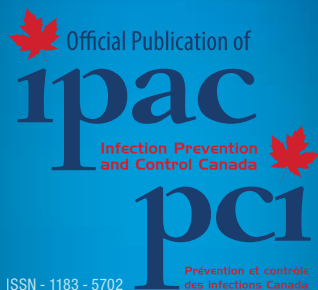


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Exploring the patient experience with recurrent *Clostridium difficile* infection in Ontario, Canada

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ABSTRACT

Background: *Clostridium difficile* (*C. difficile*) infection is a leading cause of hospital-acquired diarrhea, and many sufferers experience infection recurrence after treatment. Several aspects of the burden of *C. difficile* infection have been recognized, including a substantial morbidity and mortality and extensive healthcare costs. However, personal difficulties in the patient experience with recurrent *C. difficile* infection in Canada have not been thoroughly explored.

Methods: A mixed methods approach, involving the qualitative and quantitative analyses of a written survey that was distributed to 9 outpatients with recurrent *Clostridium difficile* infection in Ontario, Canada, was used to investigate themes related to patient-perceived quality of care.

Results: Important themes in the patient experience included knowledge and understanding of *C. difficile* infection, access to adequate care in times of need, and emotional and physical hardships in the lived experience with recurrent *C. difficile* infection. Each of these themes could be broken down into a number of subthemes. Within the knowledge and understanding theme, a prominent subtheme was confusion and uncertainty about symptoms. Regarding access to care, subthemes included timely care and access to novel treatments such as fecal transplantation.

Conclusions: These themes highlight patient attitudes and circumstances that are associated with difficulty and dissatisfaction with care. Supportive patient resources and clinical care strategies should include improved education about recurrent *C. difficile* infection and how to live with it, easy access to care when symptoms return, and counseling on management strategies for living with recurrent *C. difficile* infection.

KEY WORDS

Clostridium difficile, patient experience, hospital-acquired infection, patient satisfaction, quality of care

INTRODUCTION

C. difficile is an enteric bacterial pathogen that is spread via the fecal-oral route, causing a wide spectrum of disease, from mild diarrhea and cramping to fulminant colitis. One of the main morbidities of *C. difficile* infection (CDI) is recurrence of disease, which affects roughly 20 percent of patients and results in more complex, longer-term management (1, 2). Advanced age is a significant risk factor for recurrent CDI (3, 4). While antibiotics such as metronidazole, oral vancomycin, fidaxomicin and emerging treatments like fecal transplantation are available for treatment of acute infection, patients with recurrent disease are often stuck in a cycle of repeated episodes of disease once treatment is stopped (5-7). The burden of CDI on individuals as well as the Ontario population is well recognized, earning it a rank of nine in the top 20 diseases in the Ontario Burden of Infectious Diseases Study (8). Furthermore, a study of 19 hospitals across Canada showed that the healthcare-associated costs from hospital

readmissions alone due to CDI are approximately \$120,200 per facility per year (9).

Public awareness and fear of CDI is becoming more prominent due to its increasing prevalence and media coverage of outbreaks (10, 11). Though studies have shown that many patients would feel angry or afraid if they were to contract a CDI (12), no empiric research has been carried out to explore the patient experience with CDI in Canada. Through care of a large volume of CDI outpatients in Ontario, we have observed a number of challenges faced by individuals with recurrent CDI. Access to treatments and financial coverage for medications continue to be a struggle for many patients. Patients with recurrent CDI have encountered inadequate access to care, resulting in emergency room visits, a lack of information and educational resources, and limited follow-up. Many of these challenges are associated with a fragmented and unspecialized course of care that patients receive.

Acknowledgement: Thank you to all patients who agreed to participate in this study.

Conflicts of interest: The authors have no conflicts of interest to declare.

More robust support of this population requires a better understanding of patient challenges and concerns through exploration of personal difficulties and patient perception of care. This qualitative study of the patient experience with recurrent CDI highlights aspects of the patient experience that have a negative impact on quality of care, in order to guide the development of resources and support for patients.

METHODS

A survey was developed by the authors. The survey included both close-ended and open-ended short answer questions intended to reflect various determinants of health: health literacy, personal practices and coping skills. Respondents were asked to rate their overall satisfaction with care for CDI. Additionally, the survey included a series of written open-ended questions, which allowed patients to expand on their illness experience. Paper copies of the survey were distributed to participants, and the surveys were self-administered, completed on average within 10 minutes. The survey was distributed by a study investigator (first author) who was not a member of the clinic staff. The second and senior authors were regular clinic staff.

A convenience sample of patients with a history of recurrent CDI who visited one infectious disease clinic in Toronto, Canada was targeted for the survey. This clinic serviced patients from across Ontario with recurrent CDI. All patients who attended the clinic for a CDI between February and May 2015 were asked to participate voluntarily. Prior to completing the survey each participant was given an information document describing the study, and informed consent was obtained. Survey responses remained anonymous. Institutional research ethics board approval was obtained prior to initiation of the study.

A mixed methods analysis design was employed. Standard descriptive statistics were used where appropriate to analyze quantitative data. Qualitative data was extracted from the patients' survey comments and answers to open-ended questions. Responses were organized and reviewed as they were received. Descriptive thematic analysis, which involved transcribing the written responses to an electronic format, organizing, and indexing them, was carried out by the first author to report on patterns or themes within the data. Open coding was used to label the concepts that arose and similar or related codes were arranged into thematic categories for analysis. Codes and themes were developed by one study investigator (first author), and reviewed by two other study team members (co-authors), who made additional suggestions. In particular, themes that reflected patient satisfaction or dissatisfaction, such as difficulties, barriers, causes of frustration, and expressed needs, were explored. No formal sample size calculation was carried out *a priori*. Survey responses were analyzed as they were collected and then reviewed in an iterative process. Thematic saturation was achieved after no new themes were developed from additional completed surveys.

RESULTS

All nine patients approached for this study agreed to participate. Table 1 summarizes the characteristics of the study participants. The age of participants ranged from 40 to 90 years (mean 76.8 years) but was skewed towards advanced age (median age 83), reflecting the greater susceptibility of the elderly to recurrent CDI (13, 14). Five of the participants had experienced more than four episodes of CDI.

Within the survey, patients wrote about their experience with CDI and its management. Due to the focused nature of the questions, thematic data saturation was achieved despite the low number of participants. Though the patients generally reported feeling satisfied with all forms of care that they had received during their most recent episode of CDI, they all described difficulties that they had faced and areas for improvement. Three major themes in the patient experience with CDI emerged: 1) knowledge and understanding; 2) access to adequate care; and, 3) the lived experience. Within each of these themes arose a number of subthemes (Figure 1).

1. Knowledge and Understanding

1A. Confusion and Uncertainty

When asked about what makes their experience with CDI difficult, many patients wrote about the confusion and uncertainty they had faced. They often had comorbidities, and the medications that they took had side effects, making it more difficult for patients to understand what was causing their symptoms. Difficulties expressed included:

"Confused about other conditions versus C. diff symptoms."

"When I get symptoms, not being able to identify the cause of the symptoms."

Patients were upset about being uncertain of when their symptoms will come back, and when they would need to seek medical help:

"Not knowing when it will come back and when to call the doctor."

Although the medication regimens for treating recurrent CDI can involve dosage tapers, patients reported no difficulty in understanding how and when to take their medications (Figure 2) and likewise this was never mentioned in the open-ended responses. Of note, patients at the study clinic were provided written instructions on how to take their medications, which may not reflect the practice of all clinics managing CDI patients.

1B. Infection Control

Many patients reported worrying about passing the infection on to others (Figure 2) and wanted to know how to prevent transmission. When asked about any feelings regarding CDI, one patient expressed concern:

"Knowing how contagious it can be."

Some patients did not have a complete understanding of the nature of *C. difficile* transmission. Though most patients understood that hand hygiene is important (Figure 2), when asked about spreading infection to others, one patient commented:

"This isn't a type of disease that passes to other people, is it?"

1C. Education Medium

Almost all surveyed patients felt that understanding their disease was important to them, and most patients agreed that they would read educational pamphlets about CDI and its management (Figure 2). When asked directly about how they would prefer to learn more about their disease, many patients stated that they favoured verbal and written education. However, some other requests included online education resources, as well as group talks for discussing CDI with other patients.

2. Access to Adequate Care

2A. Timely Care

Patients stressed the importance of timely responses from clinic staff and quick access to therapies. This was an important aspect of their care, since they did not know when their symptoms would return and were anxious about being prepared for it:

"Since the symptoms are unpredictable, knowing that I can access a doctor or treatment quickly would make a big difference."

Fast responses from their care providers seemed to have a strong positive influence on the patient experience:

"Very responsive if I call the clinic. Quite satisfied with the clinic."

2B. Avoiding Hospitals

Patients were concerned about any need for hospitalization. Some patients did not trust that hospitals adequately controlled and managed the infections, while others dreaded the hospital experience in general:

"Lack of proper procedures at [hospital named removed] in handling C-diff patients like me."

"Fear of hospitalization!"

2C. Access to Improved Treatments

When asked about what would help to improve their experience with CDI, many patients expressed a desire for improved or novel therapies. They requested information about treatment alternatives:

"Explanation of what options a patient has to be cured."

Many patients expressed interest in learning more about and accessing fecal transplantation. Limited access to this form of CDI treatment, which was until recently limited to clinic trials, is a cause of frustration to some:

"I strongly recommend that fecal transplant becomes available. Accelerate the study. Find some funding so that more people can be saved."

3. The Lived Experience

3A. Emotions and Concerns

Most patients reported that their CDI made them feel stressed, and that they were frustrated by their illness and treatment (Figure 2). Additionally, in their written responses patients describe a wide array of emotions that they have experienced throughout their infection, including feelings

of embarrassment, anxiety, debilitation, and frustration. Respondents often used strong wording to explain the difficulties that they experienced with infection:

"I was traumatized by the whole experience. The weakness, exhaustion, embarrassment, total dependence, the feeling that there is no cure for it – only management – this was horrifying."

The fear of having uncontrolled symptoms for a long period of time and never being cured of the infection was frequently reported. Many patients worried about their risks of developing another episode of CDI:

"Concern and worries for taking any antibiotics for dental work."

"I have an IBD, are people who have this more susceptible? What conditions make you more at risk for the infection?"

3B. Daily Functioning

Patients reported significant debilitation from the disease and often remained housebound, as they did not know when they would next need to use the toilet. Feelings of exhaustion and dependence were also frequently reported.

"How debilitating it is. I cannot leave the house most days. When on meds I get a few hours or sometimes days of reprieve but once off them the vicious cycle starts again."

"I never know when I have to go to the washroom. Accidents are hard to clean up, especially when you're in that condition and sapped of your strength"

3C. Coping Ability

All patients reported that they received support from family or friends when sick (Figure 2). Many described the help they got from their spouse:

"Yes, my wife, my right hand."

When asked to indicate whether or not their CDI made them feel stressed, one patient reported not feeling stressed, commenting that they have adjusted to the infection after having it for a long time. In contrast, another patient indicated strong feelings of stress, reporting that their disposition contributes to feelings of stress during infection:

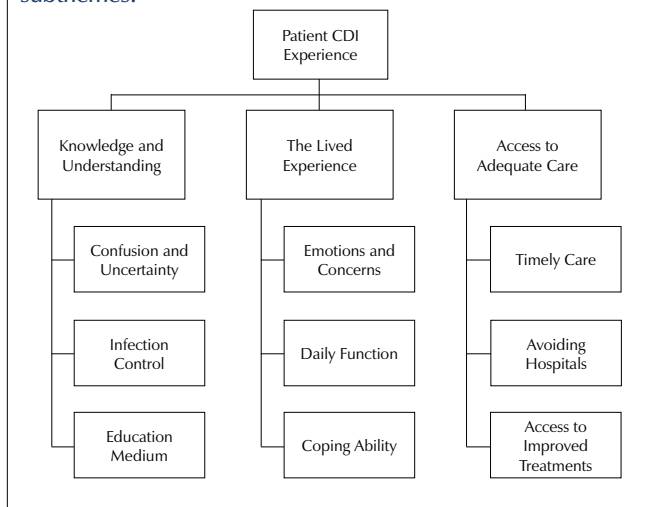
"I'm an anxious person."

TABLE I. Participant Demographics

Total Study Participants	N =9
Age	
Mean	76.8
Median	83
Minimum	40
Maximum	90
Sex	
Male	5 (55.6%)
Female	4 (44.4%)
Number of <i>C. difficile</i> Infection Episodes	
First Infection	0 (0%)
2-4 Infections	5 (55.6%)
More than 4 Infections	4 (44.4%)

FIGURE 1: Thematic Data Map

Three major themes emerged in the patient experience with CDI. These themes were further divided into numerous subthemes.



DISCUSSION

In this study, we provide empiric data on the personal difficulties associated with recurrent CDI. Similar studies of patients with other hospital-associated infections have highlighted a lack of verbal and written communication, confusion and anxiety, and discomfort with asking questions as pertinent features of the patient experience (15, 16). Patients that feel greater anxiety and perceive higher risks with respect to healthcare-associated infections generally demonstrate a limited understanding of the practical aspects of infection, such as what the causative organism is and how it is transmitted (16-18). People with higher education are more likely to have a good understanding of the

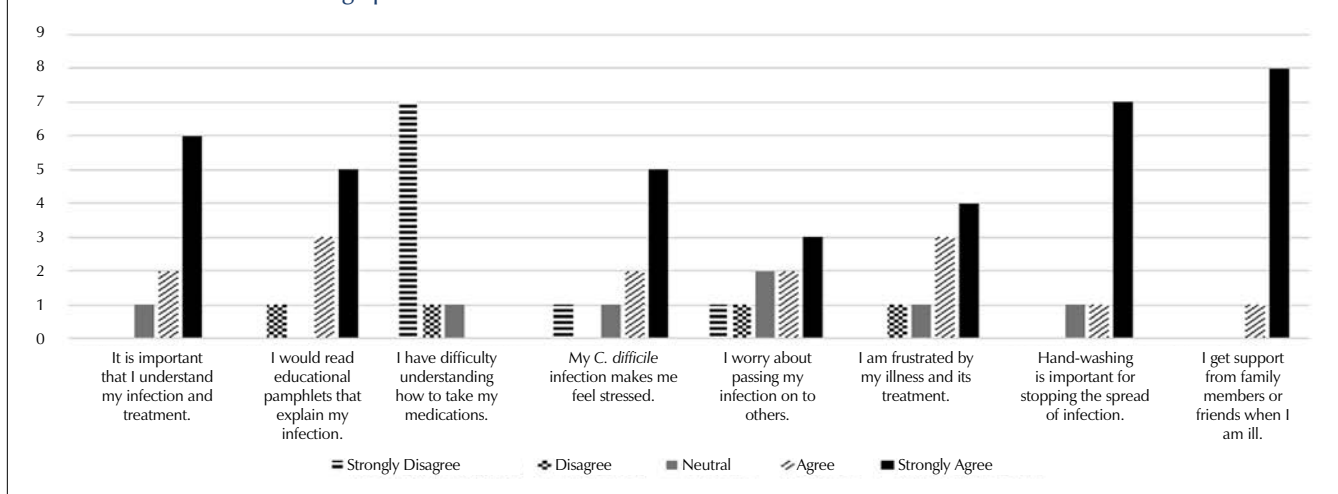
dangers and causes of healthcare-associated infections (19, 20). Patients with a past history of hospitalization or with a history of any healthcare-associated infection are more aware of the risks and consequences of CDI (21). Determinants such as these, which may include prior experiences and personal factors like health literacy and coping practices, are all an interconnected part of the patient experience with illness.

Many elements of a patient’s behavior and prior experiences impact their illness experience and satisfaction with CDI care. In our study, participants viewed their personal health-associated competencies as being important. A lack of patient knowledge and understanding contributed negatively to the CDI experience. Recurrent CDI patients were unsettled when they did not know what to expect from their infection. They wanted to understand their symptoms and know when to seek medical help. These sentiments were expressed in spite of patients having received regular verbal education on CDI at the clinic. Providing written educational materials describing the symptoms of CDI, contact information for care providers and guidance on how to react to specific types of symptoms, may help to address some of these issues. Although the CDI education administered by clinic staff also included a discussion on transmission risk and environmental management of *C. difficile* in the home, many patients remained unclear on how *C. difficile* is transmitted and the risks they pose to others. This highlights a need for ongoing patient education on the infection prevention and control aspects for CDI, both to address the excessive and unwarranted anxiety that some CDI patients feel about spreading infection, and to reinforce awareness of the risks and mechanism of disease.

This study indicates that having rapid access to medical care and medications is very important to patients. The implementation of dedicated CDI clinics, with teams of healthcare providers who have experience managing CDI patients and their medications, may address this need. With

FIGURE 2: Survey Responses

Patient responses to survey checkbox questions related to health literacy, practices, and coping abilities. Each bar represents the number of patients who answered either *strongly disagree*, *disagree*, *neutral*, *agree*, or *strongly agree*, to the survey questions indicated below each set of bar graphs.



thorough care and follow-up, as well as rapid access to medical consultation, unnecessary emergency room visits and hospital admissions may be avoided. Study participants also expressed interest in newer therapies, including fecal transplantation. As emerging therapies for CDI become more available, reliable information and guidance on how to access them would help to alleviate this area of patient frustration. Other negative aspects of the lived experience with CDI, such as problems with daily functioning during active infection, and emotional concerns such as embarrassment, may be more difficult to target through resource development. However, counseling and a thorough discussion of management strategies with the physician may help to make these difficult episodes more bearable for the patient.

