A Targeted Infection Prevention Intervention in Nursing Home Residents with Indwelling Devices: A Randomized Clinical Trial

1. Protocol

1. List of Abbreviations

CIP-R  ciprofloxacin-resistant
CTZ-R  ceftazidime-resistant
GNB  Gram-negative bacilli
HCW  healthcare worker
HH  hand hygiene
MDRO  multidrug-resistant organisms
MRSA  methicillin-resistant Staphylococcus aureus
MSSA  methicillin-sensitive Staphylococcus aureus
NH  nursing home
R-GNB  resistant Gram-negative bacilli
SSTI  Skin and soft tissue infection
PNU  Pneumonia
VRE  vancomycin-resistant enterococci

2. Study Aims

a. **Primary Aim:** Determine the efficacy of a multi-modal Targeted Infection Prevention (TIP) intervention in reducing prevalent colonization with MDROs in NH residents with indwelling devices (urinary catheters and/or feeding tubes).

b. **Secondary Aim:** Evaluate the efficacy of the TIP intervention in reducing new incident device-related MDRO infections in NH residents with indwelling devices (urinary catheters and/or feeding tubes).
3. **Study Methods**

a. **Overall Study Design and Plan**

The conceptual model for the Targeted Infection Prevention (TIP) intervention is shown in Figure 1 of this protocol (below). The study aims will be accomplished using a cluster randomized trial involving 12 NHs; 6 randomized to the TIP (intervention cohort) group and 6 to the standard care (control cohort) group. The TIP intervention incorporates the following components:

**Component 1**: Structured, active surveillance for infections in residents with indwelling devices will use clinical definitions and dissemination of results to clinical staff and administration.

**Component 2**: Institute preemptive barrier precautions for all residents with indwelling devices; active screening for MDROs (monthly) using cultures collected from multiple body sites to identify asymptomatic MDRO carriage in these residents; and dissemination of results to clinical staff and administration.

**Component 3**: A hand hygiene promotion program for HCWs that includes the use of educational posters and videos, ensuring the availability of personal-size hand hygiene products, as well as leadership involvement in the hand hygiene promotion activities to HCWs.

**Component 4**: A structured educational program pertaining to indwelling device care for HCWs in TIP intervention facilities. In this program, we will first review updated infection control guidelines for NHs and then focus on specific topics including urinary catheter and feeding tube care, MDROs including MRSA, VRE and R-GNB, and recognition of infections in NHs.

Control NHs will continue standard care practices and infection monitoring as per their existing policies.
b. Selection of study sites and subjects

i. Study sites: Twelve community-based NHs in SE Michigan

ii. Subjects

1. Inclusion criteria include:

   a) Any short- or long-stay resident with an indwelling urinary catheter or feeding tube for more than 72 hours.

   b) Ability to get informed consent from either the resident or his/her durable power of attorney.

2. Exclusion criteria include:
a) Having an indwelling device for less than 72 hours.
b) Refusal of consent to get surveillance cultures and data collection by the resident or his/her durable power of attorney.
c) Residents who are receiving end-of-life care.

3. **Enrollment**

Informational flyers on the study will be included in the admission pack for new residents. Eligible residents at the participating facilities will be approached by a trained study coordinator. A comprehensive informed consent will be obtained from the resident or from the resident’s durable power of attorney of next of kin if unable to consent for themselves.

When the residents are screened for the study, their age, gender, and date of enrollment will be recorded in a screening log; if a resident does not enter the study, the reason for non-enrollment will be recorded.

**iii. Randomization**

Randomization was computer generated and stratified based on NH ownership status (for profit vs. not-for-profit).

**iv. Blinding**

Due to the behavioral and educational-based interventions used in the TIP, blinding of assignment to either the interventional or control group will not be possible. The investigators will be aware of the assignment for each NH, in order to carry out and monitor implementation of each intervention component. The microbiology laboratory personnel will be blinded as to facility assignment, minimizing bias of the primary outcome—assessment of MDRO colonization.

c. **Implementation**

**Component 1: Surveillance for infections**
Resident medical record review by the study coordinator will be used to identify infections. Standardized data collection forms will be used to assess new infections, using clinical infection criteria. A clinically defined infection will be noted by presence of both: a) clinical note in the medical record documenting an infection and b) a prescription of a systemic antibiotic for three or more days to treat that infection.

