides the observer with more accurate information. It requires practice for observers to learn how to strategically place themselves to allow for the collection of high-quality representative data.

1.2 Training manual development

Our team has done work involving direct observation in the past (Caya et al., 2015). We have learned that it is paramount to have standard observation procedures to reduce the likelihood of inconsistencies and biases in data collection. This manual will be used as a training document for all new observers prior to conducting observations. Because the CHG bathing process requires multiple steps, we shall observe compliance with these steps using a standard data collection instrument. We will also assess, through direct observation, any observable barriers and facilitators to successfully perform the required CHG bathing process.

Development of this manual was a collaborative effort with input from both experienced and novice observers. Many ideas were borrowed from a training manual which researchers in this group have previously developed for a project that assessed checklist use in a Family-Centered Rounds study (Kelly, M. M et al., 2013). Additions and modifications were incorporated after conducting pilot observations.

Although this manual is about CHG bathing, with modifications, research projects or quality improvement projects conducting similar work involving direct observation of infection prevention interventions or activities will benefit from this document.

1.3 Overview of the chlorhexidine bathing procedure

CHG bathing can be performed using CHG foam soap or CHG impregnated wipes. The commonly used brand of the CHG foam soap is Hibiclens[®] soap (Hibiclens[®] 4%) while the commonly used CHG impregnated wipes are the Sage[®] 2% CHG cloths. The CHG bathing protocol for foam soap consists of specific observable components (see data collection instrument, Form A). CHG bathing using CHG impregnated wipes follows a similar protocol with only a few modifications (see data collection instrument, Form B).

1.4 Observer orientation

All observers must complete an orientation prior to beginning research or quality improvement activities. Orientation will be project-specific and includes human subjects and HIPAA training, and a full understanding rules of conduct, privacy and safety issues. Completion of the orientation ensures compliance with research and quality improvement policies and procedures of the university, hospital and other involved parties. Observer training will commence after completing orientation.

2 Data Collection Tool: CHG bathing checklist

The data collection tool used and described in this manual is a modification and improvement of one used in our previous study (Caya et al., 2015). In Appendix B and Appendix D we define the items for each of the data collection instruments and provide specific instructions on how to collect data for each item. Prior to conducting any pilot observations, observers must thoroughly read Appendices B and D and fully comprehend the items associated with data collection. Any concerns the new observer has regarding definitions and instruction clarity should be directed to the research team. Observers should strive to observe baths for different patients rather than observing multiple baths for one patient.

3 Conducting Observations

3.1 Who will conduct observations

Designated research team members who have successfully completed orientation and training will be responsible for conducting observations.

3.2 When will observations be done

Observations will be conducted during the day and evening shifts. In some hospital units, most baths occur during certain shifts. Therefore observation periods will need to be adapted to the unit being observed. For example, in our previous study (Caya et al., 2015), we noted that most inpatient bathing occurs on weekdays during the day shift (7:00am to 3:00pm) and, therefore, most observations were conducted during this time. In this project, prior to conducting observations, we shall determine from the unit staff when most baths are performed on their unit and observations will be scheduled accordingly. Ideally, observations shall also be conducted on weekends in order to assess variation between weekdays and weekends.

3.3 Observation protocol

Several important steps will be followed for each observation. Following is an outline of the procedure to be followed:

1. Provide the HCW to be observed with information prior to the observation, including:
 - a. Information emphasizing that the observation is about the **process** of CHG bathing rather than how well the HCW performs CHG bathing. The HCW should know that no information identifying him or her is being collected.
 - b. Clarification that the observer will not interfere with the bathing process in any way. No verbal communication by the observer will occur once s/he enters the patient room.
2. Complete the data collection instrument (Form A or B) while observing the process.
3. Conclude the observation by informing the HCW when the observation is complete and thanking them for their participation.
4. Within 48 hours, type up the observation notes and enter the raw “cleaned” data (from the data collection instrument) into REDCap.

3.4 Infection Prevention

Precautions must be taken to prevent the spread of disease in healthcare settings. Before an observation begins, after an observation ends and whenever the observer touches anything on the unit, the observer must practice proper hand hygiene. This must be done by either cleaning one's

hands using the alcohol disinfectant located throughout the units, or by washing one's hands with water and soap.

3.4.1 Attention to isolation precautions

Isolation precautions help prevent the spread of infections in a healthcare setting by creating a barrier between people and the microorganisms (germs) that cause disease (APIC 2016). At all times standard precautions such as practicing hand hygiene mentioned above should be followed by the observer. In addition to the standard precautions, the observer might encounter patient rooms with isolation precautions. There are three different types of isolation precaution:

1. Contact Isolation Precautions

These are followed for infections that are spread by touching (contact) the patient or items in the patient's environment. Examples include patients infected with Methicillin-resistant *Staphylococcus aureus* (MRSA), Vancomycin - resistant Enterococci (VRE) and patients with various diarrheal illnesses, open wounds.

