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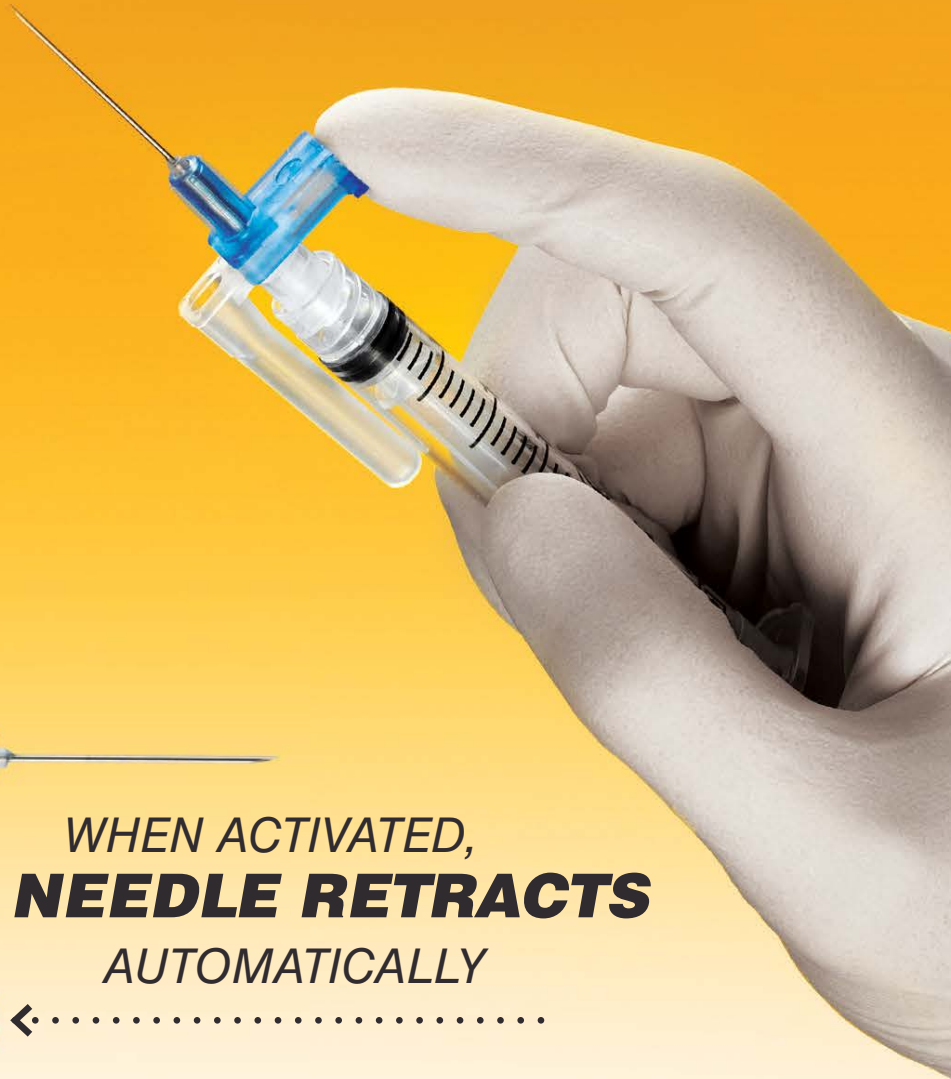
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Medical gels

This position statement was developed by the Standards and Guidelines Committee:

Chair: Madeleine Ashcroft
Principal Authors: Clare Barry, Madeleine Ashcroft, Brenda Dewar, Colleen Lambert, Anne Augustin, Mary-Catharine Orvidas
Original date: March 2003
Reviewed/revised: March 2005, 2008, 2016, December 2017

BACKGROUND

Medical gels[1] are used routinely in clinical practice during physician exams and diagnostic procedures. Contamination of medical gels from improper handling can result in serious healthcare-associated infections such as bacteremia and septicaemia [1-13].

POSITION STATEMENT

To provide for safe handling of medical gels, the following is recommended.

1. Indications for particular gels

Indication	Type of Gel	
	Sterile	Non-sterile
Whenever a biopsy, puncture of any kind, or imminent surgery is to be performed regardless of body site	✓	
Near a fresh surgical wound	✓	
Procedure penetrating mucous membrane	✓	
Endoscopies on intact mucous membranes	✓	
Non-endoscopic procedure on mucous membranes (e.g., vaginal/rectal exam)	✓	
Non-intact skin	✓	
Intact skin		✓
Babies in NICUs and critical pediatric patients [11]	✓	

2. General considerations

a) Sterile gels
- Single-use packaging is required for sterile gels: once opened, the contents are no longer sterile.
- Sterile product should be used employing the principles of asepsis.
- Discard the opened package at end of procedure.

b) Non-sterile gels
- If multi-dose containers of non-sterile gels are used on intact skin, the container should be sealed correctly when not in use [11].
- Dispensing nozzles must not come into direct contact with patients, staff, instrumentation, or the environment [5].
- Non-sterile gel containers should never be topped up (i.e., refilled when partially empty).
- Gel containers should never be washed and refilled for use but should be discarded when empty [11].
- When a new bottle is opened, the bottle should be initialed by the opener, dated, and discarded after 30 days or the manufacturer's expiry date if earlier [5].
- Bulk containers of gel should not be used due to risk of contamination.

c) Warming of gel
- Do not warm gel due to the increased risk of bacterial growth [12].
- Gels are generally stored at room temperature unless the manufacturer's recommendations state otherwise.

d) Storage of gels
- Products must be stored in clean areas that are protected from sources of contamination such as moisture, dust, insects, etc.
- Discard the medical gel if in doubt about integrity.

GLOSSARY/DEFINITIONS

As per the Canadian Standard Association:

"SHALL" is used to express a requirement, i.e., a provision that the user is obliged to satisfy in order to comply with the standard;

"SHOULD" is used to express a recommendation or that which is advised but not required; and

"MAY" is used to express an option or that which is permissible within the limits of the standard, an advisory or optional statement.

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[1] Medical gels include ultrasound gels, lubricating gels, and medicated gels.

REVIEW ARTICLE

Environmental sampling of hospital surfaces: Assessing methodological quality

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ABSTRACT

Background: Patients in rooms previously occupied by individuals with antimicrobial-resistant organisms are at an increased risk of infection. To combat this risk, environmental methods such as self-disinfecting surfaces, ultraviolet light, and titanium dioxide paint are entering the clinical setting to supplement traditional prevention methods. The advent of these novel technologies for infection control and prevention necessitates a standardized method of assessing environmental surface bioburden; however, there is currently no standardized protocol for sampling hard, non-porous surfaces.

Objectives: This article reviews the literature for environmental sampling methodologies and assesses them for rigor and appropriateness. This review and its assessment tool aim to guide a clinical audience in assessing the methodological integrity of study protocols, including collection, transportation, recovery, and culturing of environmental surface samples.

Methods: A search of PubMed and MEDLINE was performed and 122 articles and their references were reviewed.

Results: Environmental sampling methods include elution-dependent (pre-moistened swabs, sponges, wipes) and elution-independent methods (Replicate Organism Detection and Counting plates, 3M Petrifilm™ plates, dipslides). With both methods, moisture and neutralizers must be present at the time of sampling to increase recovery rates. Elution-dependent methods also require physical dissociation methods to release organisms from the collection device prior to culturing. Furthermore, special consideration is needed for the collection, recovery, and culturing of spore-forming organisms.

Conclusions: Standardization of environmental surface sampling methods in the collection, transportation, recovery, and culture of a microbial sample is needed to objectively assess and compare the efficacy of newer antimicrobial technologies.

KEYWORDS

Environmental sampling; organism recovery; collection; transport; methodology; plating

INTRODUCTION

The relative importance of environmental contamination in hospital-acquired infections is still debated; however, it is clear that patients in rooms previously occupied by individuals with antimicrobial-resistant organisms are at increased risk of colonization or infection with these same microbes [1]. Reducing the microbial burden in healthcare environments decreases the transmission of microorganisms; therefore, an increasing number of novel adjunctive technologies to supplement routine cleaning and disinfection are being developed. These include new disinfection technologies such as ultraviolet (UV) light disinfection, ozonated water, and self-disinfecting surfaces such as copper-alloy materials and titanium dioxide paints [2-4]. An assessment of antimicrobial efficacy is essential in the evaluation of these products. However, testing methodologies vary significantly in current literature due to the lack of standardization by regulatory bodies [3, 5]. Consequently, this poses a challenge to the infection preventionist when evaluating product performance.

This review summarizes the key steps in the a) collection, b) transport, c) recovery, and d) culture processing steps that should be outlined by environmental sampling studies for microorganisms. We expand on a previous review article by Galvin et al. (2012) [6] describing microbial monitoring methods of hospital environments by including an environmental sampling methodologic quality assessment tool (Figure 1),

comparison tables for specimen collection, recovery, and culturing methods (Tables 1 and 2), special considerations for clostridial spores, and information on current environmental sampling standards.

Our aim is to assist infection preventionists and clinicians in understanding the sampling methodology in order to 1) assess the quality of study results and 2) guide those who are considering performing an in-house assessment of a product.

METHODS

Articles related to environmental sampling of vegetative bacteria and spores on non-porous, solid surfaces (stainless steel, metal, glass, ceramic, painted or coated wood, plastic) were sought through both PubMed and MEDLINE with the following keywords: recovery method, environmental sampling, bacteria, spores, and non-porous surface. The abstracts and references of 122 articles were reviewed and, as part of this narrative review, 98 were selected as relevant to the theme of environmental sampling methods. Methodology was then assessed for applicability to healthcare. In addition, guidelines from the Centers for Disease Control and Prevention, the American Society for Testing and Materials (ASTM), and the International Organization for Standardization (ISO) were reviewed. Searches were limited to the English language and no limits were placed on publication dates. Adenosine Triphosphate bioluminescence testing was excluded due to its limited role as a research tool for environmental sampling despite its practical role in assessing hospital surface cleanliness following disinfectant use.

RESULTS AND DISCUSSION

Specimen collection

The most common surfaces evaluated are non-porous, including high-touch hospital surfaces such as bed rails, tabletops, and arm rests. Elution-dependent methods (swabs, sponges, and wipes) and elution-independent methods (contact plates, dipslides, Petrifilm™ plates [3M, St. Paul, MN]) are appropriate for these surfaces. Porous surfaces generally comprise textiles and, in these cases, vacuum filter socks and microvacuums, and bulk sampling methods are most appropriate [7].

1. Specimen collection for elution-dependent methods
Elution refers to the immersion of the collection device in an eluent and the use of a physical dissociation method such as shaking, sonicating, vortexing, or stomaching to recover the microorganisms. Swabs are most commonly used for regular or irregularly shaped smaller surfaces, typically between 20 cm^2 and 100 cm^2, including hard-to-reach areas such as corners, bed rails, and crevices [8, 9]. Both swab tip and shaft compositions should be reported due to their effect on recovery efficiencies (e.g., cotton swab with a wooden shaft) [8]. Cotton and calcium alginate swab buds, in particular, tend to underestimate the amount of microbial contamination in comparison to other swab buds, including rayon, macrofoam, nylon, and polyester [8, 10, 11]. The swab shaft also plays a critical role in determining the amount of mechanical energy placed on the swab bud, as more rigid materials increase recovery [8].

Swabbing technique should be specified, including the sample area, angle of swabbing, portion of swab used, swabbing duration, swabbing direction (e.g., vertical, horizontal, diagonal), strokes in each direction, and number of swabs used for each sample. A set area should also be delineated with a corrosion-resistant template that can be sterilized or replaced between swabs [9, 12]. Prior to swabbing, it is important that the swab bud be pressed against the side of the tube to standardize the volume of pre-moistening liquid in each swab. Consistency with degree of pressure and the speed of swabbing can be improved by having one investigator perform all of the sampling. In addition, one study proposes the use of two sequential swabs to increase recovery [13]. A proposed angle of sampling is 30 degrees, where swabs are rotated 120 degrees when the direction is changed from horizontal to vertical and then to a diagonal sampling pattern [14].

Sponges and wipes are generally used for sampling larger regular or irregularly shaped (100 cm^2 to 1 m^2) surface areas such as walls and floors [7, 9, 15]. They are usually made from rayon, polyester, cellulose, polyurethane, or cotton, although studies comparing recovery among these different materials are limited. Sponges may allow for better recovery of pathogens compared to swabs due to the larger surface area sampled [16]. A suggested standardization method includes sampling horizontally, vertically, and then diagonally, noting the strokes per direction while turning to reveal a new surface with each new direction [7, 14].

2. Specimen collection for elution-independent methods
Agar contact methods include contact plates such as Replicate Organism Detection and Counting (RODAC) contact plates, Petrifilm™ plates, and dipslides. They are limited to use on smaller surfaces: usually between 20-26 cm^2 for RODAC and Petrifilm™ plates or 7-12 cm^2 for dipslides [7, 9]. RODAC plates and dipslides must be used on smooth, flat, non-porous surfaces; however, due to their flexibility, Petrifilm™ plates can be used on irregularly shaped surfaces such as door handles [17]. The agar plate should be pressed firmly onto the surface for a standardized amount of time and pressure. ISO Standard 18593 for environmental sampling of food industry environments (Microbiology of food and animal feeding stuffs – Horizontal methods for sampling techniques from surfaces using contact plates and swabs) recommends ten seconds at 500 g, although other studies have used different pressure (840 g) or different times (30 seconds) [9, 18, 19].