All study facilities have access to laboratory as well as radiology services to conduct urine analysis, blood cultures, and x-rays as ordered by the residents’ primary physicians. Study coordinators will review these data when available but will not be involved in any medical management. Data on the number of infections will be ascertained in enrolled residents with indwelling devices at all intervention and control facilities using several sources of information for outcome evaluation. A formal monthly report and dissemination of the surveillance results to infection control practitioners, the facility’s medical director, the practicing physicians, and the HCWs will occur only in the TIP intervention facilities; no feedback will be given to control facilities. Our study coordinator with specific training in infection control and hospital epidemiology will present data with charts, graphs, and tables highlighting the numbers of clinically-defined infections per month at each facility. Surveillance feedback will be in formats easily understood by HCWs with limited backgrounds in statistics.

Upon enrollment in the study, the nurse, nurse aide, physician of record, infection preventionist, and the director of nursing will be provided a letter to notify them that the resident has been enrolled in the study. They will also be given a pocket guide with NH appropriate infection definitions. The cards focus on infection recognition using NH-appropriate definitions including the minimum criteria to initiate antibiotics for specific infections,\(^1\) including clinically-defined catheter-associated urinary tract infections (CAUTIs) and McGeer’s criteria for surveillance of infections.\(^2\) Infection Preventionists at the intervention NHs will also be invited to a half-day conference on surveillance methods for infections.
Component 2: Institute preemptive barrier precautions for all NH residents with indwelling devices and actively screen for MDROs

All enrolled residents with an indwelling device will be placed on preemptive barrier precautions including:

a. Placement of barrier precautions sign on the door of residents with an indwelling device.

b. Hand hygiene before and after providing any care.

c. Gloves to be worn at all times when HCWs provide AM and PM care, device care, or whenever contact with body fluids may occur. Hand hygiene performed before and after wearing gloves.

d. Protective gowns to be worn as part of barrier precautions when providing AM and PM care, device care, or whenever splashing may occur.

e. When residents leave their rooms for any activities, their wounds and other areas of drainage will be covered.

Residents will not be isolated to their rooms. Residents will be allowed to socialize and get their rehabilitation. All care providers will be asked to practice preemptive barrier precautions before and after providing care.

Intervention NHs will be provided with gowns for use with enrolled residents. NHs will also be provided with personal protective equipment caddies to place on the doors of enrolled residents’ rooms, to provide gowns and gloves at the point of care.

Trained research assistants will collect samples from both study groups to assess colonization with antimicrobial-resistant organisms. These samples will be obtained at baseline, day 15, and then monthly from the nares, oropharynx, indwelling device sites, groin, and anal area using Culturette® swabs. The presence of MDROs will only be reported back to the intervention facilities by the study coordinator on a monthly basis. Graphs, charts, and tables easily understood by HCWs will be used to present data. We will discuss our results with the infection preventionist, and encourage
them to share the results with their administrators at monthly meetings, as well as with other clinical providers, such as physicians, nurse-practitioners, and physical and occupational therapists.

**Component 3: A hand hygiene promotion program**

We will conduct an active hand hygiene campaign using CDC-approved educational posters promoting universal gloving, enhancing nail health, and promoting use of alcohol-based hand rub or antimicrobial soap and water for hand hygiene. Leadership of each TIP NH will be actively involved in promoting hand hygiene by endorsing educational posters and videos. HCWs will be in-serviced on indications and appropriate use of alcohol-based hand rub, as well as antimicrobial soap and water. They will also be asked to use antimicrobial soap and water for hand hygiene when taking care of any patient with suspected or confirmed *Clostridium difficile*.

Intervention NHs will be provided with personal-sized bottles of alcohol-based hand rub, so that each HCW will have access to hand hygiene products at the point of care. Interactive methods of hand hygiene promotion included Glo Germ™ technique demonstrations, along with pre and post hand cultures and environmental sampling to illustrate organism transference.

Structured 30-minute observations will be conducted to monitor compliance of HCW hand hygiene for all enrolled residents.

**Component 4: A structured educational program**

The education program will be designed to increase knowledge and improve infection control behavior in the HCWs at the intervention facilities. Course materials will be tailored to all HCWs working in the NHs. The program will be executed over 36 months.