Our study has a number of limitations. Study participants were selected through convenience sampling at one infectious disease clinic in Toronto, Ontario and participation in the study was voluntary, so there is a potential for selection bias in the sample population. Though clinic staff were not involved in administering or collecting the survey, it is possible that the results may have positive bias, as it was completed within the clinic. The sampled population was skewed towards advanced age, and elderly patients may be more comfortable receiving information in a different format compared to younger patients. Additionally, clinic visitors were mainly from urban areas, and recurrent CDI patients in more remote or underserved areas may experience additional difficulties related to travel distance, or other unforeseen challenges that have not been recognized by this study. Our study sample size was small; although it was not sufficient for carrying out an extensive statistical analysis of responses, we were able to achieve thematic saturation on the qualitative data. Our sample population consisted of patients with recurrent CDI, and so themes that might be prominent in the patient experience with an initial acute CDI, such as frustration due to misdiagnosis or delayed diagnosis, were not identified by our study. Finally, we sought to understand the patient experience with CDI in one Canadian jurisdiction, so some of our findings may not be transferrable to other regions with different models of health care delivery. However, we note that outside of the uncovered theme of “access to adequate care,” difficulties identified by study participants were not dependent on health care systems as much as personal experiences, making these findings broadly applicable beyond any one jurisdiction.

CONCLUSIONS

Many personal factors contribute to an individual's experience with CDI, including their own prior experiences, coping strategies, and understanding of infection. There are common themes in the patient experience that relate to dissatisfaction with care. These themes highlight patient needs and areas for improvement, such as improved education about CDI and how to live with it, easy access to care when symptoms return, and counseling on management strategies for living with CDI.

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C. difficile Clinic Patient Survey

This survey relates to your opinions on healthcare and your personal experience with *C. difficile* infection. It will take approximately 10 minutes to complete. You will be contributing to the understanding of the illness experience and helping to guide improvement of patient management. By completing this survey, you agree to participate in this research with the knowledge that you are free to withdraw your participation at any time.

Please state your age: _____

How many *C. difficile* infections have you experienced, including any current infection?

- This is my first infection
 2-4 infections
 More than 4 infections

Check the boxes to indicate how strongly do you agree with each of the following statements:

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree	Comments
It is important that I understand my <i>C. difficile</i> infection and its treatment.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
I would read educational pamphlets that explain my infection and its treatment.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
I have difficulty understanding how and when to take medications.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
My <i>C. difficile</i> infection makes me feel stressed.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
I worry about passing my infection on to others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
I am frustrated by my illness and its treatment.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Hand-washing is important for stopping the spread of infection to others.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
I get support from family members or friends when I am ill.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Rate your overall satisfaction with the care that you are receiving or have received during this infection.

- Very Unsatisfied Unsatisfied Neutral Satisfied Very Satisfied

Please provide a response to the following questions, as applicable:

What do you find most difficult, frustrating, and/or stressful about your illness and its treatment?

What would help to improve your experience?

How would you like to learn more about your illness and/or its treatment (e.g., pamphlets, verbal explanations, online resources, etc.)?

Please provide any additional comments or feelings about *C. difficile* infection.

Clostridium difficile infection in Alberta's long-term care facilities

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ABSTRACT

Background: *Clostridium difficile* infection (CDI) is prevalent in long-term care (LTC) facilities in the United States, Canada, Europe and Australia. However, to our knowledge, CDI surveillance in LTC facilities has not been documented provincially in Alberta or any other Canadian province. This study aims to identify the incidence of CDI in LTC facilities and describe the demographic characteristics of the affected population.

Methods: Administrative data from 172 LTC facilities in Alberta, Canada, was obtained from April 1, 2012, and September 30, 2013.

Results: The majority of LTC CDI cases were either residents who resided in a LTC facility for more than 72 hours and had no hospitalizations in the previous four weeks (65.7%), or residents who had a hospital visit between 72 hours and four weeks prior to their CDI case (30.3%). Fluid and electrolyte disorders, congestive heart failure, and cardiac arrhythmias were the most common co-morbidities. Approximately 30% of residents died within 60 days of their CDI episode.

Conclusions: There is a need to implement routine surveillance to continue monitoring CDI in LTC facilities to assess these findings further and to evaluate changes over time in response to improvement initiatives related to CDI prevention and clinical management.

KEY WORDS

long-term care, *Clostridium difficile*, surveillance

INTRODUCTION

Clostridium difficile is a Gram-positive, anaerobic, spore-forming bacterium with a range of clinical presentations from mild diarrhoea to toxic megacolon, which can lead to sepsis and even death (1). *Clostridium difficile* infection (CDI) is the most common cause of hospital acquired (HA) diarrhoea in the developed world and occurs primarily in older adults; infection rates in adults over the age of 65 are ten times higher than those under the age of 65 (2-4).

Although the increased risk of infection has been reported with increasing age, it is unclear if this association is due to age itself (and associated physiologic changes), or an increasing frequency of comorbidities and antibiotic use in an older population. It has been recommended that a comprehensive analysis of CDI should take into consideration the frequency, severity and type of comorbidities to determine potential predetermining factors that lead to CDI (5).

Survival following CDI is much worse for older adults; they are 3.5 times more likely to die as a result of CDI exposure (6).

In Canada, the rate of CDI-attributable mortality has been increasing. Between 1997 and 2005, HA CDI-attributable mortality increased from 1.5% to 5.7% (6). More generally, a 2013 study by Inns et al. found that in 1,426 acute care patients with CDI, there was a 25.7% 30-day and 38.1% 90-day all-cause mortality (7).

Since it is difficult to determine CDI-attributable mortality due to the labour intensive process required to affirm the direct cause leading to mortality, all-cause mortality may be more feasible to identify CDI in long-term care (LTC) facilities (8). A review of *C. difficile* by Mitchell & Gardner (2012) found an all-cause mortality at 30 days ranging between 9%-38% and 90-day all-cause mortality with a range of 27%-30% (9).

Although CDI is prevalent in LTC facilities in Canada, United States and Europe, little is known about the population who experience CDI in LTC facilities (5). A recent study by Rodriguez et al. describes the colonization

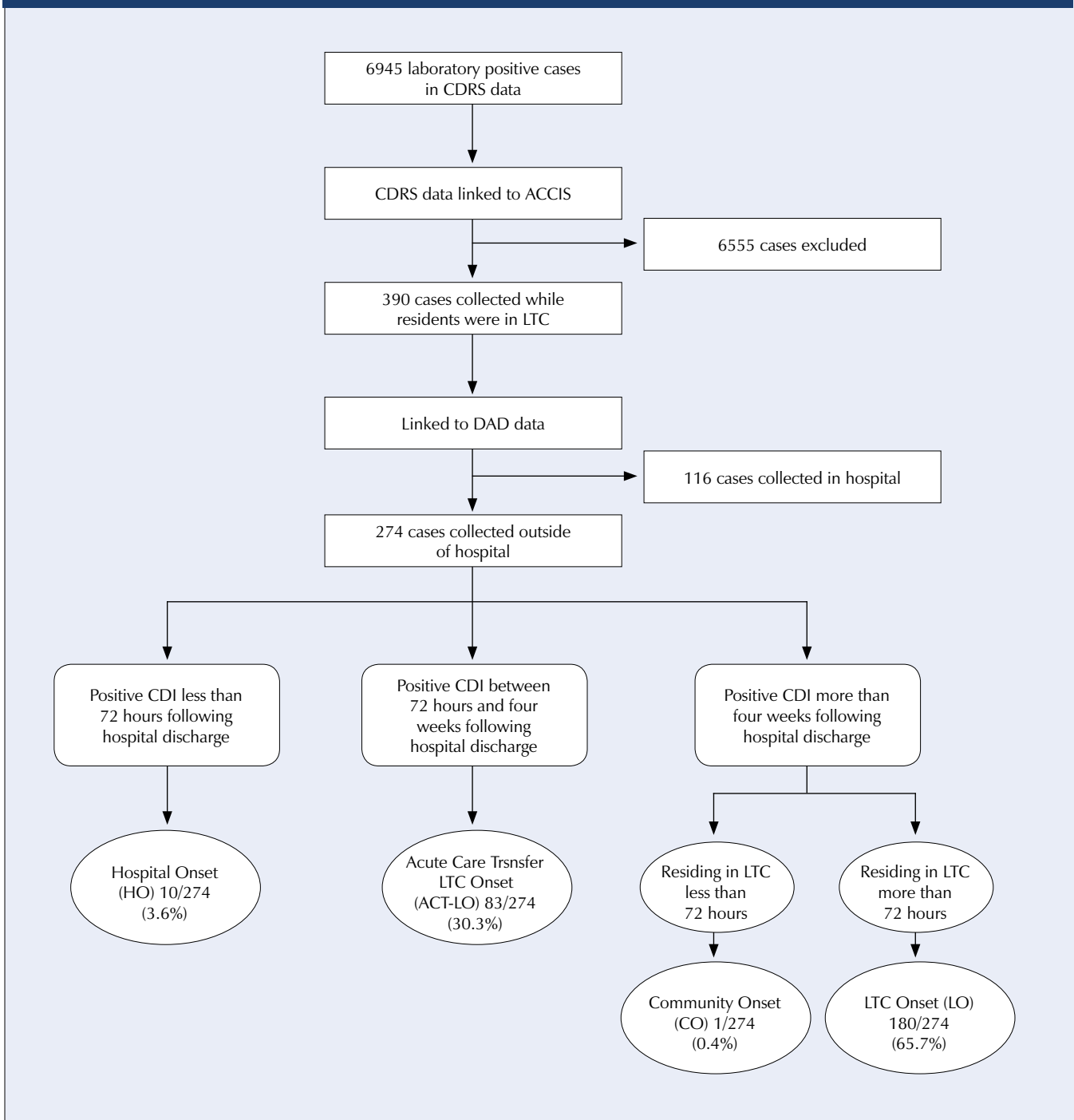
of *C. difficile* as 10 times higher among those residing in LTC facilities than those who were not (10). Therefore, there is a need to assess the incidence of CDI in LTC facilities as older adults tend to be the majority of residents and few studies have estimated the incidence of *C. difficile* in LTC facilities (10). This study investigates the incidence of CDI in Alberta's LTC facilities and presents data that describe the distribution of gender, age, the frequency of and type of co-morbidities, and proportion of all-cause mortality.

METHODS

Study population

The province of Alberta, Canada, has a population of approximately 3.7 million, of whom 405,000 (11%) are over the age of 65 (11). Alberta's LTC delivery is provided by Alberta Health Services (AHS) and its contracted partners. In the 2011/12 fiscal year, AHS provided 5,051,241 LTC resident days across 172 LTC facilities (n=78; 45.3% urban facilities) in five geographic zones.

FIGURE 1: Data Linkages and Case Classification Flow Chart



All residents with an incident case of CDI in LTC in Alberta between April 1, 2011, and September 30, 2013 (18 months), were included in this study.

There were no age restrictions on the study population, and inclusion into the study depended on the cases' identification.

Case identification

Cases of CDI were defined as a positive *C. difficile* toxin assay or positive polymerase chain reaction (PCR) test. Confirmatory testing by PCR was introduced in Alberta in April 2013 for indeterminate results of the toxin assay. All laboratories in Alberta report all *C. difficile*-positive laboratory results to the Ministry of Health's Communicable Disease Reporting System (CDRS). Incident cases were defined as either the first case in the dataset in the study time period, or those greater than eight weeks from the previous incident case. Repeated cases less than eight weeks from the previous incident case were excluded from the analysis as cases less than eight weeks from the previous case would be considered a relapse and related to the previous case and not a new episode as per the National Healthcare Safety Network (NHSN) guidelines definition for CDI (12). No symptomatic or clinical criteria were used for inclusion into the analysis.

Province-wide CDI toxin assay/PCR data from the CDRS were matched to the long-term care registry Alberta Continuing Care Information System (ACCIS) and to the Discharge Abstract Database (DAD) using residents' Alberta Provincial Health Number (PHN) to identify LTC residents. The ACCIS database is a long-term care registry that captures all admissions and discharges from an Alberta LTC facility. The DAD captures administrative, clinical, and demographic information related to an acute care hospitalization.

To identify which *C. difficile* toxin assay/PCR-positive results occurred while the person was residing in LTC, the specimen collection date for *C. difficile* was compared to the admission and discharge dates from both acute care hospitals and LTC facilities (Figure 1). If the specimen collection date for *C. difficile* occurred on or in between the admission and discharge date from a LTC facility and not while a patient was admitted to an acute care facility, that *C. difficile* toxin assay/PCR-positive result was assumed to have occurred in LTC.

All CDI cases were linked to Vital Statistics Canada data using PHN to identify all-cause mortality up to December 31, 2013.

Case definitions

Incident cases occurring in LTC facilities were classified according to their likely location of acquisition. Case classification definitions were based on the NHSN definitions for laboratory identified CDI (12). Those residents with CDI between 72 hours and four weeks after a hospital discharge were referred to as *acute care transfer long-term care facility onset* (ACT-LO). Those who had CDI greater than four weeks after an acute care hospital discharge and who had been a LTC resident for more than 72 hours were referred to as a *long-term care facility onset* (LO) classification. Those who had CDI

less than or equal to 72 hours following a hospital discharge were referred to as *hospital-onset* (HO). Finally, those who had CDI more than four weeks following a hospital discharge and resided in LTC for less than 72 hours were referred to as *community-onset* (CO) (Figure 1).

Admission(s) to acute care hospital that occurred in the six months prior to the LTC-incident CDI case were identified using DAD data and International Classifications of Disease, 10 revision, Canada (ICD-10-CA) (i.e., diagnosis codes) were used to identify Elixhauser comorbidities. A single comorbidity documented more than once during the six-month period was only counted once for the LTC resident.

Data analysis

A descriptive analysis was performed for age, gender, location of CDI, and co-morbidity information. Frequencies and proportions were reported. Incidence rates were calculated by dividing the number of incident CDI in LTC facilities over the number of resident-days per 100,000. A test of proportions was used to compare categorical variables between the LO and ACT-LO case classifications. For all statistical comparisons a *p*-value <0.05 was deemed statistically significant. All data linkages and some of the analyses were conducted using IBM SPSS, Version 19. Comorbidity significance testing was performed using Stata/IC, Version 10 (StataCorp).

RESULTS

Between April 1, 2011, and September 30, 2013, 6,945 CDI cases were identified in the CDRS database. Six thousand five hundred fifty five cases did not overlap when patients were registered in a LTC facility. Three hundred ninety (5.6%) of the CDI cases occurred while the residents were registered in a LTC facility. Of the 390 CDI cases, 274 (70.3%) incident CDI cases occurred in a LTC facility and not during a hospitalization. Of the 274 episodes, 180 (65.7%) were LO, 83 (30.3%) were ACT-LO, 10 (3.6%) were HO and one (0.4%) was CO (Figure 1). Because 263 (96.0%) fell into either the ACT-LO or LO categories, only these two groups were analyzed further.

The provincial incidence rate for the entire study period was 0.7 per 100,000 resident days for ACT-LO and 1.4 per 100,000 resident days for LO.

Table 1 shows that there were more female cases in both the ACT-LO (61.4%) and LO groups (63.4%). The median age is 85 years (Interquartile Range (IQR) 12) for ACT-LO and 86 years (IQR 15) for LO.

It was noted that 85.3% of ACT-LO resided in an urban zone of Alberta; 93.9% of LO resided in an urban zone.

One hundred three LO and 44 ACT-LO residents died following the incident CDI case. Of those, all-cause mortality at 30, 60 and 90 days was listed including the percent of the population who died within 30, 60 and 90 days (Table 1). It was found that 32.7% of LO and 30.1% of ACT-LO died within 60 days of the CDI diagnosis.