One subcategory of contact precautions the observer may encounter includes **enteric precautions**. These are followed in many healthcare facilities, particularly for patients who have active infection with *Clostridium difficile* (*C. difficile*) bacteria and those with a rotavirus or norovirus infection. The important consideration for the observer to remember is that enteric precautions are a type of contact precaution.

2. Droplet Isolation Precautions

These are followed for diseases that are spread in tiny droplets caused by coughing and sneezing and includes pneumonia, influenza, whooping cough, bacterial meningitis, and other such diseases.

3. Airborne Isolation Precautions

These are followed for diseases that are spread through the air from one person to another and include tuberculosis, measles, chickenpox, etc.

3.4.2 What to do if an observer encounters a patient's room with isolation precautions?

If a patient has been placed on isolation precautions, there will be a sign at the door to their room to remind visitors and HCWs which isolation precautions are needed. It is important that the observer looks for these signs before entering a patient's room. If one notices that there is an "isolation precautions" sign on the door to the patient's room, the observer should talk to the

HCW before entering the room. S/he will guide the observer on what steps to take, such as wearing a mask or other personal protective equipment (PPE).

In the event of isolation precautions in this project, we shall conduct observations **ONLY** for those patients under **contact isolation precautions** (therefore NOT for those under droplet or airborne isolation precautions). The observer must ask the HCW for the necessary PPE before entering the patient's room. In general, the observer will have to clean their hands (by hand washing or using a hand sanitizer) when entering and leaving the room, wear a gown and gloves while in a patient's room and remove the gown and gloves before leaving the room. The observer should not touch anything in the patient's room.

3.5 Dress code and code of conduct

Observers must dress and behave professionally. The code of conduct is found in Appendix E.

3.6 Pilot observations

Each observer must conduct at least 5 observations prior to actual data collection. These pilot observations provide opportunities for the observer to become familiar with all aspects of the observation procedure and clarify any issues that may arise.

3.6.1 Inter-rater reliability (IRR)

IRR is to be assessed while conducting pilot observations (i.e., prior to beginning formal data collection). Observers will compare data collected and assess whether the same activities are recorded. IRR observations must continue until the trainee has 3 consecutive IRR's of > 80%. To assure continued reliability of the observation data, IRR will be reassessed periodically throughout the study

Each observer shall complete at least 5 "paired" observations. The first observation is educational in nature; an experienced observer introduces the trainee (novice observer) to the methodology and healthcare setting and the trainee watches the experienced observer collect data, paying attention to how the data collection instrument is completed. The second observation will be similar, but the trainee will be expected to be more independent by

completing the data collection instrument side-by-side with the experienced observer. The subsequent (at least three) observations will be standard IRR observations; that is, the observers will not speak to each other during the observation. Once an acceptable level of IRR is attained (i.e., 80%), observers will begin to collect data alone (i.e., there are no “paired observations”).

3.6.2 Calculating the Inter-rater reliability (IRR)

The IRR shall be assessed by calculating Cohen's Kappa (McHugh 2012). Cohen’s Kappa is a measure of agreement between two raters and accounts for agreement due to chance alone.

Excluding observer notes, the observation data collection instrument items in the main section shall be used to calculate Cohen's Kappa because that is where variation is expected to occur.

The calculation of Cohen’s Kappa shall proceed as follows:

- (1) For data collection instrument items number 1-6 and 8-9, whenever observers code the same response (i.e., they agree), a score of 1 shall be assigned; when they disagree a score of 0 shall be assigned.
- (2) Item number 7 (timing of bath). A score of 1 shall be assigned if the time recorded is the same or differs by +/- 1 minute, for example if observer A records “Total time CHG is left on chest before rinsing” of 2:35; to assign a score of 1, observer B must assign a time including and between 1:35 and 3:35. Otherwise a score of 0 shall be assigned
- (3) All data of the two observers shall be entered into Microsoft Excel software and the IRR shall be calculated and expressed as a percentage. Generally, an agreement of 80% (McHugh 2012), which this project will consider acceptable, is deemed excellent agreement.

Formula for Calculating Cohen’s Kappa

$$\text{Cohen's Kappa index} = (\text{Pr}(a) - \text{Pr}(e)) / (1 - \text{Pr}(e))$$

Where,

Pr(a) - Relative observed agreement

Pr(e) - Hypothetical probability of chance agreement or Probability of agreement based on chance alone

4 After the Observation

The observer is responsible for cleaning and entering the raw data to REDCap within 48 hours of the observation. This is accomplished by reviewing the completed data collection instruments and entering information into REDCap. (See also section 3.3)

4.1 Data Analysis

Data will be analyzed by identifying the tasks performed and recorded on the data collection instrument and computing a percentage completion rate. Descriptive statistics will be calculated and we shall use logistic regression to adjust for the effects multiple covariates. We shall link direct observation data with data on CHG skin concentration obtained by collecting and analyzing patients' skin for CHG concentration (described in a different manual). Correlation between these data shall be calculated.