Ten educational modules chosen for HCW in-services have been selected based on their relevancy to infection control and prevention in NHs (Table 1). The content of these educational sessions and knowledge tests was developed by experts in the field at different levels of practice.
(physicians, nurses, infection control practitioners, and epidemiologists). Based on the content, test questions will be created and reviewed for format, consistency, and clarity. These in-services will be provided every 3-4 months and offered multiple times to include HCWs on all shifts. The educational sessions are targeted to nurses and nurse aides, although all NH staff will be encouraged to attend. The in-services will be approximately 40 minutes long and structured as follows: 5 minutes for pre-test to assess “baseline” knowledge, followed by a 20-minute DVD presentation with discussion of questions, 10 minutes for interactive skits and games, and ending with a 5-minute post-test. Copies of the DVD presentation will be given to the intervention sites for their perusal.

Interactive skits and games will be developed to complement each topic, and to reinforce important concepts and practical applications of the educational material, including infection prevention themed “Jeopardy” and “Wheel of Fortune” type games and proper device care demonstrations using skits and posters.

The control sites will receive no video or presentation and receive only one copy of the test for the HCWs to complete.

**Table 1: The Educational Intervention Topics by Module**

<table>
<thead>
<tr>
<th>Module</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>TIP Program: Introduction to Study</td>
</tr>
<tr>
<td>2</td>
<td>Chain of Transmission of Infection</td>
</tr>
<tr>
<td>3</td>
<td>Infection Prevention Programs</td>
</tr>
<tr>
<td>4</td>
<td>Infection Control Practices: Hand Hygiene</td>
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<tr>
<td>5</td>
<td>Infection Control Practices: Standard and Transmission-based Precautions</td>
</tr>
<tr>
<td>6</td>
<td>Infection Control Practices: Indwelling Urinary Catheter Care</td>
</tr>
<tr>
<td>7</td>
<td>Infection Control Practices: Medical Asepsis and Enteral Nutrition Care</td>
</tr>
<tr>
<td>8</td>
<td>Facility-level Surveillance Practices</td>
</tr>
</tbody>
</table>
4. Analysis Populations

Thirteen NHs were screened for inclusion in the study. One NH declined to participate before randomization occurred. Twelve NHs were randomized to intervention or control assignments and will remain in the study for three years.

5. Derived and Computed Variables

a. Swab collection and microbiology

Samples to assess colonization with MDROs will be obtained at baseline, on day 15, and then monthly from the nares, oropharynx, groin, rectum, feeding tube site, suprapubic urinary catheter site, and wounds if present, for both intervention and control groups using BD Culturette® swabs.

i. Identification of \textit{S. aureus} and MRSA

Swabs will be inoculated onto mannitol salt agar and incubated at 35°C for 48 hours. All bright yellow colonies suggestive of \textit{S. aureus} will be picked and inoculated onto trypticase soy agar with 5% sheep blood and incubated at 35°C for 24 hours. Catalase and coagulase tests, as well as a Gram stain will be used to positively identify \textit{S. aureus}. A standard number of \textit{S. aureus} will be inoculated on Mueller-Hinton agar containing 6 µg/mL of oxacillin and 4% NaCl. Following overnight incubation, the appearance of growth will indicate that the \textit{S. aureus} isolate is resistant to oxacillin (i.e., MRSA). No growth on the plate will indicate that the \textit{S. aureus} isolate is MSSA.

ii. Identification of VRE

Swabs will be inoculated onto bile esculin agar to detect enterococci. A standard number of enterococci will be inoculated onto bile esculin agar containing 6 µg/mL of vancomycin.
Following incubation, the appearance of characteristic growth will indicate that the enterococcal isolate is vancomycin-resistant (i.e., VRE).

iii. Identification of Gram-negative bacteria and resistance to ciprofloxacin and ceftazidime

Swabs will be inoculated onto MacConkey agar containing 1 µg/mL ciprofloxacin or 10 µg/mL ceftazidime and incubated at 35°C for 24 hrs. All GNB will be identified to the species level using API® 20E strips.

iv. Outcome

Our primary outcome is MDRO prevalence as defined by the total number of MDRO-positive anatomic sites across all MDROS per visit from each resident averaged over the duration of their participation. The total number of MDROS includes all isolates of MRSA, VRE, and R-GNB from all body sites cultured at each follow-up visit.