All ACT-LO cases had a previous acute care admission and therefore Elixhauser comorbidity data could be evaluated from the discharge diagnoses; however, only 43% (78/180) of the

TABLE 1. Resident Characteristics and Antibiotic Class Exposure

	LO N=180 n (%)	ACT-LO N=83 n (%)	p-value
Males (%)	66 (36.7)	32 (38.6)	0.77
Median Age, years (Interquartile Range, IQR)	86 (15)	85 (12)	
Urban Facilities (%)	169 (93.9)	71 (85.5)	0.03*
Deceased LTC Discharge Care Level			
30-day All-cause Mortality	40 (22.2)	16 (19.3)	0.59
60-day All-cause Mortality	59 (32.7)	25 (30.1)	0.67
90-day All-cause Mortality	64 (35.6)	29 (34.9)	0.92
Cases with Co-morbidity Data			
	n=78	n=83	
Fluid and Electrolyte Disorders	27 (34.6)	21 (25.3)	0.20
Congestive Heart Failure	15 (19.2)	19 (22.9)	0.40
Cardiac Arrhythmias	18 (23.1)	24 (28.9)	0.25
Chronic Pulmonary Disease	15 (19.2)	20 (24.1)	0.45
Renal Failure	10 (12.8)	14 (16.9)	0.47
Uncomplicated Hypertension	48 (61.5)	49 (59.0)	0.75
Valvular Disease	2 (2.6)	8 (9.6)	0.06
Drug Abuse	0 (0.0)	1 (1.2)	0.33
Coagulopathy	2 (2.6)	7 (8.4)	0.11
Blood Loss Anemia	2 (2.6)	3 (3.6)	0.70
Pulmonary Circulation Disorder	2 (2.6)	5 (6.0)	0.28
Other Neurological Disorder	10 (12.8)	12 (14.5)	0.76
Weight Loss	7 (9.0)	3 (3.6)	0.16
Depression	8 (10.3)	11 (13.3)	0.56
Peripheral Vascular Disease	3 (3.8)	4 (4.8)	0.76
Rheumatoid Arthritis	1 (1.3)	3 (3.6)	0.34
Liver Disease	0 (0.0)	2 (2.4)	0.17
Peptic Ulcer Disease (excluding Bleeding)	1 (1.3)	1 (1.2)	0.96
Paralysis	7 (9.0)	7 (8.4)	0.90
Diabetes uncomplicated	8 (10.3)	7 (8.4)	0.69
Diabetes complicated	27 (34.6)	23 (27.7)	0.34
Hypothyroidism	10 (12.8)	11 (13.3)	0.94
Solid tumor (w/out metastasis)	2 (2.6)	0 (0.0)	0.14
Obesity	4 (5.1)	3 (3.6)	0.64
Deficiency Anemia	5 (6.4)	8 (9.6)	0.45
Alcohol abuse	1 (1.3)	1 (1.2)	0.96
Psychoses	1 (1.3)	1 (1.2)	0.96
Hypertension complicated	2 (2.6)	1 (1.2)	0.52

*Difference between LO and ACT-LO is statistically significant at the .05 level

LO population had an acute care admission in the 6 months prior to the CDI event. Of those residents, 74 (89.2%) of the ACT-LO and 75 (96.2%) of the LO had at least one comorbidity identified (Table 1). Nine (10.8%) ACT-LO cases had no comorbidities listed, 22 (26.5%) had one or two comorbidities, and 52 (62.7%) had three or more comorbidities. For LO cases, 3 (3.8%) had no comorbidities, 31 (39.7%) had one or two comorbidities, 44 (56.4%) had three or more comorbidities. The most commonly found co-morbidity for both the LO (61.5%) and ACT-LO (59.0%) groups was uncomplicated hypertension, the second most common comorbidity was complicated diabetes for the LO group (34.6%) and cardiac arrhythmias for the ACT-LO group (28.9%), and the third most common comorbidity was fluid and electrolyte disorders for LO (34.6%) and complicated diabetes for ACT-LO (27.7%).

DISCUSSION

To our knowledge, this was the first province-wide study in Canada that assessed the incidence and characteristics of CDI that occurred in LTC facilities. The purposes of the study were to provide baseline CDI rates in these facilities, to inform future research, and to add to the demographic literature related to CDI in LTC facilities.

A relatively low number of studies have estimated the incidence of *C. difficile* in nursing homes and other LTC facilities (10). A comprehensive study from the Ohio Department of Public Health on the burden of CDI in LTC facilities found that the overall rate for initial cases of CDI was lower in nursing homes compared to hospitals (1.7-2.9 vs. 6.4-7.9 cases/10,000 patient days, respectively); however, the absolute number of CDI in the nursing homes exceeded those in acute care by more than 50% (13). The Alberta provincial incidence rate for LO was much lower than that found by the Ohio Department of Public Health (0.14 per 10,000 resident days).

Based on our analysis, it is difficult to pinpoint why there were more LO cases than ACT-LO cases. One potential explanation is the potential exposure to systemic antibiotics in long-term care patients. Daneman et al found a 5.9% antibiotic use based on a point-prevalence in 363 Ontario Long Term Care facilities (14). The three most prevalent antibiotics Daneman et al found were most prescribed in the context of urinary tract infections including: nitrofurantoin (15.4%), trimethoprim/sulfamethoxazole (14.3%) and ciprofloxacin (12.8%) (14). Another possibility is that in our jurisdiction patients are not often discharged from acute care to long-term care if they continue to be symptomatic with diarrhea or have an indication of CDI. This is supported by the fact that only 3.6% of cases among long-term care residents occurred in the first 72 hours following an acute care discharge (i.e., hospital-onset CDI).

The median age for CDI cases in LTC facilities in this study was 86 years for LO and 85 years for ACT-LO (Table 1). This is a similar finding to age-related demographic information found in CDI-related literature about the age of CDI patients. In acute care, the rate of CDI based on discharge diagnoses was several-fold higher in patients over the age of 65 than patients 45-64 years ($p < 0.05$) (16). The probability of CDI increases

with age: patients with CDI were nearly 20 years older (67.9 vs. 48.1 years), and patients ≥ 85 years had the highest rate of CDI (1,089 per 100,000 population) compared with patients less than 18 years (11 per 100,000 population) (16). Previous studies have highlighted factors that make people over 65 years of age more susceptible to *C. difficile* including antibiotic treatment, age-related changes in intestinal flora and host defences, and possibly underlying illnesses (10, 17).

Most cases of CDI in both the LO and ACT-LO groups occurred in LTC facilities located in urban settings. This may be due to increased laboratory testing for CDI in urban LTC facilities compared to rural facilities. Further work is required to identify other possible explanations for this finding.

Using all-cause mortality, less than 23% of both the ACT-LO and LO cases died within 30 days of CDI diagnosis. A British study by Karas et al. assessed the rate of all-cause mortality in acute care and indicated that 37.9% of patients died 30 days after a CDI episode (18). We cannot state why there is a disparity between studies. Although CDI-attributable mortality data was unavailable, all-cause mortality data for the ACT-LO and LO group suggests that the prognosis of those with CDI is poor.

Only 43.3% of residents with LO CDI had acute care data with comorbidity information that could be matched to laboratory-identified CDI case data, since comorbidity information was only available when a resident was previously admitted to an acute care facility within six months prior to the CDI case. The most common co-morbidities were uncomplicated hypertension, complicated diabetes, fluid and electrolyte disorders and cardiac arrhythmias. Studies have shown that hypertension, diabetes, and electrolyte imbalance are common comorbidities among individuals with CDI (19-21). The connection between these comorbidities and CDI is unclear; they may be related to independent medical condition(s) and not due to CDI. Further research to examine quality of life and severity of illness indicators in LTC residents before a CDI episode is needed to determine if any of these factors predispose residents to CDI. Additional research should compare CDI cases to a control group who did not get a CDI.

This study shows that CDI is prevalent in LTC facilities. It is important to stress the need for evidence-based practices being employed in infection prevention and control including the use of private rooms, contact procedures, environmental cleaning, and hand hygiene to reduce CDI in LTC facilities. The Public Health Agency of Canada lists precautions and procedures that need to be upheld in order to decrease the number of people with CDI (22). Education and awareness of the severity of this infection in terms of morbidity and mortality must be stressed with LTC facilities' staff. This could potentially inform initiatives to improve clinical management of residents to decrease the reservoir and burden of CDI in these facilities.

There are several limitations with this study. The acute care database only included diagnostic code information six months prior to the CDI case. The acute care diagnostic codes were the only source of information for co-morbidity data. It is likely that these data do not give a complete depiction of all co-morbidities, particularly of residents with no hospital

admission in the six month period prior to the CDI case. Resident-level linkages to other electronic medical records such as primary care records would provide more information about the comorbidities for this population.

The NHSN guidelines for laboratory-identified CDI is recommended for CDI identification in LTC. The limitation with this guideline is that it differs from the CDI definition for acute care which requires a clinical evaluation of symptoms and it relies on CDI testing practices in LTC facilities. The rationale for using the NHSN guideline is that it could be assumed that symptoms were present in order for a stool specimen to be collected and tested. The feasibility of collecting CDI-related symptomatic information would be challenging in LTC facilities with the limited resources available in infection prevention and control.

Finally, the mortality information within the analysis only included all-cause mortality; CDI-attributable mortality was not determined in this analysis because the data source used did not include attributable-mortality information. To include CDI-attributable mortality, a health care professional would have to assess each case to determine if CDI contributed to or was the cause of death. Using all-cause mortality does not indicate death due to CDI; this distinction should be considered when reviewing mortality-related literature.

CONCLUSION

The study found demographic homogeneity in both ACT-LO and LO classifications; there were similar distributions of gender, age, all-cause mortality, and co-morbidities. Although there were more LO situations, there was little demographic variation between the two groups. The key difference between the two case classifications was the variation in acute care exposure. Future work is warranted to further assess CDI in LTC facilities to determine if there are similar findings.

Based on these findings, we recommend routine annual provincial surveillance of CDI in all Albertan LTC facilities to identify and explain changes in CDI incidence over time. Routine annual surveillance would replicate this laboratory event surveillance on an annual basis, using the same strategy and definitions to measure incidence without requiring extensive Infection Prevention and Control support for data collection.

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Evaluation of efficacy and clinical utility of potassium peroxymonosulfate-based disinfectants

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ABSTRACT

Background: Environmental cleaning is an important aspect of infection control, especially for organisms such as rotavirus that are transmitted through direct and indirect contact.

Methods: We evaluated an intervention to prevent rotavirus infection in a pediatric ward by using wipes impregnated with a potassium peroxymonosulfate-based environmental disinfectant (PPD) for environmental cleaning. Prevalence rate (%) and incidence density rate (‰) for rotavirus were measured before and after the intervention. To estimate the efficacy of environmental cleaning, we evaluated the persistent bactericidal activities of commercially available antimicrobial products containing PPD.

Results: Prevalence rate (%) and incidence density rate (‰) for rotavirus were 5.54 and 2.85 before intervention (Apr-Jun, 2012), incidence density rate after intervention (Apr-Jun, 2013) was decreased to 1.48 despite the higher prevalence rate 8.62. PPD demonstrated persistent bactericidal activity against methicillin-resistant *Staphylococcus aureus* and *Pseudomonas aeruginosa* for up to 24 hours after application on experimental surfaces.

Conclusions: This study showed that intervention to promote the use of PPD was useful in preventing secondary infection of RV in pediatric ward. PPD was also considered to be useful from the viewpoint of persistent antimicrobial action, convenience, and safety.

KEY WORDS

Rotavirus, potassium peroxymonosulfate, environmental cleaning

INTRODUCTION

Healthcare environments are well known as propagation paths for pathogenic microorganisms. Disinfecting the hands of medical personnel as well as the medical environment, with a focus on frequently touched surfaces, is useful in infection control (1,2). As rotavirus (RV) is resistant to alcohol, the use of 200-1,000 ppm Sodium hypochlorite (NaClO) in disinfecting environments contaminated with RV is recommended (3). NaClO is a disinfectant with a broad antimicrobial spectrum. However, it is problematic for reasons such as corrosion of metal and other equipment surfaces, generation of irritating chlorine gas, and complicated management of concentrations (4). On the other hand, disinfectants and cleaning agents formulated with potassium peroxymonosulfate that are improvement over chlorine-based disinfectants and cleaning agents have been reported to be efficacious against many infectious microorganisms such as viruses and bacteria (5-9), and they have been used in a manner similar to that of NaClO in the hygiene

management of healthcare environments (10,11).

In addition, it has been reported that with hypochlorous acid as the active substance, there is little metal corrosion and no chlorine odor, and this agent is highly efficacious against many infectious organisms. Furthermore, the United States Environmental Protection Agency (EPA) states that potassium peroxymonosulfate-based disinfectants (PPD) are widely effective against such organisms such as norovirus, methicillin-resistant *Staphylococcus aureus* (MRSA), hepatitis B virus, and hepatitis C virus (12). The Centers for Disease Control and Prevention (CDC) guidelines recommend selection of a disinfectant or cleaning/disinfectant registered with the EPA for use in environmental maintenance (1). In addition, the Japanese dialysis guidelines recommend the use of potassium peroxymonosulfate in the cleaning and disinfection of environmental surfaces (13). However, reports regarding the clinical usefulness and sustainability of the effects of PPD are scarce.

Acknowledgements:

Conflicts of interest disclosure: No conflicts of interest have been declared.

In this study, we aimed to evaluate the usefulness of PPD from an actual clinical intervention and through the use of questionnaires. We also examined the persistence of the disinfection effect of PPD from a microbiological perspective.

METHODS

Clinical intervention

The infection control team (ICT) of our hospital conducted a review of the work manual in environmental improvement; in January 2013, the daily environmental cleaning practices in this hospital's pediatric ward was changed from cleaning once a day with cloths impregnated with a neutral diluted household detergent solution, to cleaning once a day with disposable wipes impregnated with 1% w/v potassium peroxymonosulfate-blended disinfecting and cleaning agent, a type of PPD (Rubysta®: Kyorin Pharmaceutical Co., Ltd.). In addition, we switched from cloths impregnated with 0.1% w/v NaClO (Yoshida® 0.1% NaClO solution, Yoshida Pharmaceutical Co., Ltd.), which were prepared in the ward, to the use of PPD wipes for environmental disinfection in the vicinity of patients infected with RV. We also provided training to medical staff and patients' families on the conscientious use of disposable gloves and meticulous hand hygiene during the treatment of contaminants of RV patients and the processing of these contaminants. Following the changes, we regularly conducted ICT rounds. Following the changes, we regularly conducted ICT rounds. Next, we retrospectively investigated the number of patients hospitalized for RV enteritis and the number of patients diagnosed with RV enteritis due to nosocomial transmission during the pre- and post-intervention periods (January-June 2012 and January-June 2013, respectively) from electronic medical records; data collected was used to calculate the prevalence and incidence density rate.

"Incidence rate" indicates the risk of newly developed morbidity over a certain period of time, while "incidence density rate" is the incidence rate for the total patient population over a period of time. In other words, "incidence density rate" is the risk of patients acquiring rotavirus after hospitalization. (14,15)

Note: Prevalence rate (%) = (Number of hospitalized patients due to rotavirus enteritis + Number of hospitalized patients with secondary rotavirus infections) / (Total number of hospitalized patients) *100

Incidence density rate (‰) = (Number of hospitalized patients with secondary rotavirus infections) / (Total inpatient days) *1000

Questionnaire survey

In September 2013, approximately 10 months after the change in procedures, we surveyed the pediatric ward nurses for their evaluation of the disinfectants used for environmental improvement.

Sustainable bactericidal action

To evaluate the effectiveness of environmental disinfectants against bacteria, we examined the sustained bactericidal

action of PPD and various disinfectants. In this study, as an alternative to RV, we evaluated three strains each of MRSA and *Pseudomonas aeruginosa*. We used disinfectants diluted with sterile purified water to obtain the specified concentrations. The disinfectants used were 1% w/v PPD, 0.1% w/v alkyldiaminoethylglycine hydrochloride ("amphoteric surfactant"), TEGO 51 Disinfectant Solution 10%®: Alfresa Pharma Corporation), ethanol for disinfection ([EtOH], Metal®: Nakakita Co., Ltd.), 0.1% w/v NaClO, and physiological saline solution [control], OTSUKA NORMAL SALINE®: Otsuka Pharmaceutical Factory Inc.). The SCDLP culture medium (Eiken Chemical Co., Ltd.) was used as a neutralizing medium, following confirmation that it demonstrated a neutralizing action against each disinfectant.

2 mL of each disinfectant was added dropwise to a sterilized disposable dish (As One Co., Ltd., diameter: 90 mm), and the solution was spread over the entire dish and dried at room temperature on a clean bench. 200 µL of bacterial solution (MRSA/*Pseudomonas aeruginosa*) adjusted to 10⁶ cfu/mL was brought into contact for 5 minutes immediately after the dropwise addition, as well as at 30 minutes, 1 hour, 3 hours, 6 hours, 12 hours, and 24 hours after.

Thereafter, the bacterial solution on the petri dish was recovered using a neutralizing medium and incubated at 35°C for 24 hours in sheep blood agar medium (Eiken Chemical Co., Ltd.) to observe whether or not bacterial growth occurred. A case without bacterial growth was judged as effective.

Ethical considerations

The present study was approved by the Institutional Review Board of Ogaki Municipal Hospital (approval number: 20160128-12).