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Appendix A – Data Collection Instrument for Baths Using CHG Foam—Form A

Begin (S): _____
Begin (B): _____
End: _____

Date _____ Day M, T, W, Th, F, Sa, Su Unit _____ Who is doing bath CNA/HCT/MSA/LPN RN
 Helper None CNA/HCT RN Other _____ Type of bath FABB PABB PAshower
 # Days since admission _____ Pt. Age _____ Pt. Sex M / F Is this the patient's first bath? Y / N
 Is there a physician order for CHG soap to be used in areas outside of standard protocol? Y (note below) / N

Helper (S): _____
Helper (E): _____

Observer initials _____

CHG bathing activities	Done?	Other information	
1. Gather supplies		7. Timing of bath	(min:sec)
1.a Basin or Ziploc [®] bag	Y / N	7.a Total time CHG is left on chest before rinsing	
1.b Washcloths	Y / N	7.b Total time CHG is left on one leg before rinsing	
1.c CHG soap	Y / N	8. Sequence of bath	Sequence (#)
1.d CHG compatible lotion (e.g., Medline [®] /Aloe-vesta [®])	Y / N	Face (done by patient)	
2. Provide education to patient and/or caregivers		Left arm	
2.a Explain rationale & process to patient	Y / N / NA	Right arm	
2.b Explain rationale & process to caregivers	Y / N / NA	Chest and abdomen	
2.c Use patient instruction card	Y / N / NA	Left leg	
3. Perform hand hygiene		Right leg	
3.a Hand hygiene performed	ALC / S&W / N	Back	
3.b Don clean gloves	Y / N	Perineum	
3.c Personal Protective Equipment (gown)	Y / N / NA	9. Interruptions	(min:sec)
4. Perform CHG bath		9.a MD	
4.a Wet washcloths	Y / N	9.b Lab	
4.b Wash patient's face using washcloth with non-CHG soap & water	Y / N	9.c Patient left room for medical testing	
4.c Use 1 washcloth to wash each body part	Y / N	9.d Physical Therapy	
4.d Apply 2 pumps of CHG to each washcloth	Y / N	9.e Electrodes replaced	
4.e Use different clean wet washcloth to rinse CHG off each body part	Y / N	9.f Left patient's room to get more supplies	
4.f Use non-CHG soap and water on genital area & perineum	Y / N	9.g Dressing changed	
4.g Rinse genital area & perineum with clean wet washcloth	Y / N	9.h Bedding changed during CHG bath	
4.h Avoid CHG soap on drains, lines &/or dressings	Y / N / NA	Observer notes:	
4.i Towel-dry skin	Y / N		
4.j Apply Medline [®] or Aloe-vesta [®] lotion	Y / N		
4.k Complete bathing with no skin below jaw line missed	Y / N		
5. Were lotions from home used?	Y / N / DK		
	Y / Not Obs		
6. Was CHG bathing documented in EHR?			

Appendix B – Definitions and instructions on how to collect data using Form A

The checklist has two major sections—the header and the main section. Items are defined below, beginning with the header items. For questions with **Y** (yes) and **N** (no) responses, the observer will circle the appropriate response, based on what they observe. For situations where a given item is not applicable to the patient, the observer will circle **NA** (not applicable). When the observer is unable to make a judgment, **DK** (don't know) will be circled. The option labeled **Not Obs** is provided only for steps that are not observed but may be performed at another point in time (i.e., documentation of the bath in the EHR).

HEADER

Begin (S): _____
Begin (B): _____
End: _____

Begin (S) Record the time (in 24-hour notation, excluding seconds) the HCW begins gathering supplies.

Begin (B) Record the time (in 24-hour notation, excluding seconds) the HCW begins doing the actual bathing process.

End Record the time (in 24-hour notation, excluding seconds) when the HCW finishes applying lotion on patient's skin.

Date The date when the observation is conducted. Record as: mm/dd/yyyy.

Day The day of the week the observation occurs. The observer should circle the corresponding day's abbreviation. For example, circle M for Monday.

Unit The unit where the observation taking place. Record as the generally accepted unit name / number (e.g., 4A, 4 East, F4/4).

Who is doing the bath? The role of the primary person giving the bath. The observer should circle: **CNA/HCT/MA/LPN** (certified nursing assistant, health care technician, medical assistant, licensed practical nurse) or **RN** (registered nurse) to denote this role of the person.