b. Infections

i. Definitions

Clinically-defined infections will be used to assess our secondary outcome. A clinically defined infection will be noted by a) clinical note in the medical record documenting an infection and b) a prescription of a systemic antibiotic for three or more days to treat that infection.

ii. Outcomes

The incidence rates of catheter-associated urinary tract infection (CA-UTI), feeding tube-associated skin and soft tissue infection (FT-SSTI), and feeding tube-associated pneumonia (FT-PNU) will be calculated as the incidence of device-associated infections per 1000 device-days.

c. Follow-up time
The follow-up time for each resident enrolled will be calculated as the time from initial enrollment visit (day 0) until the last follow-up visit completed. Residents will have a study visit at baseline, after 15 days, and then monthly thereafter for up to one year, removal of the indwelling device, or discharge from the facility or death.

d. Preemptive barrier precautions and hand hygiene compliance

Study coordinators will monitor for HCW compliance with preemptive barrier precautions (gown and glove use) and hand hygiene during interactions with enrolled residents during monthly 30-minute observation periods. A standardized tool will be used to collect compliance data.

i. Glove compliance

For the TIP intervention facilities, glove use will be encouraged for HCW-resident interactions for any AM and PM care, and device care in addition to indications per standard and transmission-based precautions (if the resident is placed in precautions per facility policy). For the control facilities, glove use will be assessed per standard precautions and transmission-based precautions (if the resident has been placed under precautions per facility policy). Glove compliance will be calculated as follows:

\[
\text{Glove compliance} = \frac{\# \text{ HCW-resident interactions compliant with glove use}}{\# \text{ HCW-resident interactions observed}} \times 100
\]

ii. Gown compliance

For the TIP intervention facilities, gown use will be encouraged for HCW-resident interactions for any AM and PM care, and device care in addition to indications per standard and transmission-based precautions (if the resident is placed in precautions per facility policy). For the control facilities, gown use will be assessed per standard precautions and transmission-based precautions (if the resident has been placed under precautions per facility policy). Gown compliance will be calculated as follows:

\[
\text{Gown compliance} = \frac{\# \text{ HCW-resident interactions compliant with gown use}}{\# \text{ HCW-resident interactions observed}} \times 100
\]
### Hand hygiene compliance

HCW compliance for hand hygiene (HH) will be assessed at the following times: a) before resident contact, b) after resident contact, and c) after contact with the resident’s environment.

HH compliance will be calculated as follows:

\[
\text{Overall HH Compliance} = \frac{\text{# HCW observations with HH compliance}}{\text{# HCW-resident/environment interactions observed}} \times 100
\]

\[
\text{Before contact HH compliance} = \frac{\text{# HCW observations with HH compliance}}{\text{# HCW-resident interactions observed}} \times 100
\]

\[
\text{After contact HH compliance} = \frac{\text{# HCW observations with HH compliance}}{\text{# HCW-resident/environment interactions observed}} \times 100
\]

e. Educational sessions

Ten educational modules will be provided to each intervention facility to enhance HCW knowledge pertaining to infection control and prevention in NHs. Pre- and post-tests will be administered to assess baseline and post-educational intervention levels of HCW knowledge for each session’s topic (Table 1).

Control sites will receive no education. However, they will receive a test for the HCWs to complete to assess their baseline knowledge of each educational topic, similar to intervention sites.

Individual questions will be coded as either right, “1,” or wrong, “0.” HCWs who do not answer or who missed questions will be coded as wrong for that question. Scores will be calculated by summing the coded answers and dividing by the total number of questions, resulting in a percent correct score. Intervention post-test scores and control test scores will be compared using a two-tailed \( t \)-test.
f. Nursing home characteristics

The NH characteristics we will examine include number of beds, presence of subacute care, and number of admissions. Ownership status and NH quality ratings will be obtained from the CMS ‘Nursing Home Compare Website’ prior to randomization of facilities.

g. Resident characteristics

The resident characteristics that will be collected at baseline include: age, gender, race and ethnicity, functional status, comorbidities, indwelling urinary catheter presence (urethral vs. suprapubic), feeding tube presence (nasogastric vs. percutaneous gastrostomy), presence of pressure ulcers, history of colonization or infection with an MDRO (any of MRSA, VRE, R-GNB), length of stay at the NH facility, prior hospitalization and antimicrobial use.