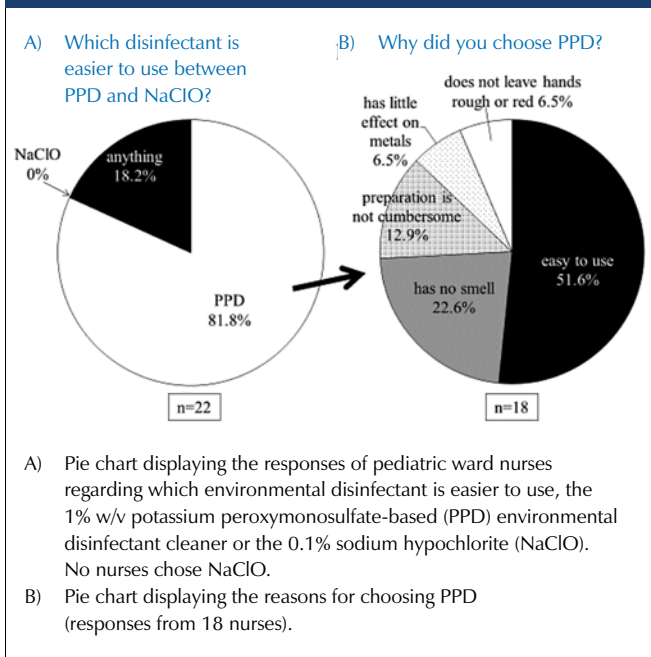
TABLE 1. Evaluation of rotavirus infection before and after intervention

	Before intervention (Apr-Jun, 2012)	After intervention (Apr-Jun, 2013)
Total number of hospitalized patients	1300	1276
Total inpatient days	7023	6752
Number of hospitalized patients due to rotavirus enteritis	52	100
Number of hospitalized patients with secondary rotavirus infections	20	10
Prevalence rate (%) ^{a)}	5.54	8.62
Incidence density rate (‰) ^{b)}	2.85	1.48

a) Prevalence rate (%) = (Number of hospitalized patients due to rotavirus enteritis + Number of hospitalized patients with secondary rotavirus infections) / (Total number of hospitalized patients) *100

b) Incidence density rate (‰) = (Number of hospitalized patients with secondary rotavirus infections) / (Total inpatient days) *1000

FIGURE 1: Evaluation of disinfectants by pediatric ward nurses



RESULTS

Clinical intervention

The Prevalence rate (%) and incidence density rate (‰) for rotavirus were 5.54 and 2.85 before intervention (Apr-Jun, 2012), incidence density rate after intervention (Apr-Jun, 2013) was decreased to 1.48 despite the higher prevalence rate 8.62 (Table 1).

Questionnaire-based survey

Of the 22 pediatric ward nurses surveyed, 18 nurses (81.8%) were more likely to use PPD compared to NaClO, the agent that had been used previously (Figure 1). The reasons indicated were 51.6% for “easy to use,” 22.6% for “no smell,” 12.9% for “preparation is not cumbersome,” 6.5% for “little influence on metals,” and 6.5% for “hands-free.”

Sustained bactericidal action

EtOH showed bactericidal action only immediately after dropwise addition, and had no bactericidal action after 30 minutes. NaClO showed bactericidal action against MRSA up to 30 minutes after the coating, and for *Pseudomonas aeruginosa* until one hour after the coating, but did not show bactericidal action after that. In contrast, PPD and amphoteric surfactant showed sustained bactericidal action against MRSA and *Pseudomonas aeruginosa* even 24 hours after the application (Table 2).

DISCUSSION

In the hospital environment, it is necessary to pay attention to transmission of infection by various pathogenic microorganisms, and RV is one of the viruses that can be transmitted via environmental surfaces, especially in children’s areas (1). Like norovirus, RV is one of the viral causes of infectious gastroenteritis that causes repeated epidemics annually. A compact, non-enveloped spherical virus, RV is stable in the environment, and its infectivity is so strong because ID₅₀ is only 10 to 100 viruses (16, 17). Nosocomial infection with RV has been reported to increase hospitalization periods in Europe (3). Every year in Ogaki Municipal Hospital

TABLE 2: Sustainable effects of environmental disinfectants against bacteria

		Processing ^{b)}					
Bacteria	Disinfectant ^{a)}	immediately afterwards	30 min	1 hr	6 hr	12 hr	24 hr
MRSA	Control	+	+	+	+	+	+
	PPD	-	-	-	-	-	-
	Amphoteric surfactant	-	-	-	-	-	-
	EtOH	-	+	+	+	+	+
	NaClO	-	-	+	+	+	+
<i>Pseudomonas aeruginosa</i>	Control	+	+	+	+	+	+
	PPD	-	-	-	-	-	-
	Amphoteric surfactant	-	-	-	-	-	-
	EtOH	-	+	+	+	+	+
	NaClO	-	-	-	+	+	+

a) PPD: 1%w/v potassium peroxydisulfate-based environmental disinfectant cleaner; amphoteric surfactant: 0.1% w/v alkyldiaminoethylglycine hydrochloride; EtOH: ethanol for disinfection; NaClO: 0.1% sodium hypochlorite; control: physiological saline solution
 b) Bacterial growth was evaluated when the bacterial solution was brought into contact for 5 minutes with a petri dish surface on which each disinfectant had been dropped and dried for a certain period of time. +: growth, -: no growth.

(our hospital), there have been cases of secondary infection in the hospital causing prolonged hospitalization of infected patients. One propagation pathway of this secondary infection is care of other patients while the hands of the healthcare workers who touched the infected patient's vomit or excretions are contaminated, and another route of propagation is by healthcare workers touching environment surfaces contaminated with RV.

Therefore, to prevent in-hospital transmission of RV, we changed our environmental cleaning wipes from those impregnated with amphoteric surfactant to those with PPD, and evaluated the clinical usefulness of PPD from the actual intervention. As a result, though the prevalence of RV was higher in 2013 after intervention than it was in 2012, a decrease in incidence density rate was observed. The decrease of incidence density rate suggested that changing the environmental wiping cloth to a PPD wipe, while reviewing the timing and method of hand hygiene, and ensuring proper guidance, education, and compliance in the ward, may have contributed to the prevention of secondary propagation of RV infections. Moreover, in the questionnaire survey, it was shown that PPD is easier to use for reasons such as "there is no irritating smell," "preparation is not troublesome," etc. compared with NaClO used conventionally. PPD is less corrosive to metals and resins and is useful in environment improvement. Since it is a weighed individually package, it is a formulation featuring comparatively easy concentration control (18). PPD is an improvement on chlorine-based disinfectants and cleaning agents. PPD shows a pale red color when dissolved. Since the color tone changes in proportion to the decrease in the effective concentration of the disinfectant, this color change can be useful for estimating the effective concentration without measuring actually it (19). In this questionnaire survey, the usefulness and utility of PPD at the clinical site were evaluated. In addition, it was revealed that PPD shows a persistent bactericidal effect for 24 hours for bacteria such as MRSA and *Pseudomonas aeruginosa*, similar to amphoteric surfactants. Low-level disinfectants such as amphoteric surfactants, chlorhexidine, and quaternary ammonium compounds have been reported to exhibit persistent bactericidal effects (20). However, there is no report on the sustainability of chlorinated disinfectants such as NaClO; the results of this study are therefore very interesting. The mechanism of action of PPD is through a production of hypochlorous acid in aqueous solution when potassium peroxydisulfate oxidizes sodium chloride as a blending component (19). In this study, it was inferred that the bactericidal effect of the component of PPD that remained dry on the surface of the petri dish reacted with the moisture in the bacterial liquid, again producing hypochlorous acid as the active ingredient. NaClO undergoes natural decomposition even at room temperature (21), and it was thought that the persistence of the bactericidal effect disappeared because the remaining ingredients had decomposed by 60 minutes after application. In further investigations, it will be necessary to examine the sustainability of the effects of PPD on viruses.

CONCLUSION

This study showed that intervention to promote the use of PPD was useful in preventing secondary infection of RV in pediatric ward. PPD was also considered to be useful from the viewpoint of persistent antimicrobial action, convenience, and safety.

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Risk factors and outcome analysis of gram-positive and gram-negative neonatal sepsis: A case-control study

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ABSTRACT

Background: In developing countries, neonatal sepsis is responsible for 30-50% of the total neonatal deaths. The aim of this study was to investigate the host related, clinical practice related and environment related risk factors for neonatal gram-positive sepsis (GPS) and gram-negative sepsis (GNS) and their effect on outcome.

Methods: We conducted a case-control study including 50 neonates with Blood Stream Infections (BSI) caused by both susceptible and resistant bacteria and 50 controls without BSI.

Results: Applying Chi square test of significance and running Logistic regression analysis it was observed that neonates with low birth weight, premature rupture of membranes, congenital anomalies (host related factors) exposure to broad spectrum antibiotics and steroids, caesarean section (clinical practice related factors), expressed milk/formula feeding, mechanical ventilation, and delay in enteral feeding (environmental factors) were the independent risk factors for blood stream infections (BSI) (p value <0.05). BSI caused by both gram-positive and gram-negative organisms increase mortality compared to the controls. The mortality rate tabulated for neonates with GPS was observed to be 45.9% and 28.6% for neonates with GNS. The odds of neonates with GPS and GNS to die are 3.55 and 6.29 times more respectively, than neonates not having sepsis.

Conclusion: Morbidity and mortality due to BSI can be prevented by controlling the risk factors at an early stage.

KEY WORDS

risk factor, outcome analysis, neonatal sepsis

INTRODUCTION

Neonatal sepsis is responsible for 30-50% of the total neonatal deaths in developing countries (1). The reported incidence of neonatal sepsis varies from 7.1 (2) to 38 (3) per 1000 live births in Asia. Many pre- and intra-partum obstetric complications are associated with an increased risk of infection in the newborn. Sophisticated equipment used for respiratory and nutritional support combined with invasive techniques provide extensive opportunities for relatively non-virulent pathogens to establish infection and to invade the host (4).

Thus, identifying the risk and prognostic factors prevailing in the different geographical contexts has become a crucial issue for optimizing neonatal care. As there is scarce information

on these topics, this study was carried out with the aim of analysing the risk factors independently associated with Gram-positive Sepsis (GPS) and Gram-negative Sepsis (GNS) in neonates and to compare the clinical outcomes of such patients with that of the controls.

METHODS

Settings

This study was carried out at a tertiary care hospital in North India. The hospital is a 2,000-bed hospital providing dedicated medical services in all major specialties, including intensive care, medical and surgical care.

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Study design

This was a case-control study, with a 1:1 allocation. Blood stream infection (BSI) in a neonate was confirmed as per the Centers for Disease Control and Prevention (CDC) criteria (5). Neonates (age 0-28 days) meeting these criteria were included in the study as “case patients,” with an equal number of controls without BSI. Control patients had to be a neonate, admitted in the same ward on the same day (+/- 2 days) as that of the case patients. The time when the first positive blood culture was obtained was chosen as the time of inclusion into the study. The study design was approved by the Institutional Ethics Committee.

Data collection

Health records of the case and control patients were used to collect the data. The details included patient characteristics, clinical condition, practice related data, environment related data and investigation data. Outcomes of interest included length of hospital stay (LOS), post infection length of stay and in-hospital mortality.

Definitions

GPS was defined as retrieval of gram-positive organism from at least one blood culture specimen. GNS was defined as isolation of gram-negative organism from at least one blood culture specimen. Mixed cultures having both gram-positive and gram-negative organisms were not included in the study, though mixed growth of either gram-positive or gram-negative organism was included. All positive blood culture specimens were categorized as true or contaminant based upon the clinical history, physical finding, clinical course and response to treatment. Total LOS was defined as the period between admission and discharge. Post infectious LOS was defined as period between enrolment in the study and discharge. In-hospital mortality was defined as any death occurring in the hospital due to sepsis.

Microbiological methods

All microbiological specimens were processed at the Microbiology Laboratory of the tertiary care centre. Blood culture and identification was performed as per standard microbiological techniques. Antimicrobial susceptibility test was performed according to Clinical and Laboratory Standards Institute guidelines (6).

Statistical analysis

The demographic and the clinical profile of the cases and controls were compared using descriptive tables. Risk factor analysis was performed for both cases and controls. Statistical analysis was performed separately for GNS and GPS. Significant parameters were evaluated using Pearson's Chi-Square and for cases with expected count less than five Fisher's exact test was used. Logistic regression was used as confirmatory test for statistically significant parameters. Further, odds ratio (OR), probability and confidence interval at 95% significance have been tabulated, individually and

overall, to depict the association between the risk factors and neonatal sepsis. To aid the tabulation of OR, a value of 0.25 (according to recent simulation) was added to cases with cell frequencies as null. An unpaired t-test was used to compare the means of LOS for GPS and GNS. To summarize the outcome analysis, logistic regression was conducted, keeping mortality rate as a dependent variable and presence of sepsis as an explanatory variable and mortality rate of sepsis related cases was projected. All analysis were performed using SPSS statistics version 19.0 software.

RESULTS

Study population and patient characteristics

As is seen in Table 1, cases were matched to control at a ratio of 1:1 and the demographic and patient characteristics were compared. In our study the age range of the patients at the time of presentation with GPS is 1-25 days while that of GNS is 1-8 days.

Microbiological characteristics

Among the 50 cases, 48% were GPS while 52% were GNS. Among the gram-positive organisms, most commonly isolated bacteria were *Staphylococcus aureus* (18%) and coagulase negative bacteria (18%) (Confirmed on repeat isolation). Only three isolates were of *Streptococcus* and *Enterococcus* each. Most of the organisms implicated in GNS were *Klebsiella* (20%) and *E.Coli* (14%). *Acinetobacter* caused sepsis in one patient and four cases were of *Pseudomonas* septicaemia. Four cases had sepsis due to mixed flora which were all gram-negative.

Risk factors for acquisition of GPS and GNS

Table 2 presents host related, practice related and environmental risk factors associated with neonatal sepsis analysed independently for their association with GPS and GNS in neonates by appropriate statistical methods.

Clinical outcome analysis of patients with GPS and GNS

Table 3a, describes the mean LOS for cases which was higher than controls. The post infectious LOS was less in GNS cases. The factors discussed earlier are independent risk factors for causing Gram-positive Sepsis which thus led to more neonatal deaths. On running logistic regression analysis the projected mortality rate was 45.9% for neonates with GPS and 28.6% for neonates with GNS (Table 3b). The odds ratio depicts the mortality risk for cases to be 3.55 times more than controls for patients with GPS and 6.29 times higher for cases than controls for patients having GNS.

DISCUSSION

Based upon its transmission, sepsis could be classified as, early onset sepsis occurring due to vertical transmission and being mainly caused by gram-negative bacteria; while the late onset sepsis would occur by horizontal transmission and would be principally associated with gram-positive bacteria acquired after delivery (7) a finding corroborated by this study.

In the present study *Klebsiella sp.* and *Staphylococcus sp.* were most commonly isolated. Leal et al also had *Staphylococcus* as their most frequently isolated species.⁸ In a study carried out in Overall, gram-negative organisms are mainly represented by *Klebsiella*, *E.coli*, *Pseudomonas* and *Salmonella* (10,11). Of the gram-positive organisms, *S. aureus* (9,10,12,13), Coagulase negative *Staphylococci*, *S.pneumoniae* and *S.pyogenes* (14), are most commonly isolated.

Similar to our study previous studies have identified prematurity, low birth weight, premature rupture of membranes, maternal pyrexia, poor intra- and post-partum hygiene, invasive medical procedures, and hospital stay (15-17) as the risk factors for neonatal sepsis. Though no such association was seen in our study, few other studies describe a strong association between prematurity and neonatal sepsis. Multivariate analysis of risk factors for proven neonatal sepsis by Yancey MK et al, has demonstrated a statistically significant association with decreasing gestational age (18). At birth, an infant's immune system remains immature. Some protection is provided by maternal antibodies (IgG) crossing the placenta. This process is less complete in the premature baby, especially if markedly premature. Not only this, preterm infants are more likely to require invasive procedures, such as umbilical catheterization and intubation.

Whilst infections can occur in utero, birth represents an abrupt transition from a highly protected environment to exposure to a vast array of new pathogens ex utero. Parturition also places the baby in direct contact with maternal blood or genital secretions and infections may result, especially if there was prolonged or early rupture of membranes.

Hence, PROM is associated with 1% increase in the incidence of neonatal sepsis; however, when chorioamnionitis

accompanies the rupture of membranes, the incidence of neonatal infection is quadrupled (19). In our study PROM increased by 40.76 times, the chances of development of GPS. PROM may occur in response to an untreated Urinary tract infection (UTI) or birth canal infection which are themselves independent risk factors for neonatal sepsis.

Congenital malformations predisposed the infant 159.9 times to the development of GPS, as has been noticed in the present study. For example, congenital lung anomalies may cause aspiration pneumonia predisposing the neonate to sepsis. Similarly congenital malformations requiring surgical treatment form an independent risk factor for development of sepsis (20).

Neonatal fungal infection has almost exclusively been described in the very low birth weight baby. In general larger babies are almost never affected unless are on prolonged intravenous feeding, for example because of gut pathology or congenital malformation (21). In the present study low birth weight babies had 12.26 times more chances of development of GNS. Also, the study reveals that 69.7% neonates with low birth weight developed gram-negative sepsis.

Studies have consistently shown that duration of antibiotic use, particularly broad spectrum antibiotics, is a major risk factor for neonatal fungal infection (22). Here prior antibiotic administration predisposed the child to develop GPS (OR 33.2) and as well as GNS (OR 5.33). This may be because the prior antibiotic administration may be due to some other coexisting risk factor such as congenital malformations, surgery or PROM.

Similarly prior steroid use was associated with GNS with an OR of 90.26, as steroid is usually administered in case of premature delivery which itself is an independent risk factor for development of neonatal sepsis.