Helper This is applicable in baths where the primary HCW giving the bath receives assistance with activities such as turning the patient. The observer should circle: **None** if there is no one assisting the primary person giving the bath, **CNA/HCT/MSA/LPN** (certified nursing assistant, health care technician, medical assistant, licensed practical nurse), **RN** (registered nurse) or **Other** (and record the role of this person, e.g., family member) to denote the role of this person.

Type of bath Three kinds of CHG baths will be observed and for this project, including:

FABB (fully assisted bed bath): the patient does not take a role in their bathing.

PABB (partially assisted bed bath): the patient washes part, but not all, of their body during a bed bath.

PAshower (partially assisted shower): the patient washes part, but not all, of their body during a shower.

The observer circles the corresponding type of bath the patient receives.

Days since admission The number of days since admission. The observer asks the nurse or other HCW and records the corresponding number in the space provided. The day of admission is day 0 (zero).

Pt. Age The patient's age. The observer asks the HCW for the patient's age. If the observer is unable to ask the HCW for the patient's age, the observer should record whether the patient appears to be 70 years old or older (≥ 70) or under 70 years old (< 70).

Pt. Sex The patient's gender. The observer should circle **M** (male) or **F** (female).

Is this the patient's first bath? Prior to the observation, the observer asks the HCW this question and circles the appropriate response (**Y** or **N**).

Is there physician order for CHG soap to be used in areas outside of standard protocol? This refers to situations where CHG use is ordered by a physician for specific activities which deviate from protocol.

Examples include: cleaning incisions with CHG before redressing and using CHG when changing a central line or catheter dressing. Prior to the observation, the observer asks the HCW if there is a physician order for use of CHG outside the normal bathing procedure and circles either **Y** or **N**, corresponding to the response. If **Y**, then the area(s) should be recorded in the space under the question.

Observer initials Observer records his/her initials on the line provided.

Helper (S): _____
Helper (E): _____

Helper (S) Record the time (in 24-hour notation, excluding seconds) a helper first gets involved in the bath.

Helper (E) Record the time (in 24-hour notation, excluding seconds) a helper leaves the bath

Main section items 1- 4 are arranged according to the order in which a normal CHG bath generally occurs.

1. Gather supplies These are the supplies, gathered in preparation for a CHG bath, and include:

1.a Basin or Ziploc[®] bag The disposable basin or plastic bag used for one patient and disposed of when the patient is discharged. (Circle which "container" is used.)

1.b Washcloths Used for washing the patient's skin. A typical bath needs about 10-15 washcloths.

1.c CHG soap Commonly used brand is Hibiclens[®] (a 4% CHG foam).

1.d CHG compatible lotion (Medline[®]/Aloe-vesta[®]) Manufacturers of CHG recommend lotions that are compatible with CHG. Examples of these are Medline[®] and Aloe-vesta[®].

Circle **Y** or **N** to denote if the respective supply is used.

2. Provide education to patient and caregivers This category is generally relevant if it is the first bath in which the patient and/or caregiver are present. The observer should have asked the HCW, prior to beginning the observation if this is the first bath the patient is getting. If it is the first bath, either **Y** or **N** is circled for all of the categories below, unless the patient is comatose or no caregiver is present (therefore **NA** is circled).

2.a Explain rationale and process to patient A HCW provides verbal information to the patient about the use of CHG for bathing.

2.b Explain rationale and process to caregivers A HCW provides education to the patient's caregivers about the use of CHG for bathing. This is most applicable for patients who are comatose.

2.c Use patient instruction card The HCW provides education about CHG bathing by using a written "card" for patients who have temporary or permanent auditory impairment.

Circle **Y**, **N**, or **NA** as appropriate for 2.a – 2.c.

3. Hand hygiene (HH) performed This item assesses about HH.

a. Hand hygiene performed

i. **ALC** This means that an alcohol gel was used

ii. **S&W** This means that soap and water were used

Observers should indicate which type of hand hygiene is performed by the HCW by circling **ALC** or **S&W** on **N** if HH is not performed.

b. Don clean gloves Non-sterile gloves

c. Personal Protective Equipment (gown)

4. Perform CHG bath Items in this category are arranged in the order in which they are expected to occur for a CHG bath.

4.a Wet washcloths This is accomplished at the sink. Wet washcloths are placed in the basin or bag and used to rinse the CHG or soap off.

4.b Wash patient's face using washcloth with non-CHG soap and water In most circumstances, CHG soap should not be used on the face. If it was ordered to be used on the face, this should have been recorded in the header – "Is there a physician order for CHG soap to be used in areas outside of standard protocol?" – as **Y** and noted in the space below the question.