3. Pre-moistening fluid, eluents, and neutralizers
Sampling environmental surfaces requires that moisture be present either on the surface or through pre-moistened swabs, wipes, sponges, and agar plates to minimize microbial desiccation and enhance spore recovery [8]. Eluents or rinse fluids (phosphate buffered saline [PBS], buffered or unbuffered peptone water, and ringer solutions) are often used as pre-moistening liquids [7, 20]. However, environmental surfaces in hospitals usually contain disinfectant residues such as quaternary ammonium compounds, hydrogen peroxide, phenolics, and

sodium hypochlorites that may inhibit microbial growth and/or identification upon subsequent culture. Therefore, neutralizing agents are also required at collection time to counteract the effects of all disinfectant residues, except for vaporized hydrogen peroxide, whose end products are oxygen and water [7, 12, 21]. Common neutralizers include lecithin and polysorbate (Tween) 80, Dey Engley (D/E) broth or agar, sodium thiosulfate, glycine, and catalase [12]. Selection should also be based on disinfectant used, compatibility with desired assays, and toxicity to the desired microbe. In addition, if enumeration is intended, enrichment ingredients such as Trypticase soy broth or Brain Heart Infusion broth should not be added [6]. However, if identification of specific bacteria is required – for an outbreak investigation, for example – enrichment can be considered. It is important to note that some eluents such as PBS may hinder microbial

recovery through salt crystal precipitation on metal surfaces [14]. Similarly, some neutralizers may have inhibitory effects, including sodium thiosulfate and D/E on some *Staphylococci* species and mycobacteria species, respectively [21, 22].

Like elution-dependent methods, moistened media and neutralizers are needed within the agar to improve recovery, increase bacterial clump dispersion, and minimize desiccation or residual effects of disinfectants [23]. In addition, direct contact agar methods can only be used on surfaces that contain low amounts of microorganisms to avoid a confluence of growth and underestimation of bioburden [10, 23]. This method does not detect dormant or sub-lethally damaged organisms, including those that are viable but non-culturable [10].

Table 1 summarizes the advantages and limitations of elution-dependent and -independent methods.

TABLE 1: Advantages and limitations of collection methods for non-porous surfaces.

Collection Method	Standard	Sampling Location	Advantages	Limitations
Elution-dependent				
Swabs Swab bud: Cotton, calcium alginate, flocked nylon, polyester, macrofoam, polyurethane, rayon Swab shaft: Wood, aluminum, polypropylene, polystyrene	Food industry: Yes Healthcare: No	Small surfaces (20-100 cm²) [9]: regular or irregularly shaped surfaces (doorknobs, keyboards, corners, crevices)	Results may be better than contact plates for Gram-negative organisms [18]	a. *Personnel*: Difficult to standardize pressure, speed; error with pipetting or diluting b. *Material* affects absorption and release of organisms c. *Nature of surface*: Disinfectant residues and biofilm reduce recovery [10]
Sponges or wipes Rayon, polyester, cellulose, polyurethane, cotton	Food industry: Yes Healthcare: No	Large surfaces (100 cm²-1 m²) [7, 9]: walls, floors, countertops; regular or irregularly shaped surfaces	Can sample multiple sites [16]	d. *Swab shaft* determines mechanical energy placed onto swab bud [8] e. *Drying effects* of wipes reduce collection over large areas [15]
Elution-independent				
RODAC plates Media Non-selective agar Selective agar	Food industry: Yes Healthcare: No	Regularly shaped (smooth, flat) surface only Size: Agar plate surface area (SA) (around 20-26 cm²) [7]	Time-efficient; no processing needed	a. *Personnel*: Hard to standardize contact time and pressure b. *Nature of plating*: Limited by surface area of contact plate Only for low number of bacteria as dilution cannot be performed [10] Excludes sub-lethally damaged and dormant bacteria Coalescence of colonies underestimates colony-forming unit [10]
3M Petrifilm™ Media Thin, dehydrated proprietary media located between two films	Food industry: No Healthcare: No	Regular or irregularly shaped surfaces Size: Petrifilm™ SA (around 25 cm²) [7, 17]	No processing; less incubator space needed; flexibility around irregularly shaped surfaces	
Commercial dipslides Media Non-selective agar Selective agar	Food industry: No Healthcare: No	Regularly shaped (flat, smooth) surfaces only Size: Dipslide SA (around 7-12 cm²) [7, 9]	No processing needed	c. *Nature of surface*: Full contact with surface needed

Transport and storage

The sample must be transported for laboratory analysis ideally within four hours [9]. Storing samples at 1°C to 8°C is generally recommended, especially if more than 24 hours' transport is anticipated [9, 24]. If shipping is required, an additional container should be used around the sample container to minimize the impact of temperature and/or altitude fluctuations.

Recovery methods

Recovery methods refer to the process of extracting microorganisms from the collection device. Swabs, sponges, and wipes should never be directly subcultured onto solid media. Rather, physical dissociation methods (PDM) are necessary to separate bacterial aggregates and allow for a more representative microbial count similar to the original bioburden. PDM include manual or mechanical shaking (vortexing), sonicating, or stomaching to release the bacteria (Table 2) [7].

Manually shaking swab containers and massaging sponge and wipe bags produce variable results that are operator- and time-dependent. ISO Standard 18593 recommends the use of a mechanical shaker for swabs and a stomacher (peristaltic homogenizer) for sponges [9]. Laboratory vortex mixers are commonly used but are limited to smaller collection devices and vials of liquid. Platform shakers are also available, although they may provide less mechanical agitation compared to vortexing, resulting in less microorganism recovery [25].

Bacterial sonication can be used to kill or declump bacteria depending on the frequency and duration; lower frequencies are preferred for bacterial declumping of environmental samples. Declumping bacteria ensures better recovery. A thorough article will specifically state the sonicator manufacturer, model number, frequency, and sonication time, though ideally output power, fluid temperature, and reaction volume will be included as well [26]. Generally, studies use low

TABLE 2: Advantages and limitations of recovery and culturing methods.			
Recovery Method	**Collection Method**	**Advantages**	**Limitations**
Elution-independent Methods			
Direct plating Contact plating	Swabs Contact plates Petrifilm™ Dipslides	No processing needed See Table 1	Inaccurate enumeration method See Table 1
Elution-dependent Methods			
Spread plate method	Swabs, sponges, wipes	Fewer microorganisms required than pour plating	Operator-dependent (e.g., pressure, time)
Pour plate method	Swabs, sponges, wipes	Better sampling efficiency compared to spread plate [8] Method suitable for anaerobic bacteria	Subsurface colonies difficult to retrieve Thermal shock and dilutional factor from melted agar reduce organism count
Drop plate method	Swabs, sponges, wipes	Less time required to drop samples than to spread Less equipment needed (four dilutions plated on one plate)	Unstandardized methodology (dilutions and volume plated) [31] Only works for pure cultures [31]
Membrane filtration method	Swabs, sponges, wipes	Suspected disinfectant residues can be rinsed multiple times Can be used with large volume rinsates	Labour-intensive Chemicals or particles on membrane may inhibit growth of organism
Physical Dissociation Methods			
Manual shaking	Swabs, wipes	No equipment needed	Labour-intensive Operator-dependent (strength, fatigue)
Bag massaging	Sponges, wipes		Limited to smaller items that fit in a test tube, flask, or beaker
Vortex	Swabs, wipes	Allows for standardization	Limited to smaller items that fit in a test tube, flask, or beaker
Sonication	Swabs, wipes	Allows for standardization (power, frequency, temperature, reaction volume, time)	Higher frequencies or direct probe sonicators may kill microorganisms Cost of sonicator
Stomaching	Sponges, wipes	Allows for standardization	Only for soft items that will not puncture the bag Cost of sonicator

ultrasonic bath frequencies (around 20-40 kHz) to declump bacteria since baths have less potential to inactivate bacteria compared to direct probes [26, 27]. Sonication has been used more frequently in biofilm prostheses, where an ideal sonication time of one to five minutes is used to declump and dislodge bacteria from surfaces; however, this method is rarely used in environmental sampling [28].

Stomaching occurs when the bag containing the collection device and rinse fluids is placed inside a machine, pounded by paddles, and exposed to compression and shearing to remove the bacteria from the collecting device [29]. This method is more appropriate for softer, larger materials such as wipes, gauze pads, and sponges. Manual stomaching is not recommended due to the increased variability of operator force.

Culture plating methods
Eluents are often serially diluted following PDM of the microorganism sample and prior to plating to achieve countable colonies. The ASTM Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate, Hard, Nonporous Non-Food Contact Surfaces recommends standard spread plate, pour plate, and membrane filtration techniques [30].

Spread plating disperses the rinse fluid onto an agar plate with a sterile spreader and is relatively easy to perform [12]. Pour plating mixes an aliquot of the rinse fluid with molten agar medium. Although pour plating has higher sampling efficiencies than spread plating, colonies exhibit slower growth and a higher bacteria inoculum is required due to the extra dilution factor from the agar medium [8]. The membrane filtration method filters the eluent and microorganism through a membrane filter and then rinses the membrane filter with eluents containing neutralizers if disinfectant residues are suspected. The filter, now containing microorganisms, is then placed onto the agar medium and incubated. This technique is appropriate for large-volume rinsates, low microorganism numbers, and when toxic residues have not been adequately neutralized [12]. Drop plating involves placing drops of different sample dilutions onto each of the four quadrants of an agar plate but requires pure cultures because it cannot distinguish microorganisms in polymicrobial samples [31]. These methods differ in the maximum volume that can be used except for membrane filtration, which has flexible volumes: spread plate 0.1 ml; pour plate 0.5-3 ml; and drop plate 0.1-0.2 ml [12, 31]. Table 2 shows the advantages and disadvantages of each method to help guide selection.

Assessing environmental sampling studies
It is important that each step in the method has been appropriately selected to reflect the study design. Collection, recovery, transport, and culturing methods should be chosen based on the given organism, surface type (porosity, composition), surface size, and location (see Table 2). This also includes a critical analysis of whether elution-dependent or -independent methods should be used. Figure 1 presents an

assessment tool for clinicians and infection preventionists when evaluating articles utilizing environmental sampling methods.

There are situations in which one method may be more ideal than others, with surface size and location being key considerations. Swabs are usually used for areas from 20 cm^2 to 100 cm^2; sponges for areas from 100 cm^2 to 1 m^2; Petrifilm™ and RODAC plates for areas from 20 cm^2 to 26 cm^2; and dipslides for areas from 7 cm^2 to 12 cm^2 [7, 8, 9]. Swabs, sponges, and Petrifilm™ plates can be used for regular and irregular surfaces, including hard-to-reach areas, whereas contact plates and dipslides require a flat surface. Qualitative assays, including outbreak investigations, usually require larger surfaces to be investigated; therefore, sponges and wipes may be a good option. Quantitative assays require sampling of specific sites and thus swabs, contact plates (usually non-selective), Petrifilm™ plates, and dipslides can be considered.

The swab composition favoured by most researchers includes macrofoam, flocked nylon, rayon, or polyester. Flocked nylon swabs, a newer technology, have demonstrated the ability to release microorganisms more rapidly and completely, with one study demonstrating 92% release capacity compared to 21% with rayon swabs [32].

Selection of elution-independent methods are equally challenging due to the lack of comparison articles. Two studies, an in-vitro and a clinical study, found Petrifilm™ plates to be more effective than RODAC plates in increasing colony-forming unit detection, except for the detection of methicillin-resistant *Staphylococcus aureus* (MRSA) on stainless steel surfaces [17, 33]. Dipslides were shown in one study to be more sensitive than contact plates in detecting MRSA [34].

Regardless of the collection method, a moistened collecting device must be used at collection time to improve recovery rates. Appropriate neutralizers must be added and should be selected depending on the disinfectant used. Qualitative studies should be enriched with broth media or use selective agar; quantitative studies should not be enriched and should use non-selective agar.

Importantly, any variable that can impact microorganism recovery requires its own control. At minimum, a surface control, a clinical environmental handling control, and a laboratory control should be used. A surface control is used to compare the results of a sampled surface to a control surface. A clinical environment handling control is used to detect contamination from sample handling by removing the collecting device from its sterile packaging and exposing it to the environment without sampling the surface [7]. A laboratory negative control of unused samples should be standard.

Special considerations for clostridial spores
Environmental sampling of clostridial spores is difficult due to limitations by low sensitivities, anaerobic culture conditions, and extended incubation periods [35]. Spores have been sampled in studies using pre-moistened swabs with or without broth, sponges, and contact plates. In general, sponges and contact plates have been shown to have higher recovery efficacy than swabs [16, 36, 37]. Increased recovery has been

FIGURE 1: Assessment tool for environmental sampling methodologic quality.

COLLECTION

Is the collection method appropriate for a non-porous surface with its given composition, size, and location?

Are pre-moistening fluids and neutralizers used at sampling? If qualitative study, consider enrichment.

Are the following controls used?
1. Surface control 2. Clinical environmental handling control 3. Laboratory control

Is the collection method appropriate for qualitative/quantitative study?

Qualitative detection of specific microbes (sampling larger surfaces)
Elution-dependent: Sponge, wipe
Elution-independent: Selective agar contact plate

Quantitative detection of microbial burden (sampling specific sites)
Elution-dependent: Swab
Elution-independent: Non-selective agar contact plate, Petrifilm™, dipslide

TRANSPORT

Is the sample transported to laboratory within 24 hours? Is it stored appropriately according to the organism?