TABLE I: Demographic and clinical characteristics of study population (n=100)

Characteristics	Patients with gram positive bacteremia		Patients with gram negative bacteremia	
	Cases (n=24)	Controls (n=24)	Cases (n=26)	Controls (n=26)
Sex n (%)				
Male	18 (66.6)	12 (50)	15 (57.7)	17 (65.4)
Female	6 (33.3)	12 (50)	11 (42.3)	9 (34.6)
Diagnosis at Admission n (%)				
Medical	19 (79.2)	24 (100)	20 (76.9)	22 (84.6)
Surgical	5 (20.8)	0 (0)	6 (23.1)	4 (15.4)
Fever/hypothermia n (%)	11 (45.8)	2 (8.33)	17 (65.4)	4 (15.4)
Respiratory Rate >60/min, n (%)	19 (79.1)	16 (66.67)	10 (38.5)	14 (53.8)
Total Leucocyte Count <5000 or >15000, n (%)	6 (25)	4 (16.7)	13 (50)	12 (46.1)
Immature WBCs <20 %, n (%)	10 (41.7)	2 (8.33)	11 (42.3)	11 (42.3)
Lethargic n (%)	14 (58.3)	4 (16.7)	9 (34.6)	6 (23.1)
Age at admission (age in hours)	16 (>72)	5 (>72)	24 (≤72)	26 (≤72)

Table 2: Risk factor analysis for gram positive sepsis in neonates												
Characteristics	GPS						GNS					
	Cases (n=24)	Control (n=24)	P value	Odds Ratio	Probability	CI (95%)	Cases (n=26)	Control (n=26)	P value	Odds Ratio	Probability	CI (95%)
Host Factors												
Low Birth Weight	8	16	0.021				23	10	<0.001	12.26	69.7%	2.908-51.76
Prematurity	5	14	0.008				13	10	0.402			
Maternal Infection	0	2	0.489				1	3	0.698			
PROM	7	0	0.009	40.76	undefined		3	0	0.235			
Meconium staining	1	6	0.097				8	5	0.337			
Congenital anomalies	15	0	<0.001	159.9	undefined		8	13	0.158			
Resuscitation	8	2	0.380				16	14	0.779			
Practice related												
Prior antibiotic use	6	0	0.022	33.2	undefined		16	6	0.005	5.333	27.3%	1.595-17.829
Prior steroid use	2	8	0.033				12	0	<0.001	90.26		
Caesarean section	5	8	0.330				12	2	0.002	10.28	14.3%	2.004-52.749
Previous surgery	2	0	0.489				6	4	0.482			
Environment related												
Mechanical ventilation	20	8	<0.001	10.0	28.6%	2.545-39.293	25	7	<0.001	67.8	21.8%	7.682-599.415
Venous catheter	20	18	0.477				26	18	0.004			
Expressed/ formula feed	20	12	0.014	4.99	37.5%	1.311-19.074	26	15	<0.001			
Delayed enteral feed	3	4	0.683				23	9	<0.001	14.48	28.05%	3.4-61.689

TABLE 3a: Clinical outcome of patients with sepsis caused by Gram Positive (n=24) and Gram Negative (n=26) organisms						
	GPS	Controls	P-value	GNS	Controls	P-value
Length of stay (LOS)(mean±SD)	12.75±10.16	10.88±5.4	0.43	12.46±8.24	9.85±7.34	0.23
Post infection LOS (mean±SD)	11.96±10.01	10.46±5.57	0.52	8.46±5.32	9.77±7.39	0.46
Mortality	13	6	0.038	13	6	0.002

Unpaired t test was applied.

TABLE 3b: Mortality in patients with GPS and GNS		
Mortality	Odds Ratio	Probability
Gram Positive Sepsis	3.55	45.9%
Gram Negative Sepsis	6.29	28.6%

Though delivery due to caesarean section may protect the child's exposure to the microflora of the birth canal during delivery; nevertheless, some data suggest an association between caesarean section and increased neonatal respiratory morbidity and lacerations (23). Not only this, the indications of caesarean section may themselves be independent risk factors contributing to neonatal sepsis. In our study the odds for developing GNS in neonates with caesarean section were 10.28 (OR). A total of 14.3% neonates born by caesarean section developed GNS.

It was observed that an invasive procedure such as mechanical ventilation was associated with 10 times increased risk of GPS and 67.8 times increased risk of GNS (with probability values 28.6% and 21.8% respectively). Central venous catheters, peripheral arterial and venous cannulas, hyperalimentation infusions and assisted ventilation provide enormous opportunities for relatively non-virulent pathogens to establish infection and to invade the host.

Neonates on expressed and formula feed had more chances of acquiring GPS (OR 4.99 probability 37.5%). GNS was 14.48 times more common in neonates with delayed enteral feeding (probability 28.05%) as seen in our study. In a study conducted by Ashraf RN et al (24) a highly significant odds ratio of 18 was obtained for formula fed neonates, showing that even partial breastfeeding protects against sepsis. Our findings indicate, however, that early breast milk may have a direct anti-infective action and may stimulate neonatal immune function as well as decreasing the ingestion of infectious pathogens. Close contact between the infant-mother dyad and stimulation of the entero-mammary mucosa-associated lymphoid tissue system may also contribute (25). Delayed enteral feed also increased the risk of GNS in the present study. The risk of death as a result of infectious causes increased with increasing delay in initiation of breastfeeding (26).

A further aim of the present study was to evaluate clinical outcome variables of neonatal sepsis caused by gram positive and gram negative bacteria. As expected the mean LOS and post infectious LOS, is more in GPS as compared to controls. The lower mean post infectious LOS for GNS may be due to the earlier mortality in these cases. The in-hospital significantly greater mortality rate of the neonates with sepsis is in line with other studies (8,27).

This case-control study provides a preliminary evidence on which further larger trials may be planned in order to provide higher experimental evidence.

CONCLUSION

To define effective strategies to prevent neonatal sepsis risk-factor analysis should be done and possible sources of infections should be defined. Proper ante natal check-ups and monitoring play an important role in improving the outcome of pregnancy. Exclusive early breastfeeding practices and rationale antibiotic use should be practiced. Minimizing invasive procedures has shown an impact in reducing nosocomial infections. Fewer venepunctures and

intravenous catheters minimize the risk for infections (2). Skin preparation before procedures has been shown to be effective, but studies are needed on the exact procedures and antiseptics to be used in newborn. The importance of appropriate sterilization procedures for the equipment used in neonatal units also needs to be emphasized.

Studies looking at early discharge policies for low risk new born as a means of reducing infection need to be undertaken. In summary longer hospitalization periods and increased mortality caused by neonatal sepsis, suggest the need to control influencing risk factors in such patients at an early stage. Not only this, the presence of the particular set of risk factors can help in deciding the empirical antibiotic therapy and there by prevent delay in starting appropriate treatment.

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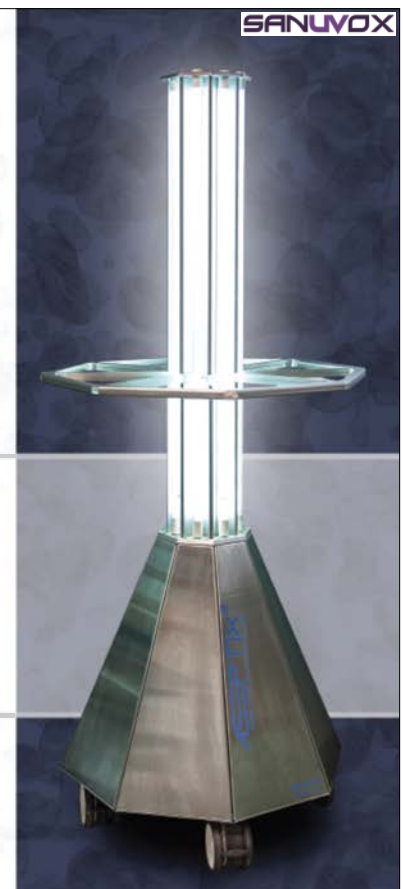
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Clustering of *Serratia marcescens* infections during six years: Epidemiology and risk factors for mortality

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ABSTRACT

Background: *Serratia marcescens* is responsible for hospital-associated infections found in clusters and outbreaks. Based on a previous outbreak in our institution, we aimed to evaluate epidemiological characteristics and risk factors for mortality of patients with *S. marcescens* infection in the previous five-year period.

Method: A retrospective analysis of the patients with *S. marcescens* colonization and infection between January 2008 and December 2012 was included. Data included demographical characteristics, co-morbidities, and invasive procedures performed were obtained from the computer databases, the microbiology laboratory, and infection control surveillance data. Data were plotted monthly on process control charts including Exponentially Weighted Moving Average (EWMA) statistics.

Results: We identified 378 patients colonized or infected with *S. marcescens* between January 2008 and December 2012. The median age of patients was 57 years (0-90 years). Of all hospitalized patients 60 (21.7%) expired and 216 (78.2%) survived. Previous ICU stay, respiratory failure, loss of consciousness, total parenteral nutrition, mechanical ventilation, intubation, central catheterization, urinary catheterization, hemodialysis, previous use of antibiotics were significant risk factors for mortality. Multivariate analysis showed that mortality risk of *Serratia* infection increased threefold for hemodialysis patients and fivefold for intubated patients. A mean monthly level of *Serratia* infections hospital-wide identified from process control chart statistics was 6.3 and ranged from 5.2-8.8 over five years. For ICU cases the mean was 1.9 and ranged over five years from 1.1 to 3.3.

Conclusions: *S. marcescens* is an opportunistic pathogen associated with significant mortality. We documented that *S. marcescens* strains persisted over prolonged periods causing cluster of infections. Clinicians should consider that small clusters of *S. marcescens* infections are the tip of the iceberg and may be a predictor of an outbreak.

KEY WORDS

Serratia marcescens, cluster, intensive care units, outbreak

INTRODUCTION

Serratia marcescens is responsible for hospital-associated infections found in clusters and outbreaks (1). We have previously reported outbreaks of postoperative empyema due to *S. marcescens* that was recognized in the intensive care unit (ICU) of our Division of Thoracic Surgery between 3 and 19 March 2013 related to a contaminated portable suction machine (2). All isolates were found to be identical by repetitive sequence-based polymerase chain reaction. Based on this outbreak, we aimed to evaluate epidemiological characteristics and risk factors for mortality of patients with *S. marcescens* infection in the previous five-year period. We also reviewed clustering of *S. marcescens* infections in the past years and the pattern of *S. marcescens* outbreaks in our institution.

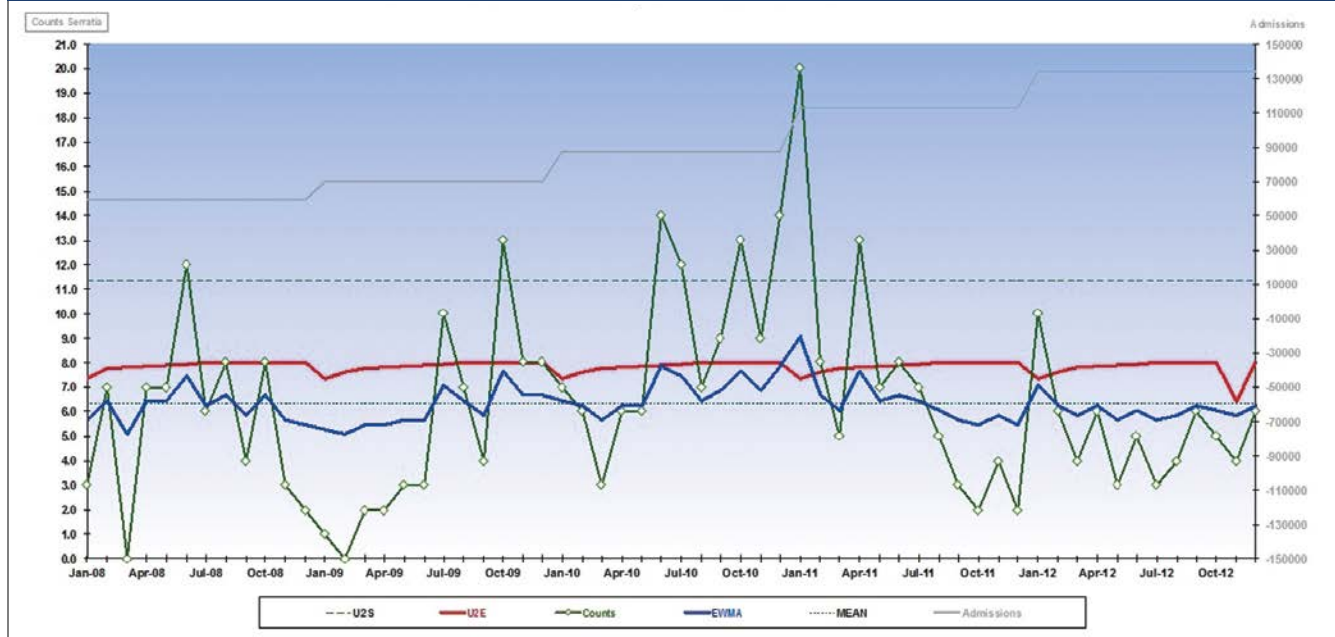
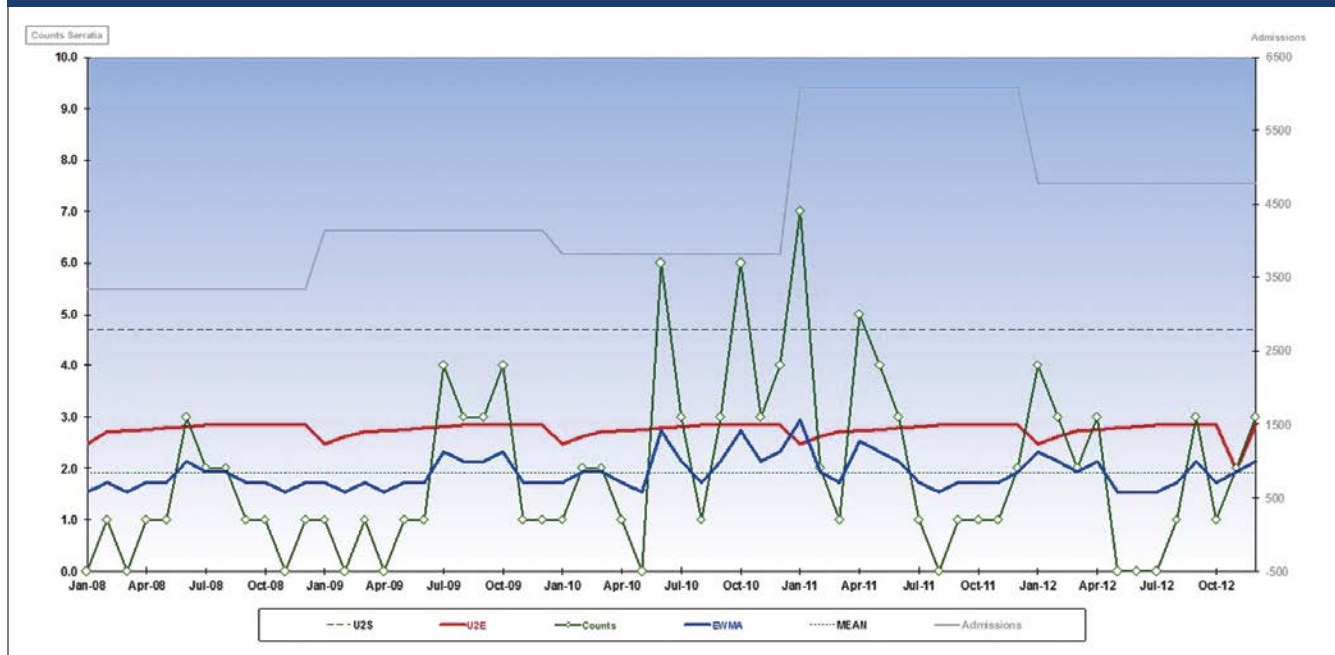
METHODS

We performed a retrospective study at Erciyes University Hospital. Patients with *S. marcescens* colonization and infection were included between January 2008 and December 2012.

Data included demographical characteristics, co-morbidities and invasive procedures performed was obtained from computer databases, the microbiology laboratory and infection control surveillance data. A retrospective data analysis was conducted to evaluate the risk factors for 30-day mortality.

We utilized process control charts to plot all *S. marcescens* infections in an attempt to visually demonstrate the statistics and identify the rapid increases in the number of cases (3). Data were plotted monthly on process control charts including Exponentially Weighted Moving Average (EWMA) statistics.

Statistical analysis: The statistical analysis was performed using SPSS software version 16 (USA). The chi-square test was used for the categorical variables. Mann-Whitney U test was used to determine the differences between the two groups. Univariate and multiple binary logistic regression analyses (model: backward Wald) were performed to analyze the effects of variables. The level of significance was set at $p < 0.05$ for all tests.

FIGURE 1: *Serratia* infections hospital-wide between 2008 to 2012 presented in EWMA statisticsFIGURE 2: *Serratia* infections from Adult Intensive Care Unit between 2008 to 2012 presented in EWMA statistics

RESULTS

We identified 378 patients colonized or infected with *S. marcescens* between January 2008 and December 2012. Of all patients with *S. marcescens* 17% (66/378) were outpatients and the remaining 83% (312/378) were inpatients from internal medicine, surgery, pediatrics and intensive care units. Overall, 51% of strains were isolated from the ICU patients.