4.c Use 1 washcloth to wash each body part This is an "all or none" question. If a single washcloth is used on more than one body part, **N** should be circled.

4.d Apply 2 pumps of CHG to wet the washcloth At least two pumps are applied to each washcloth (when washing the patient). If this is not done (even if only one body part is washed with less than two pumps), **N** is recorded.

4.e Use different clean wet washcloth to rinse CHG off each body part One clean washcloth is used for each body part. This is an “all or none” question. If a single washcloth is used on more than one body part, **N** should be circled.

4.f Use non-CHG soap and water on genital area and perineum Clean washcloth is used.

4.g Rinse genital area and perineum with clean wet washcloth Clean washcloth is used.

4.h Avoid CHG soap on drains, lines, & dressings If this is done, it should have been ordered (and therefore noted in the header question related to use of CHG outside standard protocol).

4.i Towel dry skin This is done to prevent the patient from getting cold.

4.j Apply Medline[®] or Aloe-vesta[®] lotion Manufacturers of CHG recommend lotions that are compatible with CHG. Examples of these include Medline[®] and Aloe-vesta[®] lotions.

4.k Complete bathing is completed with no skin below jaw line missed If any parts are missed, the observer should note this in the observer notes.

5. Were lotions from home used? It is difficult to know if lotions from home are compatible with CHG. This can be determined by listening to the HCW and patient talk about the lotion or by asking the HCW after the observation is complete.

6. CHG bathing documented The observer circles **Y** , **N** , or **Not Obs**.

7. Timing of bath Here the observer records the skin contact time of CHG.

Observers shall be provided with stop watches to help record this time. Observers should record this time in the space provided. For example, if it lasted for one minute write down 1:00, it lasted for 30 seconds write down 00:30, if it lasts 1 and half minutes, write down 1:30.

7.a. Total time CHG is left on chest before rinsing Here the observer captures the amount of time CHG soap is applied and left on the chest until the time rinsing is initiated.

7.b Total time CHG is left on one leg before rinsing Here the observer captures the amount of time CHG soap is applied and left on one leg until the time rinsing is initiated.

8. Sequence of bath

The observer captures the order of the bath steps by recording the numbers 1 through 8 according to the sequence followed. For example, if the HCW starts the bath by bathing the chest, then the left arm and so on, then “**1**” should be written in the space for chest, “**2**” in the space for the left arm, etc.

9. Interruptions An interruption is defined as “cessation of activity before the current task is completed for an externally imposed reason” (Flynn, Barker & Gibson, 1999). A CHG bath may be interrupted by numerous activities. Eight common examples of interruptions are included, based on previous work. Here the observer records how long the interruption lasts, using a stop watch (as in section 7). These include:

9.a MD This is when a physician enters the patient's room during the CHG bath and the HCW must wait for the physician to finish with the patient before completing the bath.

9.b Lab Laboratory person draws blood or collects specimen from patient.

9.c Patient left room for medical testing The patient must leave the room (and not finish the bath at that time) for a procedure (e.g., radiology) to be performed elsewhere.

9.d Physical therapy Physical therapy is performed during the bath, therefore extending the time of the bath.

9.e Replace electrodes Patient with electronic monitoring (e.g., ECG) has electrodes replaced during the CHG bath.

9.f Left patient's room to get more supplies Any of the supplies needed for the bath ran out and nursing staff had to go outside the patient's room to get more.

9.g Dressings changed HCW changes dressings while performing the CHG bath.

9.h Bedding changed during CHG bath HCW changes patient's bed during CHG bath.

The observer should record the time the interruption lasted in minutes or seconds as applicable. For example, if it lasted for one minute write down 1:00, it lasted for 30 seconds write down 00:30, if it lasts 1 and half minutes, write down 1:30.

Observer notes

The observer should record relevant notes in the "**Observer notes**" section. Examples would include interruptions not those listed on the tool and anything else the observer finds peculiar or worth noting during the observation. For example, the room might have a lot of clutter, the HCW might not have help when needed, etc.

Appendix C – Data Collection Instrument for Baths Using CHG Wipes—Form B

Begin (S): _____
 Begin (B): _____
 End: _____

Date _____ Day M, T, W, Th, F, Sa, Su Unit _____ Who is doing bath CNA/HCT/MSA/LPN RN
 Helper None CNA/HCT RN Other _____ Type of bath FABB PABB PAshower
 # Days since admission _____ Pt. Age _____ Pt. Sex M / F Is this the patient's first bath? Y / N
 Is there a physician order for CHG soap to be used in areas outside of standard protocol? Y (note below) / N Observer initials _____