RECOVERY

For elution-dependent methods:
1. Elution with compatible eluent ± neutralizer
2. Physical dissociation
3. Plating (spread, drop, pour plate, membrane filtration)

CULTURE

Qualitative: Selective agar

For elution-dependent and -independent methods:
Is the culture media appropriate?

Quantitative: Non-selective agar

Qualitative: Identification

Results

Quantitative: Enumeration

shown when using lysozyme or bile salts such as sodium taurocholate and cholic acid in combination with Cycloserine-Cefoxitin Fructose Agar or its broth equivalent [36, 38]. One study demonstrated that broth is better for spore recovery than agar, especially in environmental swabbing, where there are fewer spores than in fecal samples [39]. The use of alkaline thioglycolate as pre-exposure to sensitize spores to lysozyme effects is controversial, with one study demonstrating no difference [38] and two studies demonstrating better recovery, particularly for heat- or alkali-treated spores [35, 40]. Newer media, including *C. difficile* brucella broth with thioglycolic acid and L-cystine, has not yet been extensively peer-reviewed, although their potential advantage is the ability to be incubated in routine clinical laboratory atmospheres.

CONCLUSION

The lack of environmental sampling standardization in healthcare hinders the ability to objectively assess and compare the quality of articles evaluating the efficacy of newer antimicrobial technologies. This variability needs to be addressed by regulatory agencies. The many variables in each of the four process steps (collection, transport, recovery, and culture) can independently influence the quality of the sampling methods and inter-study comparisons are thus admittedly difficult. It is tempting to suggest a limited number of environmental sampling methods to facilitate standardization. Unfortunately, this is a challenge specifically because the selection of each method within the four process steps depends upon the surface, its size, shape, and location, and the results desired (qualitative versus quantitative). In the interim, this article and its assessment tool will hopefully help readers assess the methodologic quality of environmental sampling in healthcare facilities. At a minimum, a description of methodology should consider these elements: 1) moisture must be present at the time of sampling, 2) a neutralizing solution is necessary to arrest residual disinfectant action, 3) a physical dissociation method must be used to release organisms from the collection device prior to culturing, and 4) special consideration is required for the collection and culturing of spore-forming organisms.

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ORIGINAL ARTICLE

A spatial, temporal, and molecular epidemiological study of hospitalized patients infected with community-acquired or healthcare-associated *Clostridium difficile* in the Niagara Region, Ontario, Canada between September 2011 and December 2013

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ABSTRACT

Objectives: To investigate and compare the incidence, geographical distribution, temporal patterns, and genetic relatedness of hospitalized patients with community-acquired *Clostridium difficile* infections (CA-CDI) and healthcare-associated *C. difficile* infections (HA-CDI) in the Niagara Region, Ontario over the time of a large, multi-hospital outbreak.

Methods: We conducted a retrospective case series study of the consecutive hospitalized confirmed CDI cases between September 2011 and December 2013 using SaTScan statistics and Statistical Process Control.

Results: Using provincial guidelines on classification of *C. difficile* cases, we estimated that, of the 629 CDI cases, 318 were CA-CDI and 311 were HA-CDI. The rate per 1,000 patient days for the entire study period for the hospitalized CA-CDIs was 3.9 CDIs/1,000 patient days and 3.8 CDIs/1,000 patient days for HA-CDIs. We identified spatial clusters for CA-CDIs using the first three digits of the patients' home postal codes. A temporal cluster of HA-CDI was identified after a period of time when a high number of CA-CDI cases were hospitalized. Molecular typing was done on 6% (40/629) of patients that met study definition; 13 were CA-CDI and 27 were HA-CDI. The majority (44.4%) of the NAP1 strains (12 of the 27 tested) were seen in patients with HA-CDI. Various unrelated strains were also identified.

Conclusions: Geographical clustering, temporal features, and genotypic features of CDI cases appear to be unique to CDI cases in the community, compared to those in hospital. Nonetheless, understanding the potentially bi-directional transmission pathways between hospitalized CA-CDI incidence and HA-CDI manifestation, as well as the community drivers of CA-CDIs, can inform clinical and public health patient safety and prevention policies.

KEYWORDS

Community and healthcare-associated *Clostridium difficile*; spatial; temporal; clustering

INTRODUCTION

Clostridium difficile (*C. difficile*) has emerged as a significant source of infectious diarrhea beyond hospital settings, resulting in community-acquired *C. difficile* infections (CA-CDI) [1, 2]. The community reservoirs of CA-CDI remain unclear and many of those infected with CA-CDI do not have the conventionally established risk factors for healthcare-associated *C. difficile* infections (HA-CDI) [1, 3]. CA-CDI has been linked to various environmental sources such as floodwater, rivers, lakes, marine sediments, food, farm animals, and household pets [1, 4, 5]. Yet unlike other gastrointestinal infections, increases in CA-CDI rates in the northern hemisphere have not been associated with the warmer summer months [6-8]. Conversely, research to date has pointed to the increased use of antimicrobials in winter and spring months as a contributing risk factor in both CA-CDIs and HA-CDIs [9, 7].

Researchers also debate whether asymptomatic, previously hospitalized patients can be a source of transmission in the community and/or whether hospitalized CA-CDI plays a role in spreading the spores in hospital settings [10, 11]. In a bid to answer these questions, we investigated and compared the geographical distribution, temporal patterns, and genetic relatedness of CA-CDI and HA-CDI cases admitted to the Niagara Health System (NHS) between the summer of 2011 and the winter of 2013, during which period a series of *C. difficile* outbreaks occurred in the region's hospitals.

METHODS

Study design, study period, and setting

The design featured a retrospective case-series study of consecutive patients with confirmed CDI infections hospitalized in NHS hospitals between September 2011 and December 2013. NHS hospitals are the service providers for the Niagara Region in Ontario; they offer a wide range of programs and services to a catchment area spanning 12 municipalities with a population of approximately 430,000 [12].

Case definition, identification, data source, and privacy

Case definition and eligibility criteria followed the provincial guidelines for CDI prevention in healthcare settings [13], as reflected in NHS infection prevention and control (IPAC) policies (see Appendix A).

Cases of CDI were identified after laboratory testing of stool samples from symptomatic patients. Daily surveillance by IPAC service personnel at NHS sites confirmed the laboratory testing results. Confirmed cases were then approved and finalized in consultation with an external infectious diseases and infection control physician.

Data for this study were aggregated in a central database. Data came from each of the NHS hospitals' IPAC offices, administrative databases, and medical records. For more accurate data collection, expert personnel in the NHS Decision Support department conducted a retrospective query in its databases. Where data were missing, an electronic record review and a paper chart review were conducted using name,

date of admission, and site-specific medical records numbered to match the records. A de-identified data set was used for final analysis.

C. difficile testing and strain typing methods

Between September 2011 and April 2012, all CDI samples were sent to an academic hospital laboratory that used DNA amplification technique to identify toxin-producing CDI strains. The BD GeneOhm™ Cdiff Assay had a sensitivity of 93.8% and a specificity of 95.5% [14]. From April 2012 to December 2013, NHS sent the CDI samples to an external commercial laboratory that used a Nucleic Acid Amplification Test (NAAT), the BD MAX™ Cdiff Assay, with a sensitivity of 96.3% and a specificity of 92.4% [15]. The provincial reference laboratory performed strain typing of the *C. difficile* isolates using a pulsed-field gel electrophoresis (PFGE) technique, a standard National Medical Laboratory procedure.

Statistical analysis

We stratified the CDI cases using CA-CDI and HA-CDI incidences. Data included CDI discreet count values, month and year of laboratory testing, the first three digits of the eligible CDI patients' postal codes or forward sortation area (FSA), and total patient days for all NHS sites per month for rate calculation. Rate per 100,000 population was calculated for CA-CDIs, and rate per 1,000 patient days was computed for HA-CDIs. When needed, we used information on the Niagara Region's population from Statistics Canada's 2011 census for data analysis. Monthly incidence measures were calculated and out-of-control ranges searched using Statistical Process Control (SPC).

Spatial Cluster Analysis

Complementing geographical distribution maps with spatial randomness statistical tests indicate whether the clustering is an act of chance or the result of an underlying risk factor. We performed a purely spatial and spatio-temporal scan of the CA-CDI and HA-CDI cases to test for the presence of patterns in their approximate geographical origin and conducted a space-time permutation study to identify clusters independent of time and location. The application of spatial Scan Statistics allows researchers to measure the significance and the location of a general or focused cluster [16] that subsequently leads to clues about the disease under investigation. Spatial scan statistics employ a likelihood ratio test to assess clusters of various sizes and adjust for multiple testing [17]. The Monte Carlo simulation of 999 randomizations of the data set ranks the likelihood of the cluster's significance [18]. Focused clusters are detected based on multiple circular (or other shaped) windows of variable sizes, scanning the given geographical area for the variable of interest. The null hypothesis of equivalent risk inside and outside the circular scan windows is rejected when the number of cases inside the cluster zone is more than the expected number of cases, independent of the specific geographical locations and administrative boundaries.

1. Purely spatial Scan Statistics for investigation of non-random clusters

Using a circular scan window centred on each possible point throughout the study area, this one-dimensional spatial Scan Statistic process compares the disease risk observed inside the window (cluster) with the risk outside the window (cluster). The most likely cluster has the highest likelihood ratio, with p values of 0.005 or less.

2. Spatio-temporal Scan Statistics for investigation of non-random clusters

The space-time Scan Statistics identify clusters throughout the study region by scanning for cases using a cylindrical window, where the base of the cylinder centres on one of the multiple centroids within the study area. The cylinder's height defines the time interval as a whole for the entire study period. The cylindrical window then scans the geographic base while changing the radius of the base as well as scanning for possible time intervals (changing the height of the cylinder).

3. Space-time permutation Scan Statistics for investigation of independent clusters

This model identifies the increased risk of a disease or differences in geographical distribution at different times by adjusting for time and space. Therefore, the number of observed cases in a cluster is compared to the expected number of cases if all cases were independent of each other in terms of infection time and spatial locations. The ability to adjust for purely temporal clusters of this type of scan means that it can highlight the locally initiated clusters.

For computation purposes, a Poisson distribution model was used while operating the SaTScan software. The first three digits of individuals' postal codes were used to identify the locations or smaller geographical units within the overall study area. The time precision was set by the day. Temporal and geographical checks were in place to ensure that all cases, controls, and populations were within the study's specified temporal period and geographical area. The maximum temporal cluster size was set for 50% of the study time and the maximum spatial cluster size was set for 50% of the study's at-risk population.

Temporal Cluster Analysis

SPC charts to investigate out-of-control abnormalities and outbreaks

The SPC approach was used to provide information on unusual variations and exceptional changes in CDI infection rates between months and seasons [19]. Rare events of disease clustering in a given time period are best explained by the Poisson process [20]. Therefore, this analysis used u control charts for discrete data (numerator) with a varying size of monthly patient days (denominator) to monitor the total number of incidents per month [19, 21] . Although in an industrial environment the use of process control charts with ±3-sigma control limit has been recommended (99.73% of all plot points in a normal distribution and stable process), use of a 3-sigma control limit has been questionable for healthcare [21]. Therefore, for epidemiological investigation of infections, more sensitive and less specific standards should be applied to increase the power and confidence of the "out of statistical control" state of CDI [20]. For this study, the control limits were set at ±2-sigma covering 95% of the plotted points; smaller variations in data could be identified, which, in practice, are signals for thorough epidemiological investigation [21]. Choosing a tighter control limit increases the rate of false positives or out-of-control points (type I error) to 5% for each plotted value (compared to 0.27%); this can also be clarified by epidemiological investigation.

Temporal Scan Statistics for investigation of non-random clusters

Scan Statistics identifies and evaluates clusters of cases in a purely spatial, purely temporal, or space-time setting [22]. A Bernoulli distribution is a 0/1 case-control type of binary data. To evaluate the temporal pattern of the CDIs and investigate non-random clustering, we used a purely temporal statistics test. HA-CDI were considered cases and CA-CDI were considered controls. Scan Statistics used multiple different window sizes to gradually scan across time and/or space and document the number of observed and expected observations inside the windows. The risk inside the clusters compared to outside the clusters, measuring for irregularity of the potential cluster, was based on a likelihood ratio [23]. The cluster that yielded the most extreme ratio was least likely to be by chance [23].

TABLE 1: Rate of hospitalized CA-CDI and HA-CDI for NHS hospitals between September 2011 and December 2013.					
	2011	**2012**	**2013**	**Overall rate for study period**	**Reported rates in other studies**
CA-CDI (rate/100,000 population)	14.84	33.22	25.5		11.6 [36]
HA-CDI (rate/1,000 patient days)	3.7	3.36	4.34	3.83	0.3 in 2011 [29] 0.35 in 2012 0.33 in 2013

A purely temporal retrospective multivariate Scan Statistics was conducted, scanning for clusters with high rates using the Bernoulli model. The minimum temporal precision was set at one month and the maximum temporal cluster size was set at 50% of the study period. A maximum temporal cluster size limits the maximum size of the population at risk within the cluster to no more than 50% of the population at risk in the study [24, 16].

Random replication of the data set using computer simulation is a feature of Scan Statistics that adds to the power of the test. The number of replications under the null hypothesis for the standard Monte Carlo test was set at 999 to ensure statistical power for the Scan Statistic and the *p*-value calculation [22]. Under this setting, a high likelihood ratio rejects the null hypothesis and favours the clustering inside the scanning window(s) [22]. In this step of the temporal study, the null hypothesis assumed that the temporal clusters of hospitalized CA-CDI and HA-CDI occurred at the same time. The alternative hypothesis suggested the presence of clusters in hospitalized CA-CDI that did not show up at the same time as those in HA-CDI.