6. Sample Size

The primary outcome for this project is the difference in prevalent colonization with MDROs between the intervention and control groups. The secondary outcome is the difference in incident infections between the intervention and control groups. Our study sample includes community NHs with an average of 120 beds and an average of 10 new admissions/month or 120 new admissions/year. The enrollment period is 36 months or three years. Based on our preliminary data, we estimate that each NH will have an average of 22 of all new and old NH residents/year with an indwelling device (average of 14 with indwelling catheters on admission and 8 with pre-existing or new feeding tubes at a 120-bed facility). Based on prior data in acute care, we expect to have a 30% reduction in MDRO prevalence as a result of our intervention. The expected incident and prevalent rates of MDROs in the intervention group are 42 MDROs/1,000 device days. The expected rate of MDROs in the control NHs is 60 MDROs/1,000 device days. The desired power of the study is 80% and the desired significance level is 0.05. Since our study is a prospective cohort study of patients in clusters at each NH, we will need to adjust for intracluster correlation. We assume intraclass correlation coefficient to be at 0.07 (varies between 0.03-0.1 in NH studies). We expect to follow each device resident for an average of two months. Using these assumptions, we used the formula below for our power calculation.
\[
c = 1 + (z_1 + z_2)^2 \left( \frac{(r_1 + r_2)/y + k^2 (r_1^2 + r_2^2)}{(r_1 - r_2)^2} \right)
\]

Where:
- \( c \) = cluster size
- \( r_1 \) = prevalence density rate, intervention sites
- \( r_2 \) = prevalence density rate, control sites
- \( z_1 \) = the desired significance level, 0.05 with the corresponding value of \( z_1 \) to be 1.96
- \( z_2 \) = desired power of the study, 80% with the corresponding value of 0.84
- \( y \) = follow-up time, about 2 months/each device resident = 792 device months
- \( k \) = ICC, intracluster correlation, 0.07 based on prior studies

The 12 NHs are sufficient to reach 80% power to reject the null hypothesis of no difference in overall MDRO prevalence rate between the intervention and control NHs.

7. References


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Summary of Protocol Changes

The majority of our protocol changes relate to modifications in our implementation tools.

1. Implementation

   a. For Component 1: Communication at Enrollment

      Upon enrollment in the study, the resident’s nurse, nurse aid, physician, infection preventionist, and the director of nursing will be provided with a letter to notify them that the resident had been enrolled in the study. They will also be provided with a pocket guide with standard infection definition criteria. This will done to: 1) increase communication between the study coordinators and NH staff on which residents will be enrolled in the study and 2) raise awareness of the standard infection criteria for initiation of antibiotics.

   b. For Component 2: Provide gown and personal protective equipment caddies

      Intervention NHs will be provided with gowns to use for direct care of enrolled residents with indwelling devices. NHs will also be provided personal protective equipment caddies to place on the doors of enrolled residents’ rooms, to provide gowns and gloves at the point of care. We found that many of the participating NH facilities do not routinely stock gowns, and/or they are not conveniently available at the point of care. Therefore, the study will provide these materials to the intervention NHs to increase compliance with preemptive barrier precautions for direct care of enrolled residents.

   c. Component 4: Changes to educational curriculum
The list of topics for the educational intervention has been modified based on education needs of the frontline HCW at the participating NHs, in keeping with the overall goals of the TIP intervention. Several sessions of basic infection prevention concepts will be presented to augment the existing infection control programs at the intervention facilities. The educational in-services will be provided to each intervention facility every 3-4 months, rather than the bi-monthly as originally proposed. This will be done to accommodate scheduling of the in-services. In addition, interactive skits and games have been developed to complement each topic, and to reinforce important concepts and practical applications of the session material, including infection prevention themed “Jeopardy” and “Wheel of Fortune” type games and proper device care demonstrations using skits and posters. Copies of educational materials and DVDs will be left with the facility’s infection preventionist for their perusal such as during new employee orientation, in response to state inspections or during outbreaks.