Helper (S): _____
 Helper (E): _____

CHG bathing activities	Done?	Other information	
1. Gather supplies		6. Sequence of bath	Sequence (#)
1.a CHG prepacked wipes pack	Y / N	Face (note if done by patient)	
1.b Gloves	Y / N	Left arm	
2. Provide education to patient and caregivers		Right arm	
2.a Explain rationale & process to patient	Y / N / NA	Chest and abdomen	
2.b Explain rationale & process to caregivers	Y / N / NA	Left leg	
2.c Use patient instruction cards	Y / N / NA	Right leg	
3. Perform hand hygiene		Back	
3.a Hand hygiene performed	ALC / S&W / N	Perineum	
3.b Don clean gloves	Y / N	7. Interruptions	(min:sec)
3.c Personal Protective Equipment (gown)	Y / N / NA	9.a MD	
4. Perform CHG bathing		9.b Lab	
4.a Clean entire neck area including skin folds	Y / N	9.c Patient left room for medical testing	
4.b Cleans around lines	Y / N / NA	9.d Physical Therapy	
4.c Massage skin firmly with CHG cloth	Y / N	9.e Electrodes replace	
4.d Clean armpit	Y / N	9.f Left patient's room to get more supplies	
4.e Clean back of knee	Y / N	9.g Dressing changed	
4.f Clean in between toes	Y / N	9.h Bedding changed during CHG treatment	
4.g Clean in between fingers	Y / N	Observer notes:	
4.h Clean between all folds in perineal area	Y / N		
4.i Cleans between all folds in gluteal area	Y / N		
4.j Wipe occlusive dressing with CHG cloth	Y / N / NA		
4.k Wipe semi-permeable dressing with CHG cloth	Y / N / NA		
4.l Clean tubing, lines and drains closest to body	Y / N / NA		
4.m Use CHG on superficial wounds	Y / N / NA		
4.n Use CHG on skin rashes	Y / N / NA		
4.o Use CHG on stage 1 & 2 decubitus ulcers or bedsores	Y / N / NA		
4.p Use on closed surgical wounds	Y / N / NA		
4.q Allow to air dry/do not wipe off CHG	Y / N		
4.r Complete bathing with no skin below jaw line missed	Y / N		
5. CHG bathing documented	Y / Not Obs		

Appendix D – Definitions and instructions on how to collect using Form B

The checklist has two major sections—the header (with its items) and the main section. Items are defined below, beginning with the header items. For questions with **Y** (yes) and **N** (no) responses, the observer will circle the appropriate response, based on what they observe. For situations where a given item is not applicable to the patient, the observer will circle **NA** (not applicable). When the observer is unable to make a judgment, **DK** (don't know) will be circled. The option labeled **Not Obs** is provided only for steps that are not observed but may be performed at another point in time (i.e., documentation of the bath in the EHR).

Note: The “actual CHG bathing process” items described here are adapted from the Agency for Healthcare Research and Quality’s (AHRQ) CHG Bathing Skills Assessment form

<http://www.ahrq.gov/sites/default/files/publications/files/universalicu.pdf>, last accessed on April, 8, 2016).

HEADER

All header items for data collection instrument B (CHG wipes form) are the same as those for data collection instrument A (CHG foam).

MAIN SECTION

- 1. Gather supplies** The needed supplies are the CHG prepacked wipes pack and gloves. The observer should note if these are collected prior to starting the bath. Gathering the necessary supplies is important to avoid running out during the bath which may be an interruption.
- 2. Provide education to patient and caregivers** This is the same as data collection instrument A.
- 3. Perform hand hygiene** This is the same as data collection instrument A.
- 6. Sequence of bath** This is the same as data collection instrument A.
- 7. Interruptions.** This is the same as that for form A.
- 4. Perform CHG bath**
 - 4.a Cleans entire neck area including skin folds** Except the face, all areas below the jawline can be cleaned with CHG wipes. The observer should note whether the entire neck is cleaned including hard to clean areas like skin folds.
 - 4.b Clean around lines.**
 - 4.c Massage skin firmly with CHG cloth to ensure adequate cleansing** The health care worker applies a gentle pressure to ensure good CHG skin contact. The observer should observe if this is done.

4.d Clean armpit

4.e Clean back of knee

4.f Clean between toes

4.g Clean between fingers

4.h Clean between all folds in perineal area

4.i Clean between all folds in gluteal area

All these (4.d through 4.i) are difficult to reach areas and some are commonly soiled.

4.j Wipe occlusive dressing with CHG cloth This is when a wound is covered with nonporous or substances with low moisture vapor transmission. CHG can be used over these dressings.

4.k Wipe semi-permeable dressing with CHG cloth These are dressings which are moisture or vapor permeable. CHG can be used over semi-occlusive dressings.

4.l Clean tubing, lines and drains closest to body (after emptying drains). CHG is safe on devices. Cleaning should be within at least 6 inches of the patient.