FIGURE 1A
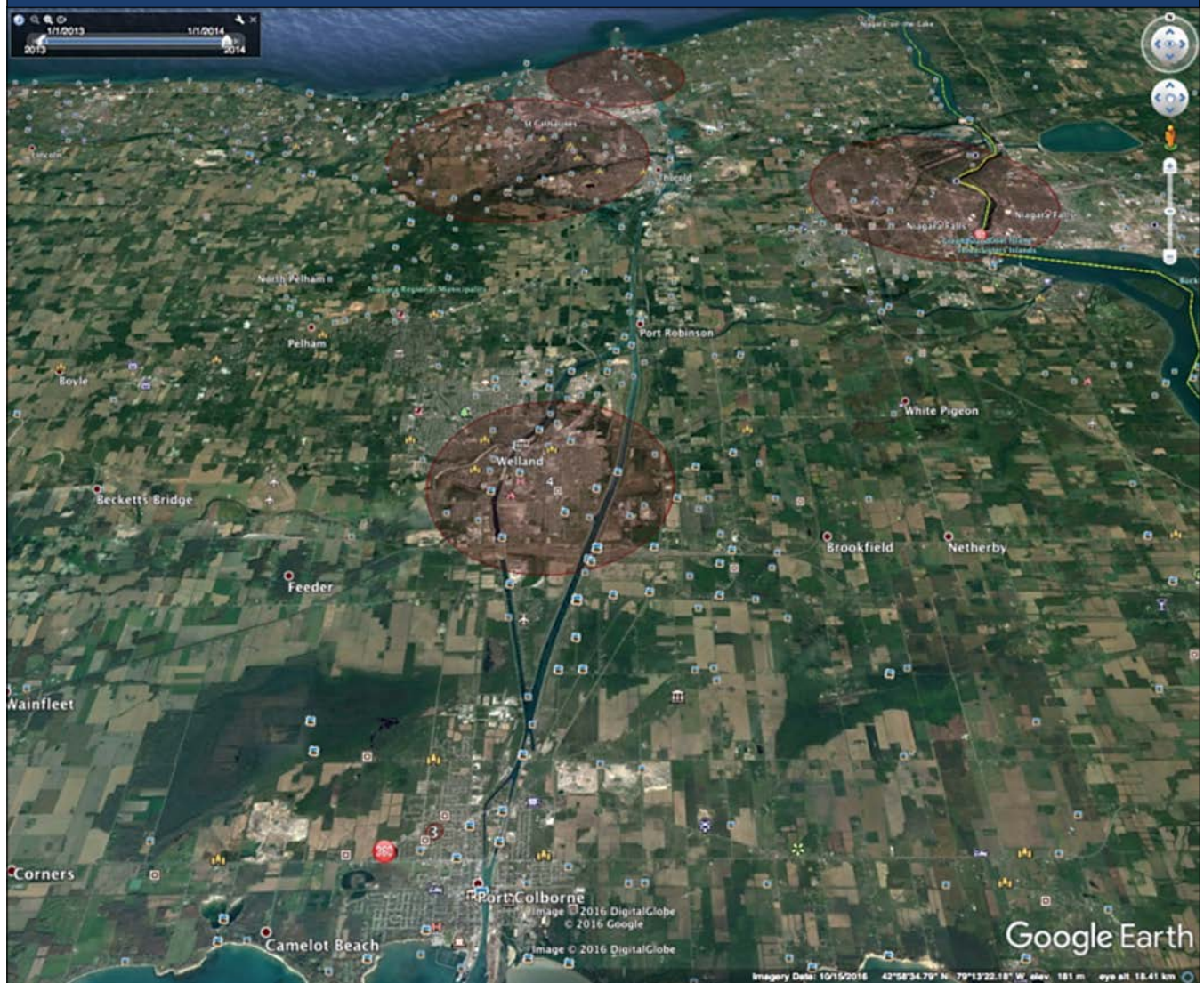
Purely spatial scan statistics of the cases of CA-CDI in the Niagara Region based on their FSA or the first three digits of the postal codes between September 1, 2011 and December 31, 2013. Number of significant* clusters (in red) with high rates identified using discreet poison model ($p<0.05$). Five FSAs of the significant clusters:

L3K: $p<0.000$; N = 26; log likelihood ratio: 8.879242
L2G: $p<0.000$; N = 30; log likelihood ratio: 7.155066
L2E: $p<0.002$; N = 25; log likelihood ratio: 6.371665
L2N: $p<0.021$; N = 31; log likelihood ratio: 4.754386
L3B: $p<0.025$; N = 24; log likelihood ratio: 4.477314

Legends:
🔴360 360 cities: Location of the panoramic cameras
🟦 small blue squares: Photos of landmark places on Google Earth

*A cluster is statistically significant when its log likelihood ratio is greater than the critical value, which is,
for significance level Standard Monte Carlo Critical Values, 0.001: 7.924854; 0.01: 5.816313; and 0.05: 3.788838.

Test of seasonality

Using the additive seasonal cases, a seasonal mean of the absolute cases was calculated for each season to allow us to test for seasonality in our relatively small data sets. To find out whether seasonal properties have a role in the increase of CDI in certain periods, the time series data for both groups, CA-CDI and HA-CDI, were adjusted for a seasonal component [25]. Given the small number of seasonal points, an analytical approach was used rather than a graphical depiction of the seasonal influences, which is more common but mainly used for longer study periods.

The additive seasonal indexes were calculated by subtracting the grand mean from each seasonal average. Subtracting each seasonal index from the associated seasonal measurement provided the seasonal adjusted values for each season [25].

Data were combined and stored in SPSS software, Version 21.0 (IBM Corp., Armonk, NY) and Microsoft® Excel for Mac, Version 15.27(161010). To determine the spatial and temporal Scan Statistics, we used SaTScan version 9.4.4 64-bit [26, 22]. Information on geocodes for FSAs was accessed from GPSVisualizer [27].

FIGURE 1B
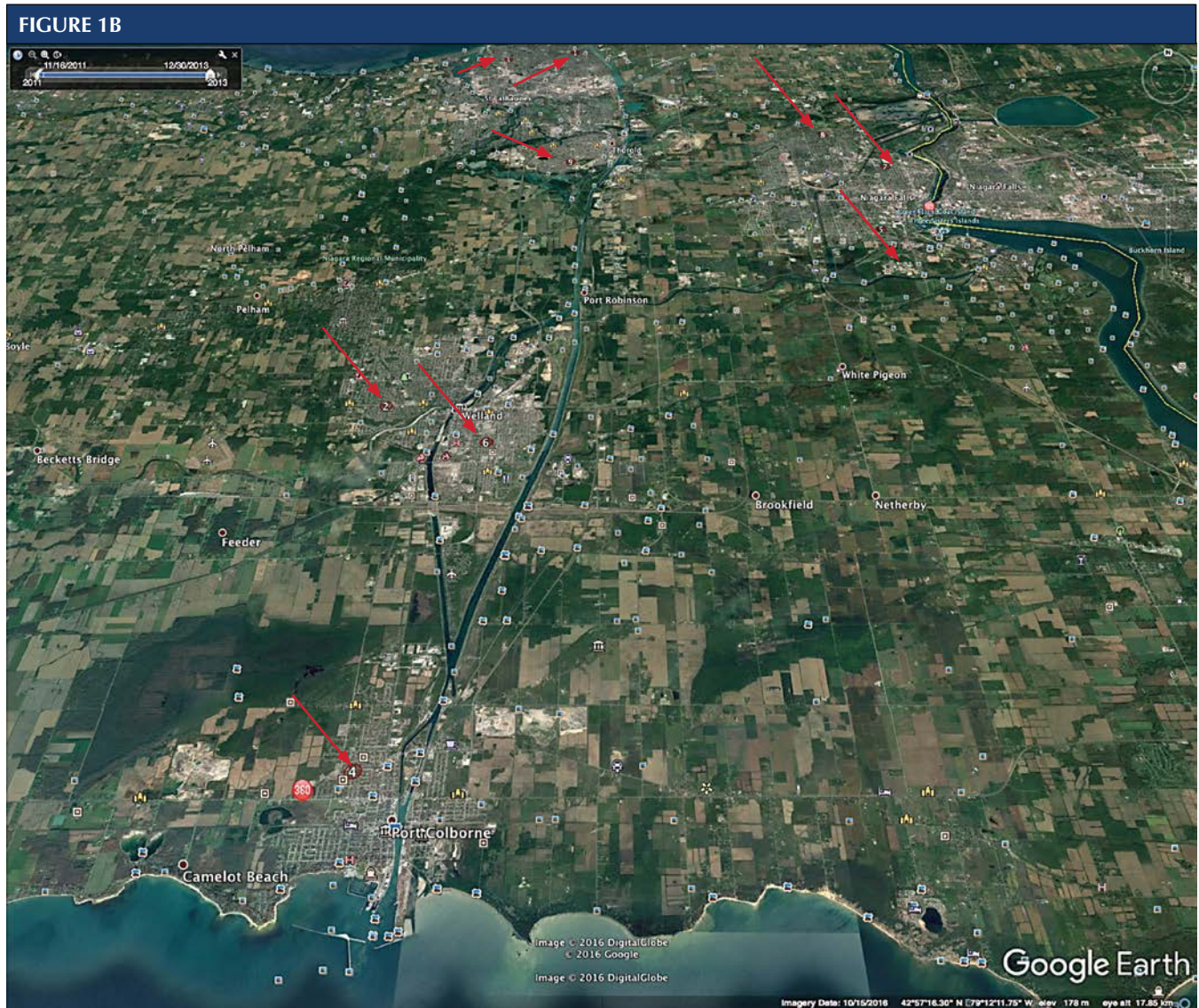
Retrospective spatio-temporal scan statistics of the cases of CA-CDI in the Niagara Region based on their FSA or the first three digits of the postal codes between September 1, 2011 and December 31, 2013. Number of significant* clusters (in red) with high rates identified using discreet poison model ($p<0.05$), identified with an arrow. Nine FSAs of the significant* clusters were identified:

L2M: $p<0.000$; N = 16; log likelihood ratio: 26.189012; L3C: $p<0.000$; N = 14; log likelihood ratio: 25.998135
L2N: $p<0.000$; N = 12; log likelihood ratio: 21.666917; L3K: $p<0.000$; N = 20; log likelihood ratio: 20.866021
L2G: $p<0.000$; N = 0; log likelihood ratio: 19.762781; L3B: $p<0.000$; N = 9; log likelihood ratio: 17.984835
L2E: $p<0.000$; N = 15; log likelihood ratio: 17.067404, L2J: $p<0.000$; N = 10; log likelihood ratio: 16.349787
L2V: $p<0.004$; N = 8; log likelihood ratio: 13.471642

Legends:
🔴 360 cities: Location of the panoramic cameras
🟦 small blue squares: Photos of landmark places on Google Earth

*A cluster is statistically significant when its log likelihood ratio is greater than the critical value, which is, for significance level Standard Monte Carlo Critical Values, 0.001: 14.909737; 0.01:12.850207; and 0.05: 11.177605.

We categorized the results of molecular testing for each category as discreet counts and as proportions of the total specimens tested.

Ethics statement

The protocol for this study was approved by York University's Office of Research Ethics and Niagara Health Service's Research Ethics Board. This study entirely consisted of secondary data analysis of de-identified quality improvement patient data; therefore, the requirement for informed consent was waived.

Results

A total of 1,051 CDI cases were identified through laboratory detection of toxins produced by *C. difficile* strains, 629 of which met the eligibility criteria; 318 (50.1%) were CA-CDI and 311 (49.4%) were HA-CDI.

Table 1 lists the rate per 1,000 patient days for each study year for the HA-CDI category and the rate per 100,000 population for the CA-CDI category.

Spatial Scan Statistics

Figures 1A, 1B, and 1C provide the Scan Statistics of the purely spatial, spatio-temporal, and time-space permutations, respectively, of the hospitalized CA-CDI cases in the Niagara Region. Cluster ($p<0.005$) identification was based on their specimen collection date and their residential FSA information. The identified clusters have different geocodes, and the radii of the circular windows were set for 1 km for each cluster.

FIGURE 1C

Retrospective space-time permutation scan statistics of the cases of CA-CDI in the Niagara Region based on the FSA or the first three digits of the postal codes between September 1, 2011 and December 31, 2013. Number of significant* clusters ($p<0.05$). Three FSAs of the significant* clusters:

Location IDs included (L3K, L3B, L3C); $p<0.000$; N = 51, test statistic: 29.779385

Location IDs included (L2E, L2J, L2H, L2G); $p<0.000$; N = 45, test statistic: 19.770718

Location IDs included (L7T, L9A, L3M, L0R, L2R, L2N, L2S, L2M); $p<0.000$; N = 45, test statistic: 19.397479

*A cluster is statistically significant when its test statistic is greater than the critical value, which is, for significance level Standard Monte Carlo Critical Values, 0.001: 11.580870; 0.01: 9.198556; and 0.05: 8.144111.

Legends:
- 360 360 cities: Location of the panoramic cameras
- small blue squares: Photos of landmark places on Google Earth

CA-CDI Scan Statistics identified five very localized, purely spatial clusters ($p<0.05$), with one FSA attributing to each cluster (Figure 1A). The clustering of CA-CDI cases in the Niagara Region was predominantly positioned in urban zones (Figure 1B). Upon further exploration and plotting of public dwellings and communal residences (such as nursing homes, shelters, schools, or group homes), we noticed multiple assisted-living supportive housing demarcations within the perimeters of the spatial clusters of CA-CDI. Figure 1C signals the CDI cluster areas based on the number of observed to expected cases.