The median age of patients was 57 years (0-90 years). Of all hospitalized patients 60 (21.7%) expired and 216 (78.2%) survived. Previous ICU stay, respiratory failure, loss of consciousness, total parenteral nutrition, mechanical

ventilation, intubation, central catheterization, urinary catheterization, hemodialysis, previous use of antibiotics were significant risk factors for mortality. Multivariate analysis showed that mortality risk of *Serratia* infection increased threefold for hemodialysis patients and fivefold for intubated patients (Table 1).

A hospital-wide mean monthly level of *Serratia* infections identified from process control chart statistics was 6.3 and ranged from 5.2-8.8 over five years (Figure 1). For ICU cases the mean was 1.9 and ranged over five years from 1.1 to 3.3 (Figure 2). Charted EWMA statistics illustrate fluctuations in

TABLE 1: Univariate and multivariate analysis of risk factors for mortality of *Serratia marcescens* infections

Risk factors	Died patients n: 60 (21.7 %)	Survived patients n: 216 (78.3 %)	P	Multiple analysis	
				OR (95% CI)	P
Age	60 (0-84)	57 (0-90)	0.157		
Male gender	18 (30.0)	66 (30.6)	1.000		
Internal medicine	6 (10.0)	54 (25.0)	0.001		
Surgical units	8 (13.3)	70 (32.4)			
Intensive care units	40 (66.7)	68 (31.5)			
Pediatrics	6 (10.0)	24 (11.1)			
Previous ICU stay	46 (76.7)	89 (41.2)	0.001		
Transfer from another institution	3 (5.0)	27 (12.5)	0.107		
Transfer between units	16 (26.7)	32 (14.8)	0.036		
Malignancy	15 (25.0)	54 (25.0)	1.000		
Multiple body trauma	4 (6.7)	11 (5.1)	0.747		
COPD	6 (10.0)	13 (6.0)	0.385		
Previous use of steroids	8 (13.3)	31 (14.4)	1.000		
Diabetes mellitus	9 (15.0)	34 (15.7)	1.000		
Unconsciousness	8 (13.3)	9 (4.2)	0.015		
Cardiac failure	5 (8.3)	13 (6.0)	0.555		
Immune-suppression	2 (3.3)	7 (3.2)	1.000		
Respiratory failure	38 (63.3)	67 (31.0)	0.001		
Renal failure	12 (20.0)	18 (8.3)	0.017		
Total parenteral nutrition	23 (38.3)	41 (19.0)	0.002		
Mechanical ventilation	44 (73.3)	73 (33.8)	0.001		
Transfusion	29 (48.3)	71 (32.9)	0.034		
Surgery	25 (41.7)	77 (35.6)	0.450		
Enteral feeding	22 (36.7)	34 (15.7)	0.001		
Urinary catheterization	46 (76.7)	115 (53.2)	0.002		
Hemodialysis	12 (20.0)	15 (6.9)	0.005	3.071 (1.267-7.447)	0.013
Intubation	44 (73.3)	73 (33.8)	0.001	5.244 (2.750-9.998)	0.001
Tracheostomy	13 (21.7)	33 (15.3)	0.327		
Drainage	5 (8.3)	18 (8.3)	1.000		
Thorax tube	9 (15.0)	41 (19.0)	0.572		
Central venous catheterization	32 (53.3)	54 (25.0)	0.001		
Bronchoscopy	5 (8.3)	7 (3.2)	0.142		
Arterial catheterization	18 (30.0)	33 (15.3)	0.014		
Percutaneous endoscopic gastrostomy	5 (8.3)	10 (4.6)	0.330		
Nasogastric drainage	27 (45.0)	46 (21.3)	0.001		
Previous use of antibiotics	50 (83.3)	136 (63.0)	0.003		
Aminoglycosides	7 (11.7)	20 (9.3)	0.624		
Beta-lactams	28 (46.7)	78 (36.1)	0.177		
Glycopeptides	10 (16.7)	26 (12.0)	0.386		
Carbapenems	19 (31.7)	41 (19.0)	0.050		
Quinolones	4 (6.7)	15 (6.9)	1.000		
Cephalosporins	18 (30.0)	58 (26.9)	0.744		
Other antibiotics	17 (28.3)	32 (14.8)	0.021		
Site of infection					
Blood stream infection	49 (22.7)	9 (15.0)	0.001		
Urinary system infection	28 (13.0)	2 (3.3)			
Pleural fluid	31 (14.4)	5 (8.3)			
Endotracheal aspirates/sputum	55 (25.5)	33 (55.0)			
Others	53 (24.5)	11 (18.3)			
Length of hospital stay before infection	11 (1-472)	7 (1-138)	0.024		
Length of ICU stay before infection	20 (1-472)	23 (1-254)	0.244		

outbreaks isolated throughout various parts of the hospital, but underline that outbreaks are driven primarily by the ICU. The peak of outbreak activity in ICU occurred in June 2008 and remained within statistical control limits until July 2009, when another peak recurred until it was controlled in November 2009. From that point onward, it remained under the upper limit but did not decline to zero until May 2010. The outbreak spiked in ICU rapidly in June 2010 remaining above statistical control limits until February and March 2012. After six months of zero cases the outbreak over the upper EWMA limit commenced in January 2012 and continued into April 2012 and again in September, November and December 2012. There were 10 months out of a total 48 months when no cases occurred.

The resistance rate of *S. marcescens* clinical isolates to ertapenem was 1.7% (3/172), imipenem 2.2% (6/268), amikacin 4.3% (12/276), ciprofloxacin 11.3% (31/274), cephalexin 26.9% (35/130), cefepime 15.3 (42/274) and ampicillin/sulbactam 4.45 % (9/202).

DISCUSSION

S. marcescens is an opportunistic pathogen associated with significant mortality. Infections caused by this bacterium have become a significant concern for its ability to cause hospital outbreaks, especially in ICUs and neonatal units (1,4). In this study, we retrospectively analyzed hospital-wide epidemiology of *Serratia* infections; its distribution among wards, antimicrobial resistance, clustering patterns and predictors of mortality.

Individuals at risk for *Serratia* infection tend to be inpatients with a prolonged hospital stay and history of invasive procedures. In our study, 17% of isolates were obtained from outpatients. However, while *S. marcescens* is a rare cause of community-onset infections, some part of them is considered to be health care associated. Antibiotic resistance is increased among patients with *S. marcescens*. High resistance rates to third-generation cephalosporins were previously reported from Taiwan and Korea (6,7). Though resistant strains have been associated with adverse outcomes, lower resistance and mortality rates were found in this study. Several risk factors were associated with 30-day mortality due to *S. marcescens* infections (7,8). In this study, the variables independently associated with 30-day mortality were history of hemodialysis and intubation.

One of the limitations of the study was that we did not perform molecular and epidemiologic analysis of clonal relatedness among *S. marcescens* strains. Since such analysis is costly, we took the advantage of using EWMA to detect suspected outbreaks retrospectively. Small clusters of *S. marcescens* infections are potential predictors of outbreaks (5). Clustering of cases in the ICU where we achieved several consecutive months of zero cases suggests that interventions need to be implemented early and be continuously reinforced.

In conclusion, *S. marcescens* is an opportunistic pathogen associated with significant mortality. We documented that *S. marcescens* strains persisted over prolonged periods causing

cluster of infections. These clustered cases require early detection and intervention to prevent outbreaks. Clinicians should consider that small clusters of *S. marcescens* infections are the tip of the iceberg and may be predictors of a likely outbreak.

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EMERGING TECHNOLOGIES

Surface and air: What impact does UV-C at the room level have on airborne and surface bacteria?

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Conflict of interest:

Dr. Lee is employed by VidaShield, which provided the UV-C products used in this study.

ABSTRACT

Background: Short-wave ultraviolet light (UV-C) is known to have the ability to render bacteria inert. We theorized that using UV-C in a continuous fashion at the room level would not only lower the amount of bacteria circulating in the air, but also lessen the amount of bacteria found on surfaces in the same space.

Methods: We set up field trials at three hospitals (Texas, Nevada, and Massachusetts) where we tested air and surface for bacteria, installed continuous UV-C products at the room level, and then tested air and surface again.

Results: In all cases, airborne bacteria was reduced between 79 and 91% over pre-installation values. Most surfaces also showed reductions in bacteria from 48 to 69%, although we report one incident of an increase of 288%.

Conclusion: The data indicate that using active air UV-C technology at the room level reduces the bioburden in the air and on surfaces, including in occupied spaces. Hospitals should consider implementing active UV-C technology to improve air quality.

KEY WORDS

air disinfection, UV-C, airborne bacteria

INTRODUCTION

An early publication on the effectiveness of ultraviolet light on bacteria is from 1877, when two British scientists noticed that Pasteur's solution, when placed in lead-covered test tubes, grew innumerable bacteria, while the same solution in unshielded test tubes placed in sunlight, did not (1). Since then, many studies have demonstrated that UV rays are a powerful way to render bacteria inert, beginning with Coblentz in 1922 (2) and Sharp in 1939 (3).

It has been known for decades that many diseases, such as tuberculosis and influenza, are spread via airborne and/or droplet transmission. More recently, studies have shown that pathogens thought to be spread through direct contact can also become aerosolized. Roberts et al. demonstrated that *Clostridium difficile* (*C. diff.*) spores could be disseminated through the air (4) as did Best et al. (5). Li et al. reviewed 40 studies to show a strong association between building ventilation and the transmission of airborne disease (6). Eames et al. wrote similarly, but with a tighter focus on hospital acquired infection (HAI), including methicillin-resistant *Staphylococcus aureus* (MRSA) (7). Nazaroff's discussion of indoor bioaerosol dynamics lays out how the airflow in a space moves particulate matter, including microbes (8).

Knowing that disease could be spread through the air, and that short-wave ultraviolet (UV-C) can render pathogens inert, it is logical that the medical community would turn to UV-C to reduce the amount of bacteria circulating in the air. Bolton and Cotton discussed how UV disinfection works in general (9) and Boyce discussed specific technologies for using UV-C in hospitals (10).

Rutala et al. studied how UV-C worked at the room level to eliminate bacteria (11).

Over the decades, several approaches to UV-C were developed. These methods included using UV-C as part of the water filtration system, using it in the HVAC system, and using it as a stand-alone, mobile product. Each method has some things to recommend it, in terms of effectiveness, ease of use, and cost, but also each one has drawbacks, including these same factors and, in the case of the mobile unit, the necessity for training as well as the requirement that the space to be treated be unoccupied. Reed provided an excellent historical perspective (12) and Memarzadeh et al. concluded that ultraviolet germicidal irradiation (UVGI) is a useful addition to the disinfection toolbox (13).

The potential for surfaces to hold onto microbial contaminants despite standard cleaning methods is clear. Hospodsky et al. noted that an important source of airborne materials is a result of human activity, such as entering a room, which resuspended particles from surfaces (14). Our study was designed to examine the effect of using UV-C at the room level on the amount of bacteria in the air, and whether cleaning the air would have a positive effect on surface bacteria.

METHODS

Environmental studies were conducted at an acute-care hospital in Massachusetts (Hospital A), an acute-care children's hospital in Texas (Hospital B), and an acute-care hospital in Nevada (Hospital C). In each case, the study materials and methodology

were the same. Baseline air and surface samples were taken, UV-C units were installed, and several weeks after that, air and surface sampling were repeated, and before-and-after results compared.

Baseline microbiologic sampling for the studies was accomplished by collecting air samples onto trypticase soy agar with blood (TSA) plates (Hardy Diagnostics, Santa Maria, CA). The sampler works by pulling air in through a perforated cover. The air impacts the agar plates, which are coated with blood. The cells that land on the plates start to reproduce and form colonies. These colonies are counted (raw CFU). This number is adjusted using a standard method for the probability that more than one viable particle was pulled through a single sampling hole and merged with other particles on the plate to produce a single colony. This adjustment is the correction hole factor.

Multiple samples were taken from each location. Representative areas sampled included next to the bed, at the window, near the linen cart, at the nightstand and near the window.

Air samples were collected with SAS 180 samplers (BioScience International, Rockville, MD). All air samples were run at 1000L (approximately five and a half minutes), and air was collected onto 90 mm sampling plates. As plates were collected, they were packed in coolers with gel packs, then packaged with gel packs and shipped overnight to an independent laboratory (Antimicrobial Test Laboratories (now Microchem Laboratories), Round Rock, TX).

Surface samples of 25 cm² were collected directly onto the Rodac sampling plates, using a straight downward motion to insure the sampling plate contacted the surface with sufficient pressure to collect the sample. Plates were then refrigerated and prepared for overnight shipping to the lab. For surface bacterial sampling, TSA with Lecithin and Tween plates were used.

Multiple samples were taken from each location. Representative areas sampled included the bed rails, the over-bed table, keyboards and chair arms. All plates were refrigerated and prepared for overnight shipping to the same independent lab. At the lab, all plates were incubated at 30 ± 2° C for 5-7 days, after which they were evaluated. Total colony forming units (CFUs) were recorded for each specimen.

In each study location, after pre-installation sampling was complete, UV-C units (VidaShield™; American Green Technology, South Bend, IN) were installed. Each unit contained a fully shielded UV-C bulb housed atop a standard 2 x 4 ceiling light fixture. A 59 watt shielded UV lamp produced 15 watts of high output ultraviolet-C energy at a wavelength of 253.7 nanometers. Because the radiation chamber where the UV lamp is housed is enclosed and the air passes through the chamber, there is little to no distance from the lamp to the air that passes directly over the lamp. At its furthest point, the span is 6 inches. Each unit holds four small fans (similar to those in a desktop computer) that create differential pressure to continuously draw air into the system at 50 cubic feet per minute. On the way to the irradiation chamber, the air passes through a MERV 6 filter to remove dust and large particulates and then, once treated, the cleaned air is pushed back into the room. The intake and exhaust baffles are set at a 30-degree angle, which moves the air in a pattern that avoids repeatedly recirculating the same air. The fans draw air into the unit at a rate of 50 CFM. When operating continuously, the unit theoretically will treat a volume of

FIGURE 1. UV-C unit diagram

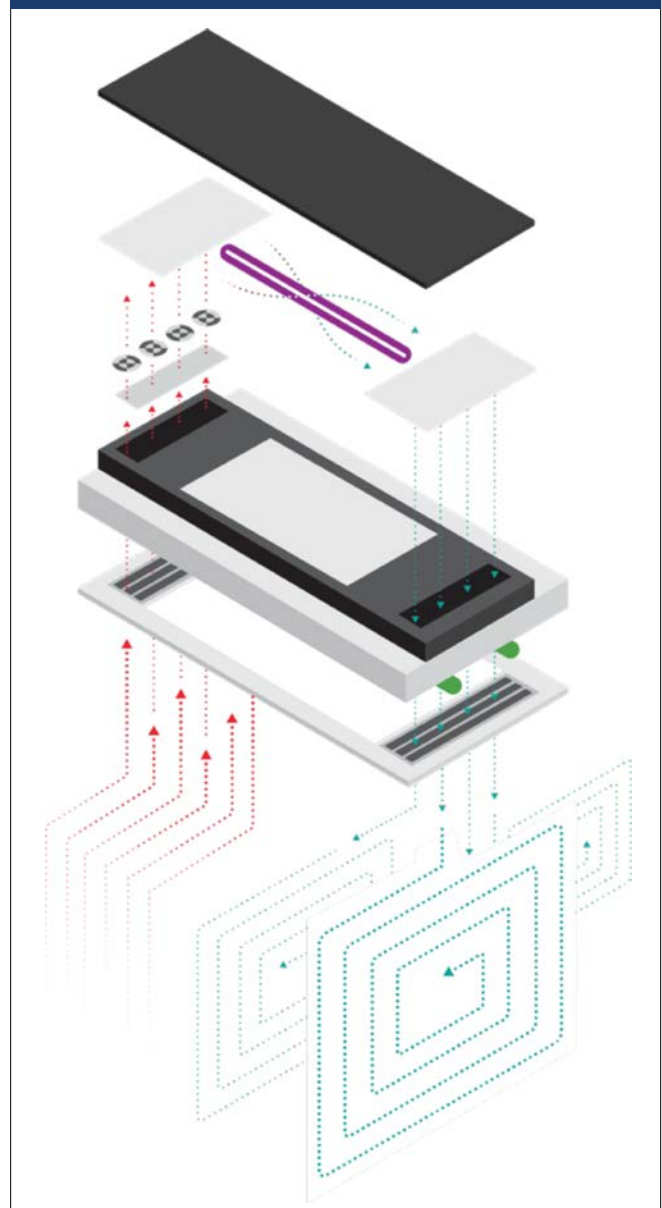


FIGURE 2. UV-C unit installed



air equivalent to an 8' x 10' x 10' (800 cubic feet) room four times per hour. The UV-C portion of the units run continuously, 24/7 whether the overhead room light is on or off. The units available for test were with no downlight, fluorescent/LED downlights and LED array downlights. Units were installed following each facility's infection control risk assessment (ICRA). Once the units were operational all areas were reopened for normal use. The product used in this study requires only minimal maintenance (an annual bulb and filter change), easily performed by existing facilities services staff.