4.m Use CHG on superficial wounds These are wounds which only involve the superficial layer of the skin (epidermis). CHG is safe for superficial wounds

4.n Use CHG on skin rashes CHG is safe to use on skin rashes

4.o Use CHG on stage 1 & 2 decubitus ulcers These are superficial bedsores. These are contrasted with stage 3 and 4, which involve full thickness skin or tissue loss. CHG is safe for stage 1 & 2 decubitus ulcers or bedsores with or without dressings.

4.p Use CHG on closed surgical wounds Closed surgical wounds are ones where the skin has been closed using a surgical procedure. CHG is safe for closed surgical wounds, but not on open large or deep wounds.

4.q Allow to air dry/do not wipe off CHG CHG should not be rinsed off, the patient should be allowed to dry naturally.

4.r Complete bathing with no skin below jaw line missed If any parts are missed, the observer should note this in the observer notes.

5. CHG bathing documented: Bathing should be documented in the patient's EHR. The observer should circle **Y**, if documentation is done. If it is not done we cannot ascertain if the HCW decided to wait and complete documentation at a later time. Therefore, if the observer does not see documentation of the CHG bath being done, then they should circle **Not Obs** for not observed.

Appendix E1 – Formal Code of Conduct for Observers in Healthcare Settings
University of Wisconsin-Madison, Center for Quality and Productivity Improvement

Purpose: Observers should be aware of the unique nature of healthcare environments. It is important to establish a set of standards for observers in order to protect the privacy of the patients, their families and other study participants. The research team realizes their presence could potentially be distracting to the normal workflow. Abiding by a code of conduct increases the likelihood of a positive experience for all and a continued collaborative spirit between researchers and clinicians.

1. All observers entering clinical areas of healthcare organizations must document their vaccination status. Observers should make an appointment with University Health Services or their personal health care provider to have a vaccination form completed. Blank forms can be obtained from the project manager.
2. All observers must complete both the online UW HIPAA and IRB Human Subjects Training modules. A copy of completion certificates should be given to the project manager.
3. All information collected during the observation is confidential as per the IRB protocol specifications and the HIPAA and IRB training modules. Although patient- or staff-identifiable data are generally not collected, observers may be exposed to identifiable data and sensitive conversations. All elements of the observation are to be kept confidential.
 - a. Do not record patient names or birthdates. A general description of the patient is acceptable, e.g. gender, approximate age (recorded as a range; e.g., 45-50 year-old), style of dress.
4. If the observer knows a patient personally, the observer will temporarily discontinue the observation and leave the room while discussion regarding or with that patient occurs.
5. All observers must obtain and wear an ID badge at all times, per the healthcare organization's requirements. Information about this can be obtained from the project manager.
6. Most observation sessions should be pre-scheduled through informational activities described in the IRB protocol. Always introduce yourself and re-explain what you will be doing, giving the participant a copy of the Information Sheet, as per the IRB protocol.
 - a. Explain that you will never interrupt patient care.
 - b. Explain that you will speak to the clinicians only when it is clear that you are not interrupting the workflow.
 - c. Remind the clinicians to let you know if you are asking questions at an inopportune time so you can refrain from interrupting.
 - d. Let the clinician know that you will stay as physically-out-of-the-way as possible but still enable yourself to collect necessary data.
 - e. Let the clinician know they can cancel or postpone the observation if they feel uncomfortable or that it impedes patient care.
 - f. It is OK to show the clinician the notes that you are taking. Sometimes this helps to relieve any concerns associated with being observed.
7. At no time are you allowed to participate in the care of the patient while observing. Although a clinician may ask you to hold something or participate as a way of being nice or engaging, you must politely refuse their request. If there is a patient or staff emergency, you are not obliged to help and should use your judgment. If you touch anything, promptly wash your hands. If you are exposed to blood or body fluids at any time, stop the observation and thoroughly wash the exposed area. Consult the study PI immediately and let the clinician that you are following know that you were exposed and what you were exposed to. There may be additional precautions that need to be taken.
8. Observers may witness patients and healthcare professionals sharing personal/sensitive information or performing personal/sensitive physical exams and procedures. Patients may be in various stages of undress, which may fluster him/her or the observer. Following are some general guidelines:
 - a. Avoid direct eye contact with the patient or the healthcare professionals that you are observing. Watch your body language. Avoid shaking your head, making faces or reacting visibly to anything said by the clinician or patient.