Time series analyses and SPC charts
Figures 2A, 2B, and 2C explore the time series pattern of CDIs in NHS hospitals. When the control limit is set at ±2 sigma, the control chart for CA-CDIs indicates many months of higher-than-average CA-CDI rates with no out-of-control range. The control charts show an out-of-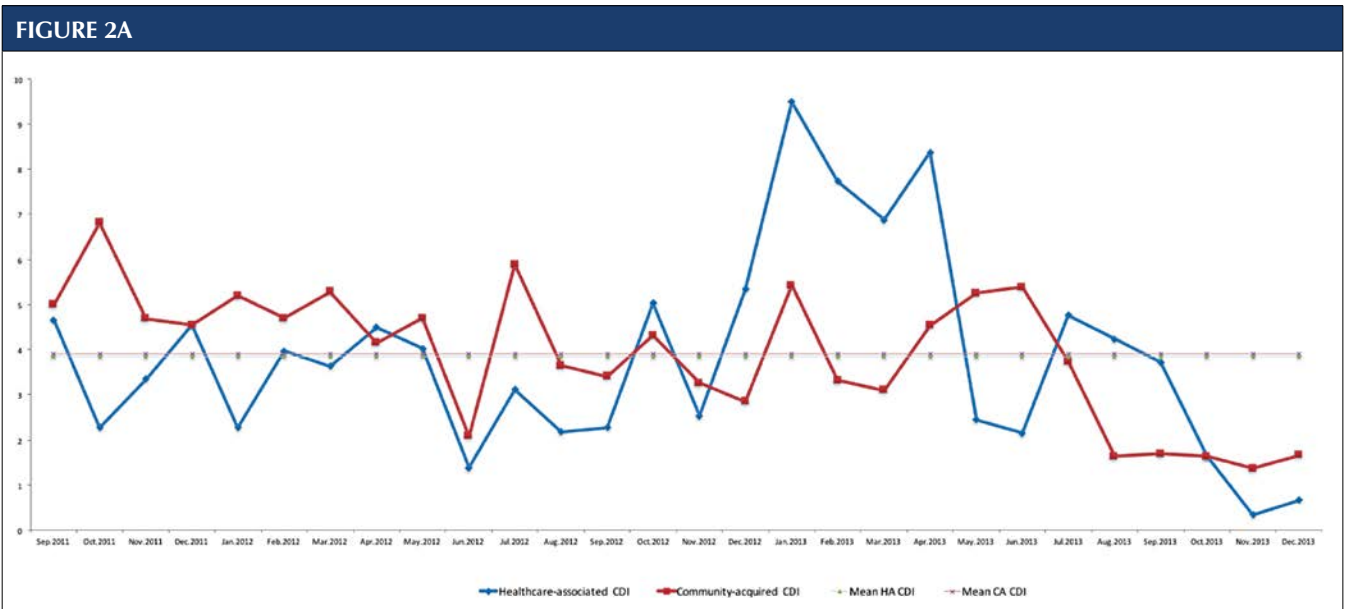control period for HA-CDIs starting in January 2013 and lasting until April 2013. To confirm this result and to understand whether the increase in CA-CDI and HA-CDI cases co-occurred, we turned to purely temporal analysis.

FIGURE 2A

Temporal visualization of CDI cases in the Niagara Region. Comparison of time series trends of CA-CDI and HA-CDI patients hospitalized in NHS hospitals between September 2011 and December 2013.

FIGURE 2B
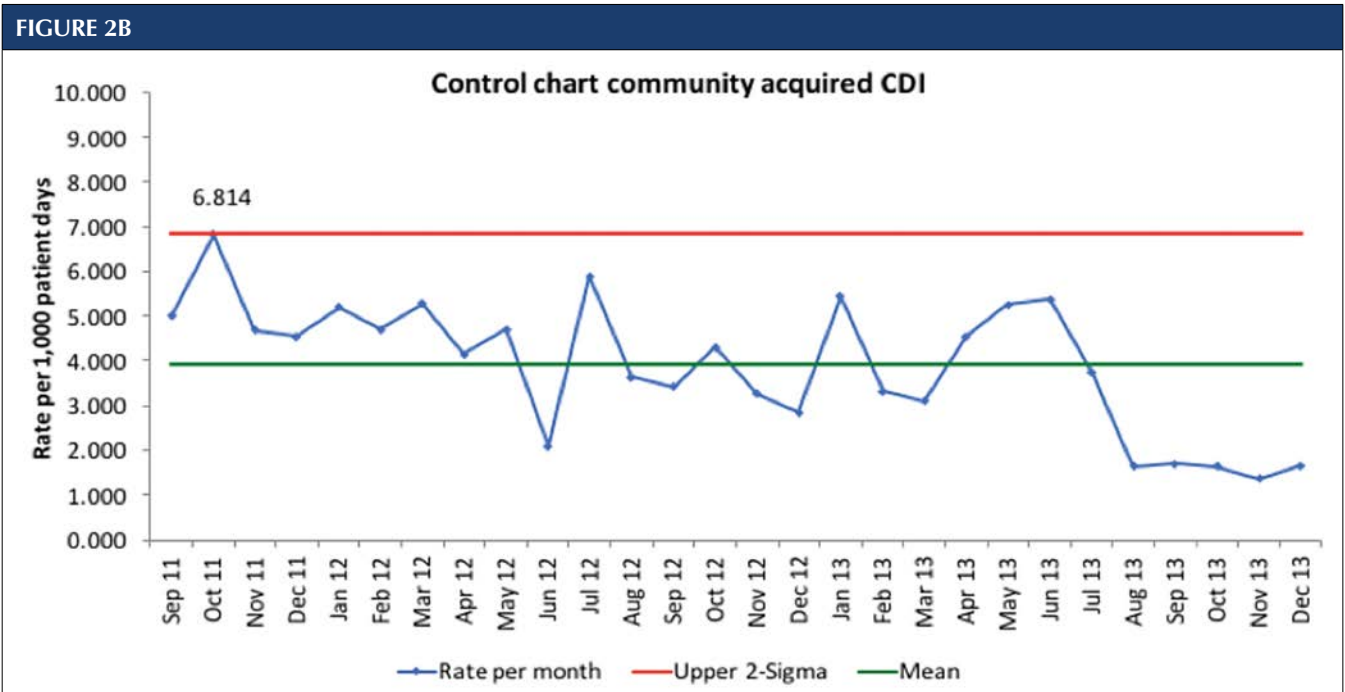
SPC display of hospitalized CA-CDI rates per 1,000 admissions hospitalized in NHS hospitals between September 2011 and December 2013.

FIGURE 2C
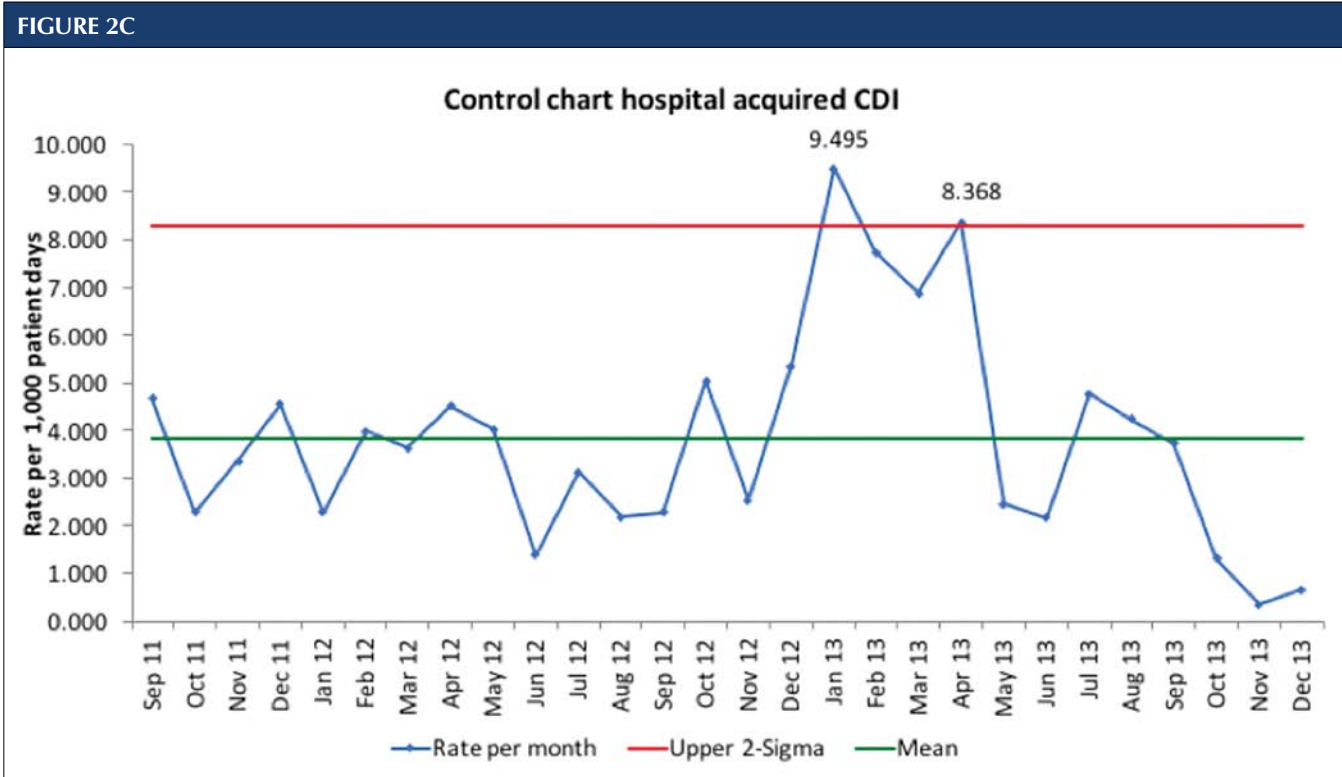
SPC display of hospitalized HA-CDI rates per 1,000 admissions hospitalized in NHS hospitals between September 2011 and December 2013.

FIGURE 3
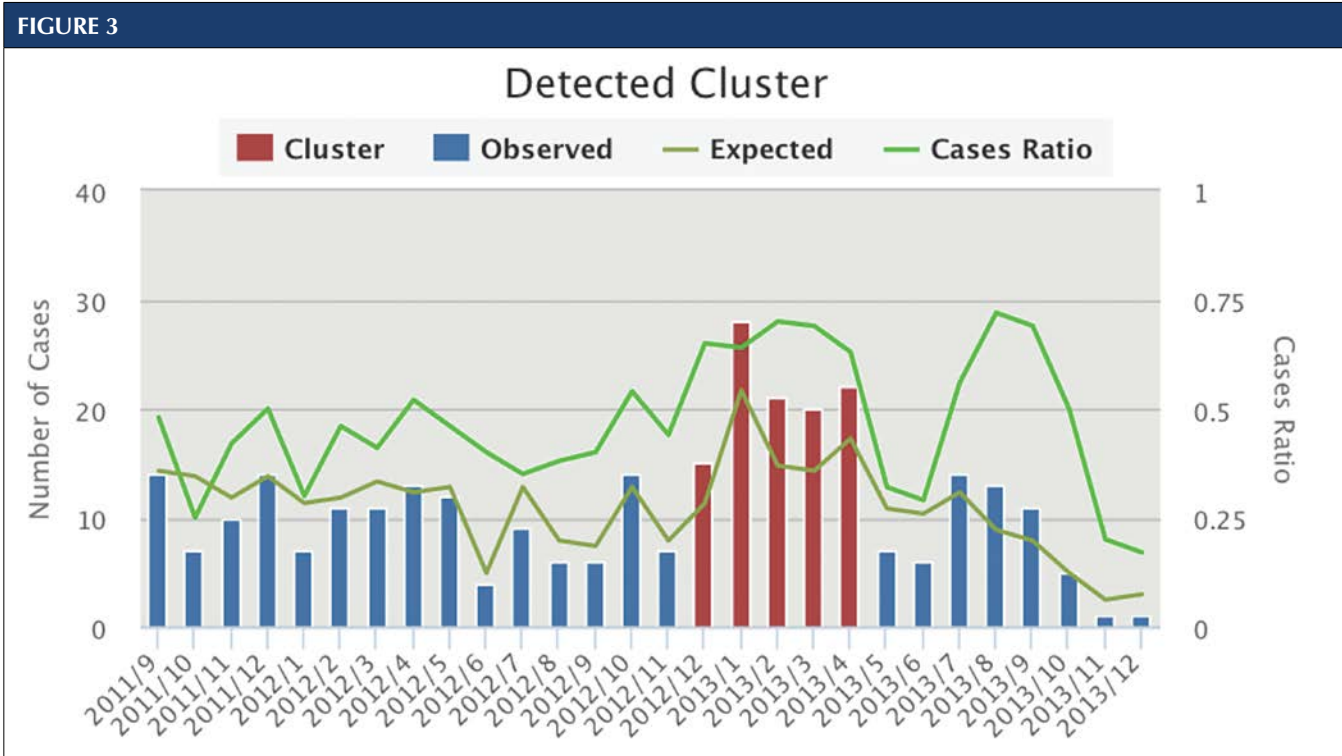
Purely temporal analysis scanning for clusters with high rates. A retrospective study of CDI cases in NHS hospitals between September 2011 and December 2013 using the Bernoulli model, SaTScan v9.4.4. Information on the detected temporal cluster:

Time frame: 2012/12/01 to 2013/4/30; Log likelihood ratio: 12.027272; Monte Carlo rank: 1/1,000; *P*-value: 0.001

A cluster is statistically significant when its log likelihood ratio is greater than the critical value, which is, for significance level:

Gumbel critical values: 0.00001: 13.971596 and 0.0001: 11.659499; Standard Monte Carlo critical values: 0.001: 8.060346; 0.01: 7.215835; and 0.05: 5.575158

Temporal scan statistics

Figure 3 illustrates a cluster of HA-CDI that was identified between December 2012 and April 2013, following a period of high CA-CDI hospitalization. Identification of a cluster rejects our null hypothesis that the cases in hospitals and the community happened at the same time. Instead, cases acquired in the community occurred at a different time than those acquired in hospitals during the period of the cluster.