For a variety of hospital operational reasons, after intervals of 228, 35, and 70 days (for Hospitals A, B, and C), the sampling was repeated. The same materials were used and the same methodology was followed. The same lab performed all testing. The intervals were counted from the day of the first unit installation. Room availability dictated the speed of installation and post-installation testing.

RESULTS

It is well established that UV-C is effective at treating the air. Therefore, results showing that airborne bacteria counts would be lower at the room level post-installation were expected. Because the air would be cleaner after UV-C treatment, we also anticipated a reduction in bacteria on surfaces, which we found in most cases.

By trialing continuous UV-C air purification technology in geographically distinct areas we hoped to discover its efficacy when implemented at the room level. In every case, the amount of airborne bacteria was greatly reduced, and in most cases, surface bacteria was also reduced.

Hospitals reported that healthcare-associated odors were diminished considerably. This was especially evident at Hospital C, where foul odors had been a constant in the closed unit psychiatric holding area, but also mentioned at Hospital A. We believe that cleaning the air with active UV-C technology not only reduced the number of CFUs present, but also resolved

odors. This may be due, at least in part, to the UV-C acting on the biological nature of the odors.

DISCUSSION

Hospodsky et al. documented human occupancy as the major source of indoor airborne bacteria but observed that the skin, nasal and hair that is shed becomes not only airborne but also settles on surfaces (14). Huang et al. explored the likelihood that a hospital patient could acquire antibiotic-resistant bacteria from someone who had been in the room before (15). Mitchell et al. expanded by performing a meta-analysis on the same topic. They noted the use of UV-C lighting fixtures as a way to reduce the likelihood of a future patient acquiring infection from a prior room occupant (16). King et al. studied surface contamination as a result of airborne disposition of bacteria. They found that small particle bioaerosols are spread with no correlation between surface area of contaminants and distance from the source (17).

Schabrun and Chipchase identified healthcare equipment as a significant source of nosocomial infections (18). Otter et al. agreed that contaminated surfaces are implicated in transmission of pathogens, and further called out UV-C as a disinfection technique with improved efficacy over conventional methods (19). Dumford identified portable hospital equipment as holding reservoirs of *C. diff.* (20) and Stiefel et al. investigated surfaces as a source of MRSA contamination (21). Shiomori et al. demonstrated that making the bed of a patient with MRSA dispersed MRSA into the air in significant amounts for at least fifteen minutes (22).

Kramer, Schwebke and Kampf looked at how long pathogens can survive on surfaces (23). *Acinetobacter* spp. survived up to five months, *C. diff.* up to five months, *Escherichia coli* up to 16 months, and *Staphylococcus aureus*, including MRSA, up to seven months. Jawad et al. pointed out that the relative humidity in a space impacts the survival of *Acinetobacter* spp. and concluded that the bacteria can be transferred from surfaces not only by moist vectors but also by dry ones (24).

It is clear from the literature that bacteria in the air and on

TABLE 1: Mean airborne bacteria correction hole factor CFUs pre- and post-installation

Study location	Mean CFUs pre-installation	Mean CFUs post-installation	Change	Student's t-test, one-tailed p value
Hospital A ICU	167	37	-79%	0.0305
Hosp. A OR Breakroom	472	92	-81%	0.0264
Hospital B patient room	599	55	-91%	0.0002
Hospital C 6 bed psych unit	439	88	-80%	0.0234

All facilities had significant reductions in airborne bacteria with 24/7 operation of the shielded UV-C ceiling unit.

TABLE 2: Mean surface bacteria correction hole factor CFUs pre- and post-installation

Study location	Mean CFUs pre-installation	Mean CFUs post-installation	Change	Student's t-test, one-tailed p value
Hospital A ICU	45	19	-57%	0.0049
Hosp. A OR Breakroom	120	62	-48%	0.2922*
Hospital B patient room	25	97	+288%	0.0104
Hospital C 6 bed psych unit	115	36	-69%	0.0288

*This p value due to small sample size

Most facilities had significant reductions in surface bacteria after implementing UV-C at the room level.

surfaces poses a risk to patients, visitors, and staff. Our study showed that using UV-C at the room level reduced the bio burden of the air, and, in most cases, of that on surfaces.

In our study, Hospital B had a very large percentage increase (+288%) in surface bacteria post-installation although the actual numbers weren't extreme (25, 97). We attribute this to the fact that the study room had been terminally cleaned before pre-installation samples were taken. The pre-installation samples were taken in a cleaned, unoccupied and closed room. The post-installation samples were taken in the room after a patient on isolation had occupied the room and had not been terminally cleaned at the time post-installation samples were taken. This result demonstrates the importance and efficacy of surface cleaning as part of the entire infection control process.

Limitations: A limitation of this study is the location of study sites in fully functioning operational facilities. We had no control over people opening and closing doors thereby affecting airflow into and out of the room, how and how often surfaces were cleaned, as well as the consistent cleaning procedures and the number and types of patients who occupied the spaces. Room furnishings were not identical, nor were layouts. Most patient rooms tested were occupied by patients or work areas were functioning as intended and in use by staff. These variables may have affected the results. A second limitation is the decision to study total bacteria CFUs, and not specific pathogens, fungi, or viruses. Because the study was in live environments, and not in a lab, we had no control over the number and types of pathogens that might be present. Because the hospital environment is dynamic and we did not seed the environment with any given pathogen we used total bacteria load as a surrogate for all pathogens. This approach might be seen as similar to using a biological indicator in a steam sterilizer to ensure hospital equipment and supplies are properly sterilized for use on patients. When the equipment is cleaned and wrapped and sterilized it would be hard to test every potential pathogen, but an indicator helps provide a level of assurance that the equipment is ready for use.

CONCLUSIONS

The data clearly demonstrate that using active air UV-C technology at the room level reduces the bioburden in the air and improves indoor air quality. In addition, the majority of the facilities had reduced surface bacteria in areas where continuous UV-C air purification at the room level was operational. Hospitals should consider adding active air UV-C technology at the room level to decrease airborne and surface microorganisms and improve indoor air quality.

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CONCISE REPORT

Comparison of bacterial loads of two types of hospital pillows: Perspectives of improving hospital hygiene standards

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ABSTRACT

There is increasing evidence that hospital pillows may spread pathogens. This study measured microbial loads inside disinfectable antimicrobial filter-equipped SleepAngel pillows (N=32) and pillows equipped with plastic covers (n=32). The bacteria were counted and identified. Filter pillows were more often sterile inside and contained fewer colonies than regular pillows (p=0.0001). Regular and SleepAngel pillows harbored equal amounts of microorganisms on surface but interior of SleepAngel pillows were more often culture negative, and hence, SleepAngel pillows transformed volumetric reservoirs to surfaces. SleepAngel pillows could contribute to a growing assortment of tools used in infection prevention and control.

KEY WORDS

microbiology, infection control, pillow, bedding, hospital hygiene

INTRODUCTION

Microorganisms can remain viable on common hospital surfaces up to several weeks. In contrast to evidence regarding hard surfaces, relatively few studies have focused on textiles (1, 2, 3, 5). Bedding constitutes a known reservoir for pathogens (8). Pillow seams and care labels that are attached by stitching to the pillow form the most significant vector for pathogens (7).

As microbes can enter regular bedding, bedding is not just a surface, but a volumetric pathogen reservoir. Usually plastic pillow protectors are used to prevent the entry. Legislation concerning microorganisms in pillows is vague – for example, EU council directive (2007/47/EC) states that a medical device must reduce risk for hospital-acquired infection. European Pharmacopoeia (Ph Eur) provides volumetric criteria for non-sterile pharmaceutical products: lack of *Staphylococcus aureus* and *Pseudomonas aeruginosa*, and the colony counts should not exceed the specific limits of each product category (4). However, these criteria appear relevant for assessment of volumetric hospital textile objects. The food industry has a standard of less than 5 cfu/cm² aerobic growth and lack of indicator microorganisms. Adaption thereof has been suggested (3) previously for surfaces of medical devices. Previously, no standards have been suggested for volumetric medical devices.

The aim of this study was to investigate and compare the microbial loads inside two types of hospital pillows after three months of use in the Turku University Hospital (Finland), maternity ward.

METHODS

Manufactured by Gabriel Scientific Ltd, the filter pillow (SleepAngel Pneumapure) is a European Conformity class I medical device designed for infection prevention. It has waterproof and zipperless structure combined with PneumaPure™ filter technology, which enables airflow into the pillow but blocks bacteria, viruses and allergens as well as ingress of liquid. Its pore size, 0.2 µm, is routinely used for guaranteeing cell culture purity (6). The filter pillows are manufactured in regular factory conditions that are not required to be sterile. The surface of the pillow requires disinfection before each patient. The regular pillows (cotton surface, synthetic filling) are equipped with open-ended plastic protectors, because sealing a pillow in the plastic would make it feel like a balloon under the head.

The pillows were used in hospital for three months. Before each patient admission, hospital personnel prepared the pillows. They disinfected the filter pillows' surfaces with an

Conflict of interest: Dr. Türk reports grants from Nautilite OÜ, during the conduct of the study; Dr. Christersson reports grants from Nautilite OÜ, during the conduct of the study; Dr. Rööp has nothing to disclose; Dr. Didenko has nothing to disclose.

all-purpose cleaner (Erisan Oxy+ 2%). They removed the regular pillows' plastic protectors and evaluated whether the pillows required laundry or merely changing the plastic pillow protector. The filter pillows (n=32) and regular hospital pillows (n=32) were collected from underneath a patient's head or from bed of a patient just discharged. Before collection, the pillows were subjected to the described hygiene routines (disinfection or cover change). None of the studied regular pillows were subjected to laundry immediately prior to collection. All pillows were collected on the same day.

MICROBIOLOGICAL ANALYSES

The pillows were packed into sterile bags, transported, treated equally, and sampled within 24 hours. The surface of the pillows was analyzed by contact plate method with blood agar (BA). The samples were taken by contacting the plate to four sites of a pillow.

Methods of interior sampling are based on Weernink et al. (8) and Ph Eur (4). Two cuts were made with a sterilized paper knife to diagonally opposed corners of the pillows in laminar flow cabinet. The contents (20 to 25 ml) were pulled out with sterile forceps and inserted into 20 ml sterile saline in 50 ml sterile falcon tube. The samples were shaken and then vortexed for two minutes. 100 µl samples were plated on horse blood agar (BA), CLED agar and Saboraud Emmons (SE). BA and CLED were incubated for 32 hours at 37°C; SE was incubated for 80 hours at 37°C.

The number of colonies and types of colonies was recorded and pure cultures were isolated onto Mueller-Hinton agar for further analysis. The pure cultures from pillows were identified by means of MALDI-TOF (database: MBT Compass Library DB-5989) according to manufacturers' instructions. In case of unclear identification, the analyses were repeated.

RESULTS

Interiors of regular pillows were more often culture positive than filter pillows (Fisher's exact test $p=0.0002$) (Table 1), the total counts of microorganisms from inside of regular pillows were higher, as well (T-test $p=0.035$). One regular pillow interior yielded more than 100 CFU per milliliter of interior

material. The surfaces of regular pillows yielded greater counts of bacteria but the difference was not statistically significant. The diversity of microorganisms on regular pillows appeared higher than that of filter pillows. The microorganisms detected from insides and surfaces of the pillows appeared mostly commensal, no serious healthcare-associated pathogens were detected. Any pillow with any bacteria would have exceeded the Ph Eur standard for mass 10^1 CFU/g, and is identical to analysis of sterile vs nonsterile. Some of the microbes could not be identified by means of MALDI-TOF. No mechanical failure was observed in any pillow.

DISCUSSION AND CONCLUSIONS

This study highlights the role of regular hospital pillows as bacterial reservoirs. We did not detect any known healthcare-associated pathogens; typical bacterial isolates were coagulase-negative staphylococci. Moreover, we considered the counts of microorganisms as low even in the regular pillows. It is possible that this was influenced by clinical setting, which in our study was maternity ward. Perhaps a different picture would have emerged in an infectious diseases, urology or intensive care ward. On the other hand, reducing transmission of coagulase-negative staphylococci has been highly relevant to immunocompromised patients for decades (9).

Filter pillows mitigated the reservoir function from volumetric to that of surface. The bacteria inside the filter pillows were probably sealed into the pillows during production, while majority of microorganisms isolated from the regular hospital pillows probably originated from the patients (the bacteria bypassed the plastic pillow protectors into the interior). This would provide rationale for the higher inside counts in the regular pillows. The disinfection of the filter pillow surfaces reduced microbial counts more effectively than passive protection provided by the pillow covers. This would provide rationale for the trend towards higher surface microbial counts on the regular pillows.

A larger study with in a more challenging hospital setting is necessary to investigate whether filter pillows' mitigation of reservoir function from volumetric to that that of the surface translates to actual reduction of hospital-acquired infections.

TABLE 1: Distribution of bacterial colonies from pillows

Number of contaminated pillows by identified microorganisms

Sample	N of samples	N of colonies	MSSA [§]	CoNS [€]	<i>M. luteus</i>	<i>Bacillus</i> spp. [#]	<i>Caulobacter</i> sp.
Interior	Filter pillow	32	3	0	0	0	1
	Regular pillow	32	65	0	6	1	0
Surface	Filter pillow	32	82	0	1	0	3
	Regular pillow	32	264	1	16	5	0

[€] Coagulase-Negative staphylococci: *S. epidermidis*, *S. warneri*, *S. hominis*, *S. capitis*, *S. pettenkoferi*.

[#] *Bacillus mycoides*, *Bacillus* spp.

[§] methicillin-susceptible *Staphylococcus aureus*

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Through the generous support of SealedAir Diversey, 19 IPAC Canada members were supported to attend the 2017 annual conference in Charlottetown. The recipients included members with novice, intermediate, and advanced expertise. IPAC Canada thanks SealedAir Diversey for the opportunity for selected candidates to have the support needed to attend the conference. Watch for an announcement of the 2018

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CONCISE REPORT

Lipid emulsion increases the risk of central line infection in Japanese adult inpatients: A retrospective study

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ABSTRACT

Background: Several studies have suggested that lipid emulsion (LE) increases the risk of central line infection (CLI) in adult patients. However, there are limited data on the relationship between LE and CLI.

Methods: We retrospectively reviewed all patients who had had a central venous catheter (CVC) inserted during a 13-month period at our institution. CLI was defined as a catheter-related local infection or a central line-associated bloodstream infection.

Results: We observed 25 CLIs in 163 cases (143 patients) of CVC insertion, giving a rate of 4.6 per 1000 catheter days. In multivariate logistic regression analyses, administration of LE was associated with an increased risk of CLI (odds ratio 3.12, 95% confidence interval 1.22–8.58). Parenteral nutrition was also associated with an increased risk of CLI (odds ratio 7.86, 95% confidence interval 1.45–146.10).

Conclusions: Our results suggest that administration of LE is associated with an increased risk of CLI in hospitalized Japanese adults.

KEY WORDS

lipid emulsion, central line infection, parenteral nutrition

INTRODUCTION

Infusion of lipid emulsion (LE) during the early period following injury has been reported to increase susceptibility to infection (1). Further, LE administered more than twice weekly is associated with central line-associated bloodstream infection (CLABSI) in patients receiving home parenteral nutrition (PN) (2). Freeman et al. (3) showed that catheters could be colonized within 24–48 h of insertion, and when a nutrient-rich growth medium such as LE is infused through the colonized catheter, only a few hours of rapid growth are required for numbers of coagulase-negative staphylococci to reach levels sufficient for bloodstream invasion. Moreover, some studies have suggested that infusion of LE is a risk factor for coagulase-negative staphylococcal bacteremia in very low birth weight newborns (4) and *Malassezia furfur* fungaemia in infants (5). Further, in a systematic review and meta-analysis, Austin et al. showed that inclusion of LE in PN is one of several factors that may influence microbial growth (6). These observations suggest that LE may be

associated with an increased risk of central line infection (CLI).

However, a database analysis by Pontes-Arruda et al. (7) reported no significant association between LE administered with premixed PN and increased risk of infectious morbidity when compared with PN that did not contain lipids. In contrast, several studies have reported that LE increases the risk of CLI in adult patients receiving critical care (1) and home PN (2), while Austin et al. (6) reported that the evidence base for an association between LE and microbial growth is equivocal. The aim of this study was to examine the relationship between LE and CLI in Japanese adult inpatients.

METHODS

This 13-month retrospective study and its protocol were approved by the Ethics Committee of Kaetsu Hospital. The records of all patients who had undergone insertion of a central venous catheter (CVC) in Kaetsu Hospital, a 261-bed facility

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Conflicts of interest: None declared.

with 6 wards in Niigata, Japan, between 1 January 2014 and 31 January 2015 were reviewed. The demographic and clinical characteristics of patients who developed CLI were compared with those who did not (Table 1).

The frequency of administration of LE was calculated as the duration of administration of LE divided by the duration of catheter insertion. We excluded patients who received LE for the delivery of pharmaceutical agents (e.g., propofol, flurbiprofen, or alprostadil), had subcutaneous ports, had the catheter removed for ≤ 2 days, did not undergo catheter removal (continued CVC for home PN or transferred to another hospital), or had the catheter removed after February 2015. We excluded episodes of CLI that followed a second CLI during a single hospitalization (several patients experienced multiple CLIs).