- b. Be aware that taking notes during sensitive times may cause the patient or healthcare professional to worry about what you are recording. It is OK to periodically stop taking notes and later record what was observed during sensitive times.
 - c. Many clinic exam rooms have curtains that may be pulled to shield the exam table in the room from the doorway. Consider stepping into the doorway behind the curtain when the patient is undressing, has sensitive body parts exposed or the clinician is performing a sensitive part of a physical exam, e.g. a female pelvic exam, breast or exposed abdominal exam, or male genital or rectal exam. Alternatively, you may turn your back or turn your body away during this time. Patients appreciate observers proactively taking this action.
 - d. The clinician and/or patient may ask you to step out of the room or away from the observation during this time and call you back when they are finished. Always respect their requests.
9. Observers may encounter situations that are disturbing to them or make them feel uncomfortable or ill. It is acceptable to end the observation or step away momentarily if this occurs. For example, you may see blood or needles or hear disturbing noises from equipment or patients in pain or distress. Even if these have not bothered you in the past, there may be circumstances in which they bother you. Here are some tips to avoid feeling ill:
 - a. Eat and drink before the observation to ensure that you are well hydrated. This will protect against a dramatic vagal response (feeling faint, nauseated, queasy, and/or jittery).
 - b. Do not overdress for observations. Feeling warm can exaggerate any sick response.
 - c. If you begin to feel sick, immediately remove yourself from the situation. If you are dizzy and feel like you may pass out, sit down, on the floor if needed, or lean against something. Use your notepad to fan yourself; get something cold to drink.
 - d. Do not restart the observation until you feel “normal”.
10. You may encounter patients that are in isolation. This means that they have a condition that could be harmful to others if transferred or that they are vulnerable to illness due to a compromised immune system. Isolation precautions must be followed for any study that necessitates the observer to follow clinicians into the room of a patient in isolation. You will be trained on the procedures to follow for isolation if the study requires this. At no time should you enter the room of a patient who is in respiratory isolation requiring an N95 mask.
11. If you are pregnant or have another health condition that may be affected by observing in the healthcare setting, please talk to your study PI about the potential for exposure to conditions that may affect your health or pregnancy and precautions one should take to avoid this.
12. Observers must follow the attached dress code for researchers.
13. If observers are concerned about anything they observe in the clinical setting (such as threats to patient safety or unethical behavior), the concern should be shared with the PI as soon as possible after the end of the observation. The PI will provide guidance.

Dress Code

1. Appropriate Dress
 - Suits
 - Dress pants or casual dress pants (i.e., Dockers, chinos, khakis, etc.)
 - Skirts and dress culottes
 - Casual dresses
 - Dress shirts/blouses and collared sports shirts
 - Sweaters/vests
 - Sport coats/blazers
2. Inappropriate Dress
 - Caps, head coverings (Exception: Head coverings may only be worn when associated with professional or religious affiliation or as they relate to state/or federal legislation.)
 - Shorts, mini-skirts
 - Leggings, stretch pants
 - Blouses, shirts and sweaters which do not cover the shoulders, back or stomach
 - Flannel shirts, t-shirts
 - Exercise clothes (sweatshirts, sweatpants, jogging suits, etc.)
 - Sheer, spandex, low cut/slung garments
 - Clothing which is torn, faded, stained, frayed or gives an unkempt appearance
 - Bib overalls
 - Any jean or jean-styled pant
3. Clothing should be clean, neat, in good condition and fit properly.
4. Shoes should be clean and in good repair. When in clinical care areas, closed-toe shoes must be worn at all times. Shoes should include noise resistant soles and heels.
5. Hosiery and socks must be worn at all times in clinical care areas.
6. Appearance
 - a. Hair should be clean, combed and professional in appearance.
 - b. Make-up and specific jewelry may be worn, only sparingly.
 - c. Colognes/perfumes may NOT be used.
 - d. Other than pierced ears, jewelry worn in pierced body parts should not be visible or detectable.
 - e. Tattoos with slogans, graphics, sayings or offensive wording should be covered (e.g., long sleeve shirt, gloves, etc.).

Appendix E2-Script for Observers in Patient Rooms

Purpose: Observers should explicitly tell participants (generally clinicians or other care providers) they will be followed into the patient (exam) room to observe activities. Observers should provide the patient a handout that explains to the patient and/or their family members what is being observed and collected. The participant and/or observer should tell the patient and/or family they may decline to have the observer enter the room and may ask the observer to leave at any time.

Script:

Observer: “We want to accurately record your activities and therefore will be following you into patient (exam) rooms. Please provide a handout to the patient that explains this project and please tell him/her (and family members if they are present) about this project and ask their permission for me to enter the room for the observation. Tell them that, although the observations will not be directed towards them, they can refuse at any time to have the observer in the room.”

Attestation for formal code of conduct:

I have read, understand and will follow the above code of conduct requirements for this project. I understand that my obligation to maintain the confidentiality and security of all confidential information continues after this project ends, and after my appointment or employment with the University of Wisconsin-Madison.

Signed: _____ Date: _____

Print name: _____