Test of seasonality

The crude grand seasonal mean for the study period for all seasons was 35 for CA-CDIs and 36 for HA-CDIs. To better

FIGURE 4A
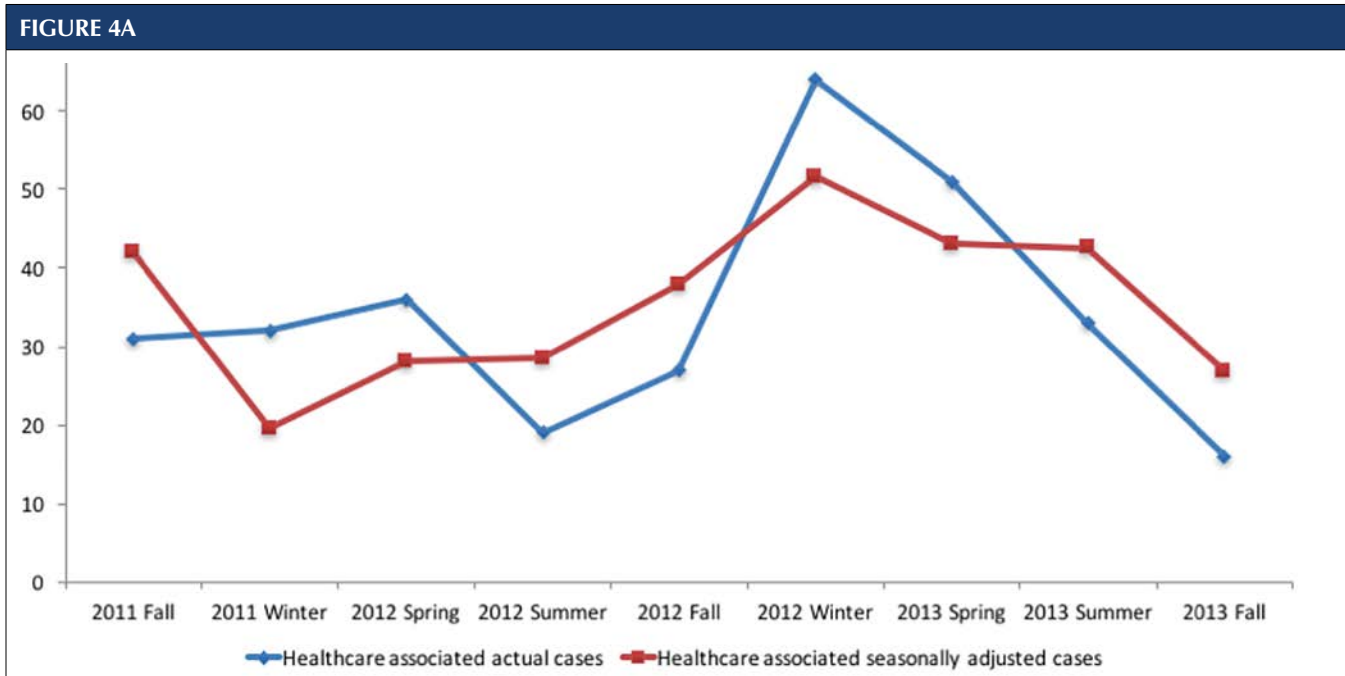
Crude and seasonality adjusted values for CA-CDI cases in the Niagara Region between September 2011 and December 2013.

FIGURE 4B
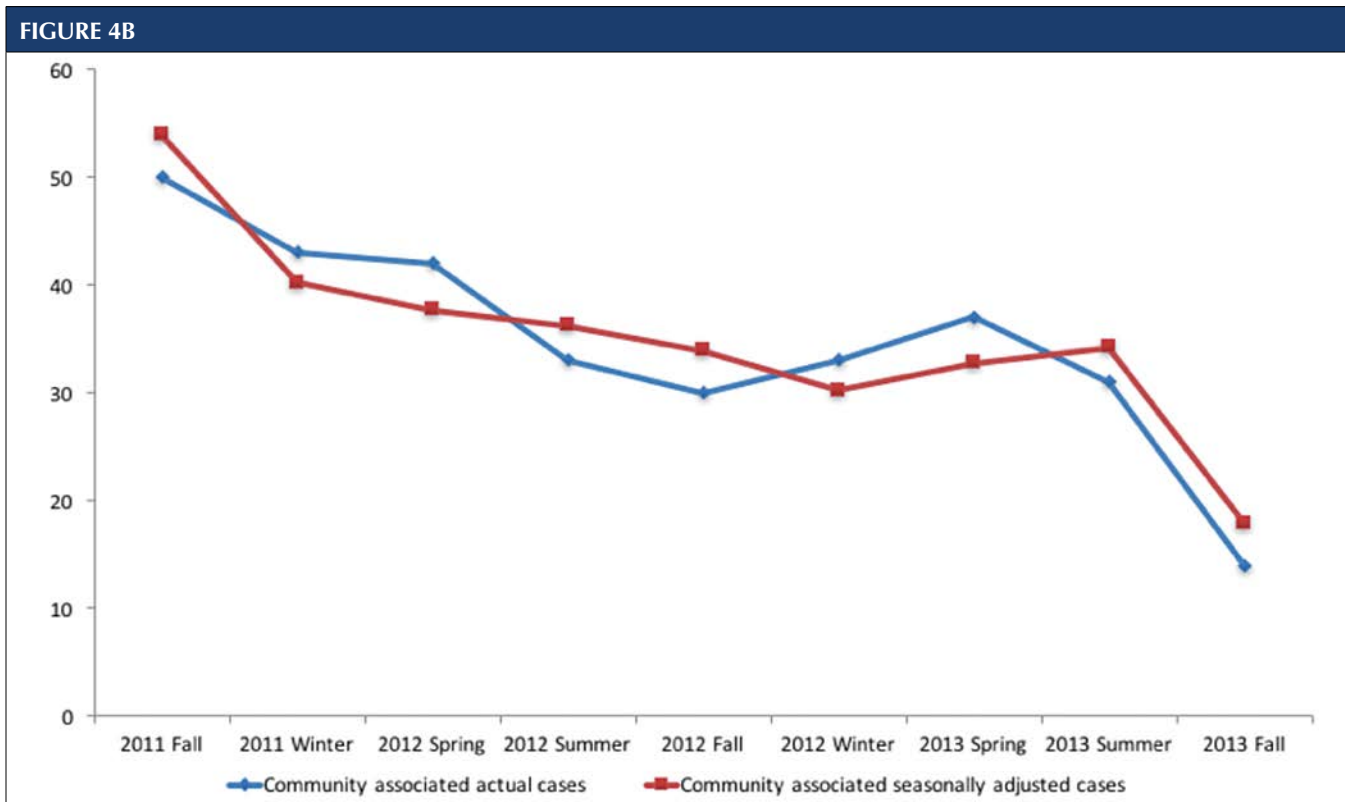
Crude and seasonality adjusted values for HA-CDI cases in the Niagara Region between September 2011 and December 2013.

understand the effect of the seasons as an influencing factor on the prevalence of CA- and HA-CDIs, we calculated the additive seasonal indexes and numerically plotted the computed seasonal effects for all seasons in the study period. Graphical evaluation of the crude and seasonally adjusted cases for CA- and HA-CDIs indicated a lower seasonal influence in the former than the latter (see Figures 4A and 4B).

C. difficile strain typing
Overall, 6% (40/629) of the study cases were tested for molecular typing. 4% (13/318) of CA-CDI specimens were tested and PFGE identified various strains, including: 2/13 (15%) NAP1 strains; the rest (85%) comprised other unrelated strains (A, B, C, D, I, M, N). 9% (27/311) of the HA-CDIs were tested for strain identification: 12/27 cases (44%) were NAP1strain, 2/27 (7%) were non-NAP1, and the rest (48%) were other unrelated strains (A, B, D, L, M, N, O, T, V).

DISCUSSION
In our case series study, we found differences between the temporal patterns of the hospitalized CA-CDI and HA-CDI cases and a unique pattern of spatial distribution for CA-CDIs. Our study did not reveal a seasonality pattern for the CA-CDI cases and we discovered that cases of CA-CDI and HA-CDI were temporally independent. Although our study was conducted only on hospitalized patients with CA-CDIs, the overall incidence was notably higher for the Niagara Region (14.84 in 2011; 33.22 in 2012; and 25.5 in 2013) than for studies done in the UK in 2004 (22.0 per 100,000 population), Connecticut in 2006 (6.9 per 100,000 population), and Philadelphia in 2005 (7.6 per 100,000 population) [28]. Similarly, given the fact that it experienced many outbreaks during the study period, the Niagara Region's HA-CDI rates were markedly higher (3.83/1,000 patient days) than the average rates/1,000 patient days for the entire province of Ontario, which were 0.30 and 0.33 in 2011-12 and 2012-13, respectively [29].

Spatial clusters of CA-CDI in our study were indicative of substantial accumulation of community cases that were admitted to the NHS hospitals from urban zones. This is in contrast to recent studies, which suggest a positive association between environmental elements such as flooding [5], rainfall, exposure to agricultural structures (exposure to soil, livestock, or raw animal products), bathing in potentially contaminated watercourses, and an increased risk of CA-CDI [30-32]. On the other hand, the proximity to communal dwellings such as nursing homes has been recognized as a contributing factor to increased risk of CDI in the community. This may therefore support the possibility of CA-CDI cases originating from shared community residences such as assisted-living supportive housings. In Ontario, the *Long-Term Care Homes Act* (S.O.2007, c.8.) [33] and the *Retirement Homes Act* (S.O.2010, c.11) [34] specify the need for infection prevention and control training and practices in these settings, but the legislation does not pertain to other fast-growing communal dwellings, such as assisted living or supportive housing.

The seasonal associations found in other CDI studies were not evident in our NHS study. Some of the studies that established a seasonal pattern suggest that the increase of CA-CDI in winter months can be attributed to the rise in antimicrobial prescribing practices during the influenza season [7, 35, 36]. However, reports of hospitalized and community-based CDI in the southern hemisphere did not substantiate the previous claim and pointed to the increased incidence in summer months, where they assumed a role for imported fresh produce for this pattern [6]. In our study, lack of a seasonal pattern may be explained by the presence of *C. difficile* in the community through other reported sources such as retail meat, farm services, soil, pets, and domestic animals [37-42].

The purely temporal study of CA-CDI and HA-CDI cases established a hospital-associated cluster spanning from December 2012 to April 2013, where a rise in CA-CDI cases predated the HA-CDI's temporal cluster (see Figure 3). One hypothesis could be that the asymptomatic carriage of HA-CDIs after discharge from NHS hospitals in the weeks or months preceding our study period might have contributed to an increase of CA-CDI patients in the community and their return to the hospitals to receive care. Another possibility is that the admission of non-suspected CA-CDI cases due to a lack of established risk factors upon admission to hospitals might have prompted HA-CDI outbreaks. Despite the moderate homogeneity between the HA-CDI strains that could point to a nosocomial transmission (12 of 27 were NAP1), more than half of the HA-CDI outbreak strains did not show a molecular relatedness. This may be explained by the introduction of multiple unrelated strains through direct or indirect contact with the CA-CDI patients admitted to NHS hospitals.

Prospective CA-CDI surveillance, added to strain typing programs inclusive of CA-CDI and HA-CDI, can identify the transmission pathways and the unique risk factors associated with CA-CDI. Added to the traditional surveillance methods used in hospitals, community surveillance of CA-CDI can inform the discourse of this infection's unique risk factors. In addition, research informed by geographical homogeneity can provide better understanding of the causal factors attributed to the infection's community clustering.

Our study was limited to hospitalized CA-CDI cases; we had no knowledge of the CA-CDI patients who did not need hospitalization. This limited the generalizability of our findings. Moreover, because we lacked access to the full postal code information, we could not document the precise location of the CA-CDIs. This reduced our ability to pinpoint the location of potential public sources of infection in the community. Furthermore, due to the short study period, the power of the seasonality analysis was limited and the identified patterns (or lack thereof) could have been influenced by multiple outbreaks during our study period. Our strain typing assessment was limited to those tested as a result of an outbreak investigation and composed a small proportion of all CDIs. The risk of misclassification of CDI cases in this study was reduced by using a comprehensive surveillance database, which was based on a case definition, case confirmation, and expert consultation.

Epidemiological evaluation by means of administrative and quality improvement databases allowed for a large-scale data set and reduced the risk of recall bias.