The insertion site was selected by the attending physician. Ultrasonography was occasionally used to guide insertion according to the physician's discretion. The skin at the insertion site was disinfected with 1% chlorhexidine in 70% alcohol. After insertion of the CVC, the area surrounding the catheter was cleaned and an occlusive dressing was applied to cover the site. The insertion area was examined daily for the presence of any abnormality by the nurse assigned to the patient. Catheter dressings were changed every seven days (the standard

time interval for dressing changes in Japan) or sooner at the discretion of the nurse caring for the patient if the dressing was contaminated. The insertion area was disinfected with 1% chlorhexidine in 70% alcohol each time the catheter dressing was changed. Connecting lines with an in-line filter were also changed every seven days. The decision to remove the catheter was made by the patient's physician. The catheters were removed when they were no longer required; other reasons for catheter removal included development of complications, accidental removal, or death of the patient. The removed catheter tips were not routinely cultured. No antibiotic creams, antibiotic lotions, or antimicrobial-coated catheters were used. For infusion of LE, 100-250 mL/day of 20% soybean oil-based LE was administered for 3-6 h piggybacked through the CVC line below the in-line filter. The line used for administration of LE was removed after the infusion was complete. The CVC line was not flushed with saline after the LE line was removed.

CLI was defined as catheter-related local infection (CRLI) or CLABSI. CRLI was defined as the presence of any sign of local infection (induration, erythema, heat, pain, or purulent drainage). CLABSI was defined as a positive blood culture obtained from a peripheral vein and presence of signs of a systemic infection (fever, chills, and/or hypotension), with no

TABLE 1: Clinical and demographic characteristics

	Non-CLI (n = 138)	CLI (n = 25)
Diagnosis, n (%)		
Gastrointestinal disease	36 (26)	2 (8)
Respiratory disease	35 (25)	13 (52)
Central nervous system disease	33 (24)	7 (28)
Cardiovascular disease	29 (21)	3 (12)
Other disease	5 (4)	0 (0)
Age, years (SD)	81 (12)	81 (6)
Sex, n male (%)	75 (54)	18 (72)
Body weight, kg (SD)	42 (12)	46 (14)
Insertion site, n (%)		
Subclavian	9 (7)	0 (0)
Internal jugular	23 (17)	3 (12)
Femoral	106 (77)	22 (88)
Duration of catheter insertion, days (SD)	33 (35)	37 (27)
Multi-lumen catheter, n yes (%)	12 (9)	2 (8)
Use of maximal sterile barrier precautions, n yes (%)	122 (88)	23 (92)
Use of alcohol-based hand rub, L/1000 patients (SD)	7 (2)	8 (3)
Administration of PN, n yes (%)	93 (67)	24 (96)
Duration of PN administration, days (SD)	19 (33)	27 (22)
Frequency of LE administration 0.2 times or more, n yes (%)	47 (34)	17 (68)

Continuous variables were reported as the mean and standard deviation and categorical variables as the frequency and percentage. Frequency of LE administration was calculated as duration of LE administration divided by duration of catheter insertion. Abbreviations: CLI, central line infection; LE, lipid emulsion; PN, parenteral nutrition; SD, standard deviation.

apparent source of bacteremia except the catheter (8).

JMP9 statistical software (SAS Institute Inc., Cary, NC) was used for all statistical analyses. Continuous variables are reported as the mean and standard deviation and categorical variables as the frequency and percentage. Multivariate modelling was performed using logistic regression with a stepwise backward-forward selection ($P < 0.25$) procedure to identify independent factors associated with CLI. Patient age, sex, and body weight, duration of catheter insertion, femoral CVC insertion, use of maximal sterile barrier precautions, use of a multi-lumen catheter, use of alcohol-based hand rub during the month of CVC insertion in the ward, administration of PN, and frequency of LE administration were included in the multivariate analysis. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated. $P < 0.05$ was considered to be statistically significant.

RESULTS

The study included 143 patients (55% male) with a median age of 83 (range 26-97) years and a median body weight of 41 (range 21-97) kg. One hundred and sixty-three cases (143 patients) of CVC insertion were included. Fifty cases were excluded, including 18 episodes for which LE was used for administration of another pharmaceutical agent (13 and 5 cases received flurbiprofen and alprostadil, respectively), one case of repeat CLI after a second CLI during a single hospitalization, eight cases where the catheter was not removed (four instances each where the CVC was continued for home PN or the patient was transferred to another hospital), and 23 cases where the catheter was removed after February 2015. No patient underwent insertion of a tunneled catheter, subcutaneous port, or a peripherally inserted central catheter.

The case profiles are shown in Table 1. The non-CLI and CLI groups included 138 and 25 cases and had 4565 and 916 catheter days, respectively. We identified 25 cases of CLI, giving a rate of 4.6 per 1000 catheter days. Twelve microorganisms were isolated from blood culture, including five methicillin-resistant *Staphylococcus epidermidis*, four *Staphylococcus aureus* (three of which were methicillin-resistant), and three methicillin-resistant coagulase-negative staphylococci.

The results of multivariate logistic regression analyses of factors potentially associated with CLI are shown in Table 2. Administration of LE 0.2 times or more was associated with an increased risk of CLI (OR 3.12, 95% CI 1.22–8.58). Administration of PN was also associated with an increased risk of CLI (OR 7.86, 95% CI 1.45–146.10).

DISCUSSION

Administration of LE was associated with an increased risk of CLI in multivariate analyses. Our findings in Japanese adult inpatients are similar to those of other studies suggesting that LE increases the risk of CLI in adults being treated in critical care units (1) and in those on home PN (2). It has been reported that administration of LE supports growth of bacteria in a CVC. Freeman et al. (3) showed that only a few hours of rapid growth are required for the numbers of bacteria to reach levels sufficient for bloodstream invasion when LE is infused through a colonized catheter. This report is consistent with our observations. However, it is difficult to stop infusions of LE when they are being administered for nutrition. We have reported that a saline flush after administration of LE might decrease the risk of CLI (9) and now recommend routine use of saline flushes for this purpose.

In our study, multivariate analyses showed administration of PN to be associated with an increased risk of CLI (the OR for PN was higher than that for LE). Austin et al. (6) showed that microbial growth could be influenced more by vitamins, trace elements, and amino acids than by LE and in this regard their findings are consistent with those of our study. Accordingly, administration of PN might increase the risk of CLI more than LE.

Femoral access tended to be associated with an increased risk of CLI in multivariate analyses, and was the site of CVC insertion in 80-90% of cases in this study to prevent accidental catheter removal by patients who were elderly and/or had dementia. In contrast, only 5-10% of CVCs were inserted via the femoral route in a study by Youn et al. (10). Femoral access has been reported to be associated with a greater risk of infectious and thrombotic complications than subclavian access (12) in patients admitted to intensive care units. Our findings regarding the risk of infectious complications are similar.

TABLE 2: Multivariate logistic regression analyses of factors associated with CLI

	OR	95% CI	P-value
Frequency of LE administration less than 0.2 times	1.00		
Frequency of LE administration 0.2 times or more	3.12	1.22-8.58	0.02
No administration of PN	1.00		
Administration of PN	7.86	1.45-146.10	0.01
Insertion site was not via femoral access	1.00		
Insertion site was via femoral access	2.85	0.87-13.06	0.09
Increase in BW by 1 kg	0.98	0.94-1.01	0.16

Abbreviations: BW, body weight; CI, confidence interval; CLI, central line infection; LE, lipid emulsion; OR, odds ratio;

In some studies, CLI (including CRLI and CLABSI) occurred at a rate of 8-9 per 1000 catheter days for CVCs (10,11). In our study population, the rate of CLI was lower and infection with *Staphylococcus epidermidis* strains was the most common. These findings are again similar to those of previous studies (10,11).

Our study has some limitations, in particular its retrospective design and small sample size. Other shortcomings include a lack of randomly assigned CVC insertion sites, with femoral access being the most common, unlike in the previous reports.

Overall, our results suggest that administration of LE is associated with an increased risk of CLI in Japanese adult inpatients. However, further prospective studies are needed to confirm our findings.

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Hypochlorous acid has been proven to remove and dissolve biofilms. Combine with PCS effective physical wiping and removal processes.

Disinfecting

Neutral Ph hypochlorous acid is considered to be 40 to 80 times more effective as an antimicrobial than alkali sodium hypochlorite.



PCS family of Stable Neutral pH sodium hypochlorite/hypochlorous acid products.

- 1) PCS 250 Oxidizing Disinfectant/Disinfectant Cleaner
New Neutral pH Formulation
- 2) PCS 1000 Oxidizing Disinfectant/Disinfectant Cleaner
New Neutral pH Formulation
- 3) NPH 160 Neutral PH Oxidizing Cleaner, Disinfectant and No Rinse Sanitizer
Contains 160 ppm neutral pH sodium hypochlorite
- 4) NPH 2000 Concentrated Neutral PH Oxidizing Cleaner, Disinfectant and No Rinse Sanitizer
Dilutes to 200 ppm neutral pH sodium hypochlorite for disinfection and no rinse sanitation
Dilutes to 50 ppm neutral pH sodium hypochlorite for cleaning.
- 5) PCS Spray and Wipe Hand and Surface Cleaner

PCS Microfibre Cloths

14" x 14" (35.56 cm x 35.56 cm) Packaged in bundles of 25
 #PCSMF-BLUE #PCSMF-GREEN
 #PCSMF-RED #PCSMF-YELLOW

7" x 14" (17.78 cm x 35.56 cm) Packaged in bundles of 50
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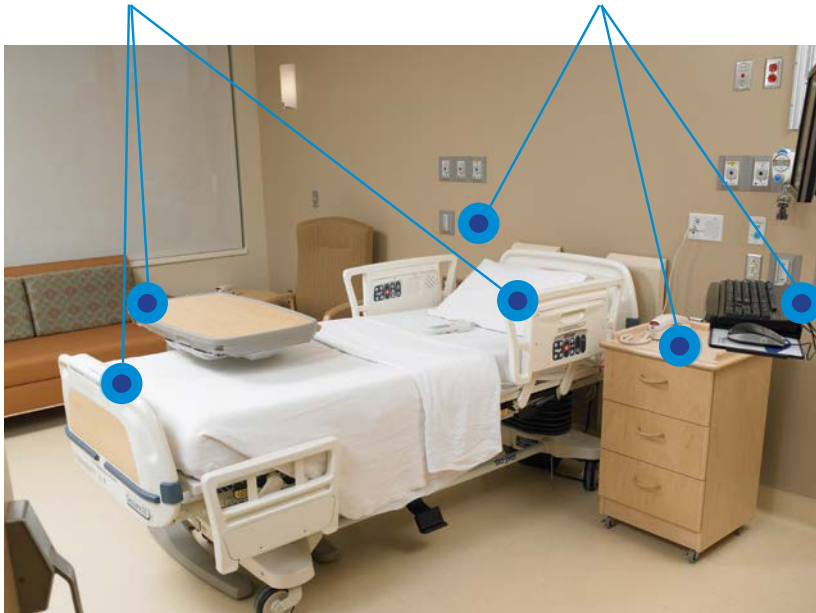


Now available Nexa™ Point-of-Care Holder

Attaches to tray tables,
bed rails or at
the end of the bed

Position on the wall,
bed side table or
even the workstation

Secure to nurse, dialysis,
anesthesiology and
phlebotomy stations or carts



**PROMOTE COMPLIANCE.
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The Nexa™ Point-of-Care Holder is part of the Ecolab hand hygiene program, designed to support your goals with best-in-class products, innovative dispensing options, staff training materials and personalized service.



Revitalizing Skin Lotion
Fragrance Free (540 mL)

Quik-Care™
Nourishing Foam* (535 mL)

Contact your Ecolab Healthcare Account Executive
at 1 800.352.5326 or visit ecolab.com/healthcare.

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Be preventive.
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CaviWipes1™ and CaviCide1™
from Metrex™.**



CaviCide1™ and CaviWipes1™ are the only low alcohol surface disinfectants with a 1 minute contact time.

- Kills all product labeled organisms in 1 minute, including Norovirus
- Allows for faster room turnover
- Same formulation in a spray and a wipe

Go to www.metrex.com/CJIC to learn more about CaviWipes1™ and CaviCide1™.



Handle Hygiene, keeps door handles clean.

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The system significantly reduces the risks of cross-contamination, by inactivating 99.9% of common viruses and bacteria, including MRSA.



Does not contain any kind of pressurized gas



Specific maintenance not required



Batteries not required

Contact SciCan today and we will help you determine the optimal deployment of Handle Hygiene in your hospital's high risks and high traffic areas.

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Is capturing **ONLY .02%** of hand hygiene opportunities enough?

IMPROVE THE QUALITY OF CARE WITH MORE ACCURATE & ACTIONABLE DATA

GOJO SMARTLINK™ Total Solutions

ACTIVITY MONITORING SYSTEM (AMS)

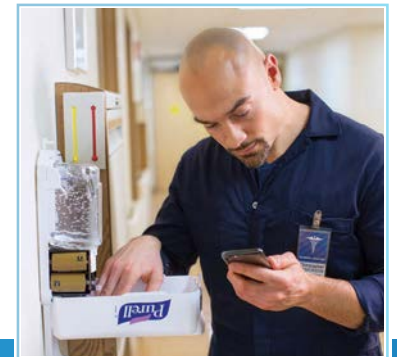
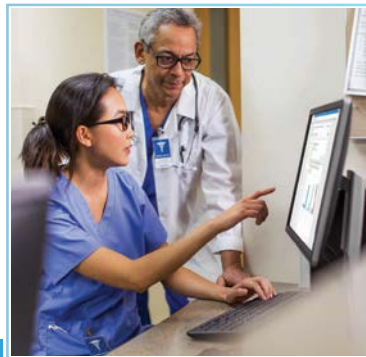
- Accurately captures event & opportunity data at Moments 1 & 4, as recommended by the **Ministry of Health and Long Term Care**
- Includes PURELL® Point of Care dispenser, allowing the system to capture critical hand hygiene events at the time of patient care

CLINICIAN-BASED SUPPORT

- Expertise to help build and sustain hand hygiene improvement

SERVICE ALERTS

- Ensures product availability with dispenser alerts for low refills, batteries and operation



A recent study in a Canadian Emergency Department using the SMARTLINK Activity Monitoring System, captured **over 300,000 hand hygiene opportunities in one month**, compared to **only 60** through Direct Observation.¹

1. Anne Bialachowski et al, "Electronic Hand Hygiene Monitoring in the Emergency Department: Charting New Territory," <http://www.gojo.com/en-CA/Markets/Acute-Care/Hand-Hygiene-Education/Technical-Publications>

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Choose your disinfectant dwell time:

Accel[®] INTERvention[™] (RTU & wipes) - effective against bacteria, viruses and TB in 1 minute.

Accel[®] PREvention[™] - 3 minutes against TB, bacteria, viruses and fungi for RTU and wipes; 5 minutes for concentrate. Liquid is UL/EcoLogo certified.

Accel[®] TB (RTU and wipes) - 5 minutes against bacteria, viruses, TB and fungi.

SPECIALTY Disinfection

Avert[®]



4 Minute Contact Time
Against *C. diff*

1 Minute Contact Time
Bactericidal/Virucidal

The sporicidal/bactericidal/virucidal solution for problem pathogens.

Avert[®] is a disinfectant cleaner that cleans, disinfects and deodorizes in one step.

Avert[®] Wipes - large 11" x 12" size wipes are ideal for large area environmental surfaces.

Avert[®] RTU Liquid - Bleach-based formula is ideal for task-oriented disinfection.

ADDED Assurance

MoonBeam[™]3



Sky[®] 7Xi

Tap into the power of UVC light for enhanced disinfection effectiveness.

MoonBeam[™]3 features three adjustable arms to deliver UVC light directly to horizontal and vertical surfaces.

Sky[®] 7Xi Mobile Device Disinfection is fast, effective and easy to use, delivering up to 5 log reduction in pathogens such as MRSA, VRE, norovirus and *C.diff* spores.

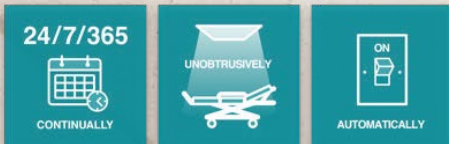
For information, visit SDFHC.com/contact-us or call 800-558-2332.

If this patient has **C. diff**, the next patient to occupy this room has a **240%** increased risk of acquiring **C. diff**.¹

C. diff can become aerosolized, travel on air currents, settle and survive for up to 200 days.
STOP C. DIFF BEFORE IT FALLS.

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**FAST, CONTINUOUS
UV-C AIR PURIFICATION**



¹Shaughnessy M, Micieli R, Depestel D, et al. 2008. Evaluation of hospital room assignment and acquisition of Clostridium difficile-associated diarrhea (CDAD). In: Programs and Abstracts of the 48th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC)/Infectious Diseases Society of America (ISDA) 46th Annual meeting. Washington, DC: American Society for Microbiology. Abstract K-4194

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