2. Outcome Measurements

a. MDRO colonization

Our primary outcome will be MDRO prevalence as defined by the total number of MDROs isolated from each resident per 1,000 device days, instead of per 1,000 device-months as originally proposed.

b. Infections

Incidence of infection as defined by the total number of all infections and new infections each resident per 1,000 device days, instead of per 1,000 device months as originally proposed. We define time-at-risk as catheter-days for patients with urinary catheters and as feeding-tube days for patients with feeding tubes.
2. Statistical Analysis Plan

In the initial data analysis, univariate and bivariate relationships will be studied. For each numeric outcome, measures of central tendency (means, medians) and variability (standard deviations, ranges) will be estimated. We will use Poisson distribution to describe colonization rates using prevalence and infection rate measures using Cox regression. The time at risk will be measured in device-days. The initial data analysis will provide us with an insight into the data, including the distributions of the variables. The data analysis will also help us to determine the most appropriate model for assessing outcomes.

There are two main approaches to the analyses of cluster randomized trials: analysis at the cluster level and analysis at the patient level. Traditionally, analysis has been focused at the cluster level (i.e., to calculate a summary measure for each cluster, such as the cluster mean or proportion). These analyses can adjust for cluster-level and patient-level covariates using a two-stage process. Since cluster-level analysis is not the most efficient method, we will use regression analyses based on individual-level data. Analysis at the patient level accounts for the intraclass correlation and thus increases the statistical power of the analyses. When utilizing patient-level data, adjustments will be made to allow for the clustering effect.

The main data analysis is designed to assess the difference in prevalence rates of all multidrug-resistant organisms (MDROs) between the Targeted Infection Prevention (TIP) intervention and control nursing homes (NHs), with NH being the unit of analysis. [Primary Outcome] MDRO rates will be compared between the two groups using the following Poisson regression model.
The Poisson model will allow us to account for interactions, adjust for various confounders, and model a linear effect. A mixed-effect multi-level Poisson regression model will be used to predict the geometric mean number of MDROs per resident/1,000 device-days as a function of the intervention, including facility as a random effect and offset by the number of anatomic sites cultured at each visit. To obtain the geometric mean, the mean number of MDROs per resident/1,000 device-days will be log transformed, and then exponentiated back to the original units. The model will be adjusted for cluster study design using random intercept, patient-specific covariates (resident-level baseline colonization with the specific MDRO, age, gender, race, functional status, length of NH stay prior to enrollment), and two NH covariates (number of beds and NH quality ratings, based on health inspections, staffing ratios, and NH quality indicators). Using Cox Proportional Hazard model, we will also conduct exploratory analyses to analyze the impact of our intervention in reducing new acquisition of MDROs.

The incident rates of infections [Secondary Outcomes] will also be compared using a Cox proportional hazard model to predict time to the first and recurrent infections, adjusting for resident-level and facility-level covariates. For the recurrent-infection, we will use the counting process approach that was proposed by Anderson and Gill.\(^2\) Analyses to evaluate the differences in recurrent infection rates will use individual residents as the unit of analysis.

In addition to the presence of an indwelling device, resident-specific covariates of interest will be age, gender, length of NH stay, presence of a pressure ulcer, functional status, co-morbidities, prior hospitalization, and antimicrobial usage. The NH covariates that will be considered include star ratings and number of beds. The variables that show a \(p\)-value of less than .1 on univariate analysis will be entered into the multivariate model.

b. References

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Summary of Statistical Analysis Plan Changes

While our original statistical plan was similar to the final plan, we made some refinements as described below:

Analyses for Primary outcome: MDRO colonization

MDRO prevalence was defined by the total number of MDROs isolated from each resident per 1,000 device days, instead of per 1,000 device months as originally proposed.

Resident-specific geometric means of MDRO colonization will be used. To obtain the geometric mean, the mean number of MDRO for each resident/1,000 device-days will be log transformed, then exponentiated back to the original units for use in the Poisson model.

Analyses for Secondary outcome: Device-related infections

Incidence of infection was defined as the total number of new infections in each resident per 1,000 device days, instead of per 1,000 device months as originally proposed.

The incident rates of infections were compared using a Cox proportional hazard model to predict time to the first and recurrent infections, adjusting for resident-level and facility-level covariates. For the recurrent-infection, we used the counting process approach that was proposed by Anderson and Gill (1982).

For catheter-associated urinary tract infections (CAUTI), two models were used to assess the time to: 1) first CAUTI and 2) all CAUTI, including first and recurrent infections.