The temporal independence of the CA- and HA-CDI cases, the higher-than-expected number of hospitalized CA-CDI cases, and the multiple reported HA-CDI outbreaks with a large proportion of unrelated molecular patterns all point to a possible association between the appearance of hospitalized CA-CDI cases and hospital outbreaks. Other studies have hypothesised a positive correlation between increased HA-CDI rates in hospitals and community prevalence and have suggested that hospital cases could be a driver of CDI in the community [10, 43, 44]. Some studies postulated a community reservoir as a potential attributing base for this infection into the hospitals [5, 39, 40]. Novel research programs that combine hospital and community findings can detect the direction of CA-CDI transmission. A better understanding of the epidemiology and the community drivers of CA-CDI will guide hospital and community patient safety policies, inform public health programs, and improve quality of health at a population level.

APPENDIX A: NHS' definitions of CDI, HA-CDI, and CA-CDI used between September 2011 and December 2013 for surveillance and case identification.

NHS Definition of CDI

- Diarrhea

WITH

- Laboratory confirmation of *C. difficile* (e.g., by positive toxin A/B assay or PCR);

OR

- Visualization of pseudomembranes on sigmoidoscopy or colonoscopy;

OR

- Histological/pathological diagnosis of pseudomembranous colitis.

Definition of HA-CDI	Definition of CA-CDI
An HA-CDI case is defined as a patient who has not had CDI in the past eight weeks but meets one of the following criteria: • They do not present with CDI upon admission but show onset of symptoms >72 hours after admission. • The infection was present at time of admission but was related to a previous admission to the same facility within the last four weeks.	A CA-CDI case matches the case definition for CDI and does *not* match the HA-CDI definitions. In other words: • CDI symptoms *were* present upon admission or symptom onset *was less* than 72 hours after admission. • No exposure to any healthcare facility occurred within the last four weeks, or the source of infection cannot be determined and the patient has not had HA-CDI in the last eight weeks.

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ORIGINAL ARTICLE

Design-Based Research:
Introducing an innovative research methodology to infection prevention and control

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ABSTRACT

Background: With the rise in the Patient Safety Movement, increased attention is drawn to the efficacy and design of healthcare worker education and how that education is researched. Several challenges with current research methodologies used in research on education have been identified in the literature. The need for alternate research methods is recognized. This second paper in a series of four examines the application of Design-Based Research (DBR) to the design, implementation, and evaluation of innovative educational practices in complex practice settings.

Methods: This paper describes how an iterative, multiphase DBR framework was implemented to study Infection Control Professionals (ICP) educational practice and evaluate the design and development of an ICP professional development experience to build expertise and change educational practices in the Alberta Health Services (AHS) Infection Prevention and Control (IPAC) program. The efficacy of DBR as an alternative methodology was examined by summarizing the outputs, outcomes, and impacts of study activities and how the defining characteristics of DBR were manifest in the study.

Results: Numerous practical and theoretical study outputs and local outcomes resulted in more active and engaged teaching and learning by ICP participants. These outputs and local outcomes impacted the AHS IPAC program, resulting in ongoing ICP educational practice and professional development. The defining characteristics of DBR were effective in systematically designing and engineering change that was relevant and sustainable in the complex context of IPAC practice in the healthcare workplace.

Discussion: DBR contributed substantively to the understanding and building of educational expertise and practice in the AHS IPAC program. DBR is well-suited for use beyond the study of educational teaching and learning environments. Although a complex time- and resource-intensive methodological approach, DBR offers a new philosophical research perspective for studying change and interventions in complex contexts.

KEYWORDS

Infection prevention and control; education; Design-Based Research

INTRODUCTION

The focus of this paper, the second in a series of four dealing with infection prevention and control (IPAC) educational practice and research, is on the application of Design-Based Research (DBR), a change-oriented research methodology from the Learning Sciences to build IPAC educational practice [1, 2].

The emergence of the Patient Safety Movement has resulted in increased research on the effectiveness of healthcare worker (HCW) education, resulting in a shift away from the provision of knowledge to creating practice change by targeting HCW beliefs, attitudes, values, norms, and behaviours [3, 4]. Research challenges related to sampling, validity, reliability, and a lack of evidence for cause-and-effect relationships have been identified, limiting the credibility of this existing research on the efficacy of educational interventions [5-8]. These problems are consistently identified in traditional reductionist research

frameworks because of their focus on prediction and control [5, 7, 8]. Creating experimental conditions to study education in healthcare settings is challenging. Contextual, social, and cognitive determinants create variability in HCWs' application of knowledge in practice [4, 5, 9]. Isolating and controlling for all of the complex interactions of such factors is not possible. There is a pressing need for different methodological approaches to studying educational practice in healthcare [4, 7, 10].

These challenges also exist in IPAC educational research [8, 11-15]. A critical review of these challenges, provided in the first paper in this series, resulted in a call for change in our IPAC educational research and practice and to open ourselves to new advances in teaching and learning to effect behaviour change in HCWs' IPAC practice [16].

Responding to this call to action, a DBR study was conducted in the Alberta Health Services (AHS) IPAC program that focused on building Infection Control Professional (ICP) educational expertise. This study involved the design, development, implementation, and evaluation of an innovative professional development experience in education for a group of ICPs that was situated in the context of a community of learning (CoL) located in the ICPs' workplace practice [2]. This paper describes the DBR methodology employed and

exemplifies how this research approach can be used to study educational interventions in complex healthcare settings. Study findings regarding ICP educational practice and the educational professional development change intervention will be reported in subsequent papers.

Design-Based Research
DBR is an innovative, change-oriented research methodology developed by educational researchers to bridge the theory-to-practice gap and balance scientific rigor with relevance [17-19]. The methodology assists researchers in identifying multiple interacting variables and enables a systems-based understanding of the events being studied, making it a beneficial approach to investigating and facilitating change in complex environments like education and healthcare.

Several defining features describe DBR, including: interventionist, theoretically-oriented, grounded, iterative, contextual, flexible, collaborative, and integrative [20, 21]. DBR is considered to be interventionist because researchers intentionally engineer transformation by developing solutions to sponsor change and influence practice [18, 20]. To guide this engineered change, theory is put to work in the research process to solve practical problems throughout the study [18, 20, 22]. DBR is theoretically-oriented because theory not only frames the

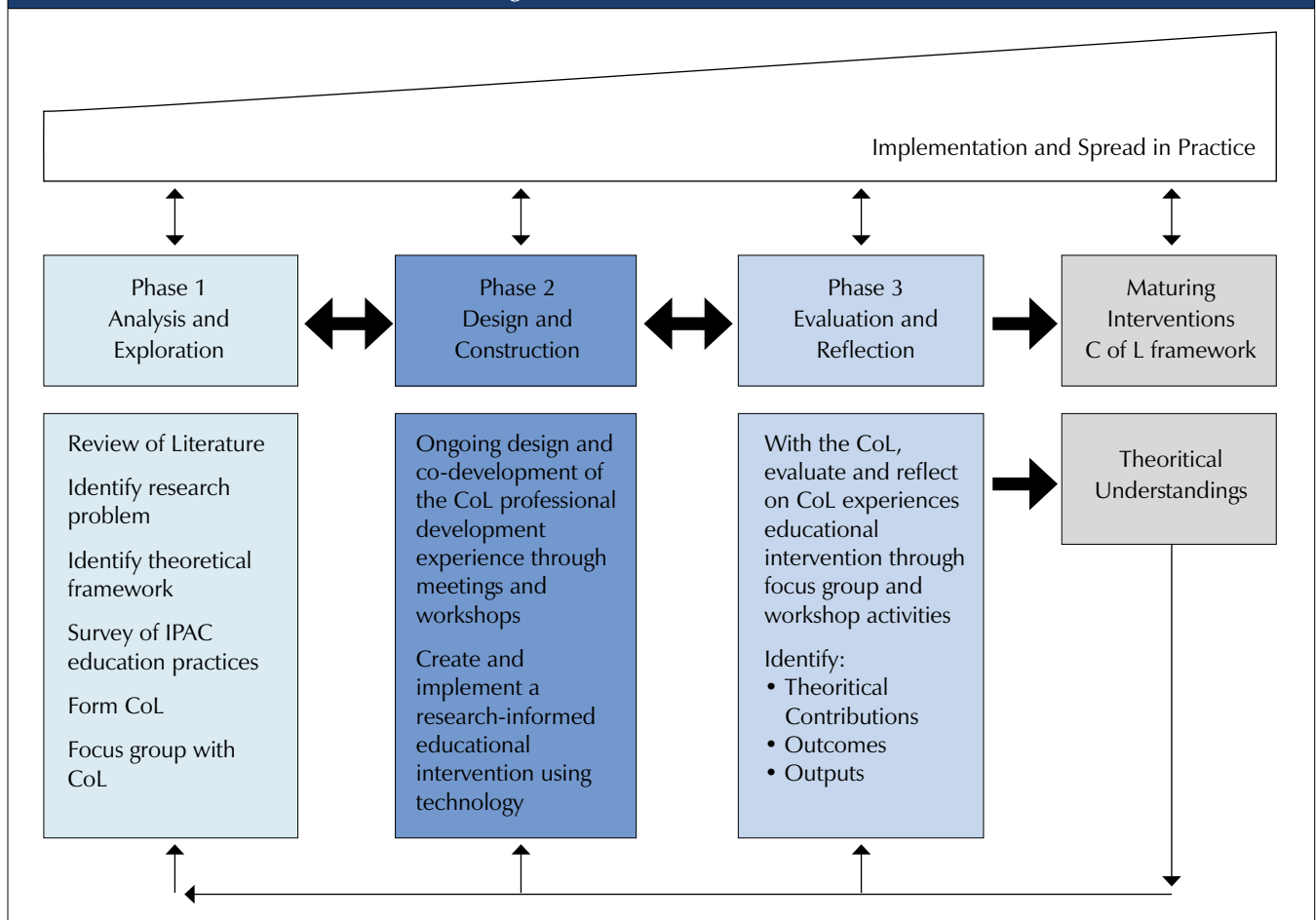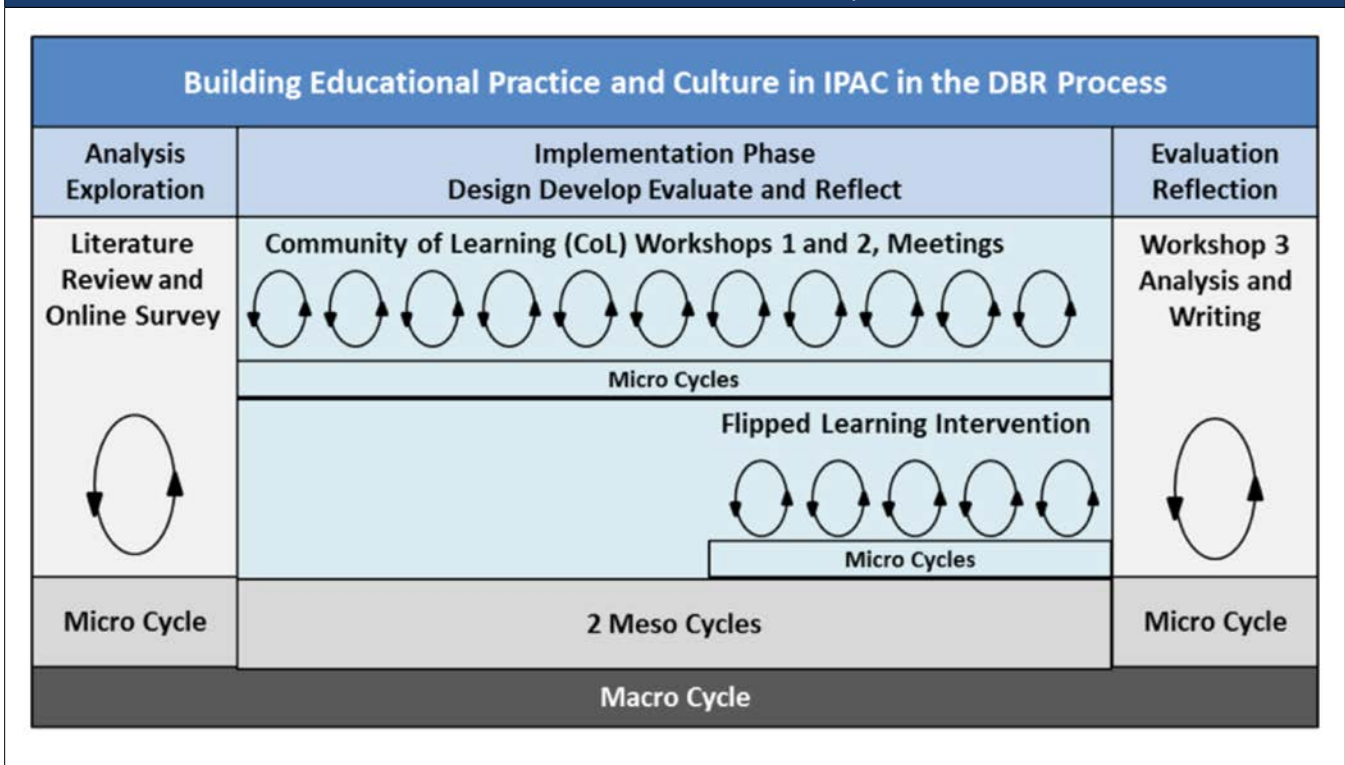FIGURE 1: The research framework based on a generic DBR model [20].

FIGURE 2: The research framework in the context of micro, meso, and macro cycles.

research process; theory and practice actively work together to both enhance practice and build theory. DBR is considered grounded because it is dually embedded in both real-life practice and theoretical frameworks. This enables the research to address process dynamics within both the study design and interventions, attending to how and why adjustments are made during the study.

This dual grounding guides an iterative development process, not just an evaluation of a set intervention. Through iterative cycles, data is re-examined and reflected upon and new designs are created and implemented [23]. In this way, not only is an intervention refined, but the theoretical framework upon which the design is based is extended, leading to a better understanding of how and why any intervention does or does not work.

Because DBR is grounded in practice, it is described as contextual, ensuring that solutions are responsive to complex issues of local practice. In this way, DBR is considered socially responsive because it puts the concerns and problems of practitioners at the forefront of the research and development process [21, 24]. DBR also involves researcher-practitioner collaborative partnerships that provide expert advice based on experience and practice wisdom, which help shape the research and the many decisions taken throughout the process [20, 21]. This approach allows for flexibility and responsiveness to emerging issues while maintaining a research focus as the study evolves.

Finally, DBR is considered integrative, drawing from a variety of research approaches and systematically using both qualitative and quantitative methodologies [21]. The combined use of mixed methods allows problems to be studied from diverse perspectives. The combination of methods and data collected from multiple sources increases the objectivity, validity, and applicability of the research.

MATERIALS AND METHODS

This section describes the DBR methodology used in the context of an IPAC healthcare setting. The purpose of the study was to respond to identified gaps in IPAC educational expertise and research methodology by employing DBR to deliberately engineer change using a systematically and intentionally designed educational professional development experience for ICPs. The study had three goals: 1) to develop ICP pedagogical expertise in ICP educational practices through participation in a learning community and the co-development of a research-informed education intervention focused on improving HCW IPAC practice; 2) to contribute to pedagogical and theoretical understandings of IPAC educational practices; and 3) to introduce DBR from educational research to a healthcare setting to explore its efficacy as an alternate research methodology with which to research IPAC education.

Implementation of the DBR process

A framework, illustrated in Figure 1, guided the study. It involved three core phases that informed each other iteratively.

The various activities involved in the study are listed under each phase. Movement through each of these phases facilitated the design and development of an intervention that

contributed to the professional development experience and to the theoretical understanding of IPC educational practice. Study activities also interacted with the ICPs' ongoing practice from the beginning and increased in implementation and spread beyond study participants as the study progressed. Figure 2 illustrates how the DBR process occurred through multiple iterative cycles within the context of these three study phases in greater detail.

The iterative cycles took the form of micro, meso, and macro cycles. Overall, this study encompassed the first of potentially several macro cycles in the DBR research process. The first macro cycle incorporated all three phases of the study in the design and development of the ICP professional development intervention experience. A second study would involve a second macro cycle in which the professional development experience would be repeated, modified, and refined. Within the first macro cycle reported here, there were several micro cycles that repeated exploration, implementation, and evaluation of activities in the ICP professional development experience. These micro cycles are grouped into two meso cycles iterating within the larger macro cycle.

Phase 1 of the study involved analysis and exploration of the research problem and theoretical framework as informed by the literature and researchers' experiences working in IPAC. An online questionnaire (N = 48 participants) was administered to obtain a deeper understanding of the identified research problem in the context of local AHS IPAC educational practices and culture. After the survey was conducted, a CoL was formed with the eight ICPs who consented to participate in a collaborative professional development experience over the course of this study. One characteristic of DBR is close collaboration with practitioners; thus, one of the CoL's first activities was to create a focus group comprising ICPs to verify and build on survey findings to co-develop a deeper understanding of IPAC educational culture and the nature of the ICPs' educational issues and concerns. The focus group interview was part of the study's first micro cycle.

In Phase 2, survey and focus group interview results were combined with information from the literature and further consultation with the IPAC program to inform the ongoing design and development of the CoL professional development collaborative learning experience. The CoL experience underwent several iterative micro cycles involving design, implementation, and evaluation phases as the professional development intervention unfolded, resulting in one meso cycle within the study. Embedded within the CoL professional development experience was the ICPs' involvement in the co-creation of a research-informed educational intervention employing a Flipped Learning design that they themselves could use to teach HCWs. This co-design process formed a second meso cycle through another series of micro iterative cycles in the design, implementation, and evaluation of the intervention. The overall goal of iterative cycles was to produce a sustainable, practical, and effective professional development experience and educational product for the AHS IPAC program.

Phase 3 of this study included the implementation of an additional micro cycle that involved the evaluation of and reflection on the overall design, implementation, and research processes used in the creation of the CoL professional development experience and the educational intervention to develop a deeper understanding of the processes, the design principles used, and their effects. Evaluation and reflections were useful not only for the enhancement of the CoL and the educational intervention, but also for understanding the learning environments in which the interventions were developed and implemented.

Data collection and analysis
Data collection occurred over a period of 19 months from April 2014 to March 2016. Table 1 summarizes the various data sources and the collection and analysis methods that were used in the various study phases. In DBR, data collection processes can be complex, with large amounts of data collected from multiple data sources using a variety of collection methods.

TABLE 1: A summary of the data source and the collection and analysis methods.			
Data Sources	**Sample**	**Method/Tool**	**Method of Analysis**
Phase 1 Online survey	Convenience sample: N = 48	Online questionnaire using Survey Select	Descriptive statistics and qualitative analysis
Phases 1 and 3 Focus group interviews	Convenience sample: N = 8 CoL participants	Question guides and digital recordings	Qualitative analysis
Phase 1, 2, and 3 Short questionnaires	Convenience sample: N = 8 CoL participants	One-page questionnaire, paper-based	Qualitative analysis
Phases 1, 2, and 3 Field observations	Subset from CoL N = 3	Observation tool, paper-based	Qualitative analysis
Phases 1, 2, and 3 Study documents and products	N/A	N/A	Content analysis
Phases 1, 2, and 3 Researcher journals	N = 1 researcher	Online journals; QSR NVivo Memos	Qualitative analysis

TABLE 2: A summary of the study outputs, outcomes, and impacts.		
Outputs	**Outcomes**	**Measurable Impacts**
Practical • Documents (e.g., teaching guide toolkit) • Online teaching and learning resources for ICPs • Development of online teaching module for HCWs • An IPAC professional development model and program • Summary report to AHS IPAC leadership with recommendations for IPAC education development • Installation and utilization of a software platform to design e-learning **Theoretical** • Descriptive local theory regarding IPC educational practice • Descriptive, explanatory, and predictive mid-range theory regarding IPC educational professional development	**Practical** • ICPs: Increased pedagogical expertise; more active teaching and less reliance on PowerPoint • Researcher: Increased educational and research expertise • Increased visibility of education within the AHS IPAC program • Increased AHS IPAC leadership engagement with IPAC education • Increased skill and facility to use software to design e-learning in AHS IPAC program • Ongoing educational professional development in teaching and learning for all interested AHS ICPs through a Community of Practice **Theoretical** Better understanding of: • Existing ICP educational practices and challenges • Strategies needed to facilitate ICP educational practice (e.g., development of IPAC identity as educator, pedagogical knowledge, and lexicon) • AHS system issues limiting effective IPAC education	**Measurable Impacts** • AHS IPAC leadership approved purchase of additional e-learning software licences (seven IPAC staff now designing with e-learning design software) • AHS IPAC leadership requested the development of two additional online modules: an Ebola (Viral Haemorrhagic Fever) PPE module and a general IPAC PPE module • Two education sessions were provided to AHS IPAC staff: one on adult learning to hand hygiene reviewers and one on collaborative and game-based learning to senior staff • An IPAC Education Community of Practice has been operating for two years. ICP attendance ranges from 25 to 30 people • Within the first six months of posting and without promotion, 1,898 HCWs accessed the online module created as part of the study (1,156 completions, 256 withdrawals, and 486 still active)

A DBR approach embraces the concept of triangulation – that is, the combination of information from mixed methods to cross-check results for consistency, enhance the confidence in research findings, and reduce possible bias from the use of a single method [25]. In this study, a combination of an online survey questionnaire, focus group interviews, short questionnaires, field observations of ICP educational practices, researcher journals, researcher and researcher assistant notes, and documents and educational products created during the study were used as sources of data. As data was collected, it was cleaned and entered into Microsoft Excel© and QSR Nvivo10© for analysis. QSR NVivo 10 is a computer program that supports the qualitative analysis process [26].

Descriptive statistics and Chi-Square tests were used to analyze several of the online survey questions. All other data were analyzed using an iterative, systematic thematic analysis [27]. This study was approved by the University of Calgary's Conjoint Health Research Ethics Board.

RESULTS
DBR outputs, outcomes, and impacts
The theoretical and practical contributions of DBR studies can be identified in terms of the study's outputs, outcomes, and impacts. Outputs are the practical and tangible products that directly result from the study activities, including emergent theoretical understandings. Outcomes are substantive changes that occurred following the designed interventions and resulting impacts are the measurable changes that occurred. Table 2 lists the study's numerous and beneficial outputs, outcomes, and impacts.

It was found that both the theoretical and practical outputs and outcomes of the study led to more active and engaged teaching and learning by ICPs and provided the foundation for continuous, ongoing development and change within the AHS IPAC program beyond the study.

Manifestation of the DBR characteristics in this study
The efficacy and utility of the DBR methodology can also be assessed by examining how its defining characteristics were realized in a study. Table 3 summarizes the results of such an examination.

The value of the theoretical, interventionist, collaborative, and flexible aspects of the study for IPAC practice bears mentioning in greater detail. The knowledge produced by DBR has been described as principled, practical knowledge (i.e., the "know-how" is combined with the "know-why") [28]. Such knowledge provides practical guidance that bridges and links theory and practice. DBR is collaboratively situated in practice; therefore, the theory developed is linked specifically to the interventional design and local context, yielding local theory [20]. Local theory provides an explanation of real-life

TABLE 3: Examining the characteristics of DBR as realized in the present study.	
Characteristics of DBR	**Realization in the Present Study**
Interventionist [18, 20]	• Created a change in participating ICPs' educational understanding and practice in terms of teaching and learning • Facilitated the development of more effective and professionally rewarding educational practices by ICPs • Produced a research-informed solution to build on IPAC educational practices and culture • Influenced AHS IPAC educational activities generally
Theoretically oriented [18, 20]	• Literature was used to identify theoretical, methodological, and conceptual problems • The research design was informed by constructivist theories of situated, collaborative, and blended learning and were used to systematically guide iterative design of the CoL and educational intervention • Findings contributed to theoretical understanding of teaching in IPAC. This was used to inform the professional development experience of the ICPs in the CoL
Contextual [21, 22]	• Was situated in the ongoing real-life practice of IPAC and the complex healthcare environment
Grounded [21]	• Research was anchored in both constructivist theoretical principles and embedded in authentic IPAC practice
Flexible [21]	• The design was responsive to the complexity of ICP professional practice demands as well as emerging issues that impacted the study and ICP practice (i.e., the Ebola epidemic)
Iterative [20, 21]	• The design of the interventions was repeatedly informed by ongoing research and emerging issues • The research focus went beyond the evaluation of an intervention to explore learning processes and develop design principles that informed the ICPs' professional development experience
Collaborative and Interactive [20, 21]	• The research was done in partnership with IPAC leadership, ICPs, and the researcher
Integrative [21]	• The research used the concept of triangulation: data from multiple sources and different data collection methods

phenomenon – in this case, representing the complexity of IPAC educational practice and how to develop and advance ICP educational knowledge, practice, and expertise.

The interventionist and collaborative aspects of the methodology were important because these facilitated active engagement with ICPs, impacted their teaching practice in real time, and also afforded increased visibility and buy-in from AHS IPAC leadership who were in positions of influence to support and encourage change. Such collaborative engagement contributed to the outputs and outcomes of the study.

The flexibility of the DBR process was both important and invaluable in CoL design and evaluation. Dynamic, real-life environments can be complex and emergent; however, unpredictability is a hallmark of an IPAC professional's work life. A lived example of unpredictability became evident with the emergence of an Ebola epidemic during the study. The AHS Ebola response preparations resulted in increased demands and a change in focus in the daily work of the ICPs, including those of the first author, during the study. The DBR methodology's flexible nature allowed the research team to leverage the living laboratory that was the Ebola epidemic. The ICPs' teaching and learning experiences while developing and implementing large-scale, just-in-time education for Ebola were incorporated into the CoL professional development experience. Field observations confirmed that some of the ICPs began to

implement teaching strategies they had learned in the CoL into their Ebola education.

Limitations
DBR is a complex research methodology that can be time-intensive and resource-intensive. DBR depends on collaborative partnerships with practitioners throughout the research process and does not always yield immediate results. While initial macro cycles of the DBR process can produce data and theory that are both valuable and relevant to local practice, it takes time to influence sustainable change. DBR is a long-term process that requires a series of macro cycles to upscale local theory and achieve relevant higher-level theory as interventions and design principles mature and emerging theories are synthesized to become generalizable theories for broader contexts and populations. One of the specific limitations of the present study is that, as a first macro cycle in the DBR approach, the findings contribute primarily to local practice and theory. Additional cycles are called for to refine the emerging theory and educational professional development framework for the broader ICP population and for ICP educational practices in general. The unique nature of the AHS organization must be considered, as healthcare is a provincial responsibility and organizational policies and procedures vary from province to province and the IPAC programs within them. It will be

important to explore IPAC educational practices in other IPAC programs across Canada to scale up this current study's findings.

DISCUSSION

The merits of the DBR methodology to research interventional designs to change learning environments are well documented [18, 20, 29]. Investments in this complex methodology have proven worth it. In the present study, DBR contributed to significant understanding and development of ICP educational practice in the AHS IPAC program. The emergence of the Patient Safety Movement in healthcare has attracted increased focus on psychosocial behavioural aspects of HCWs to improve and change practice. Randomized and controlled research on psychosocial change interventions and inherently complex HCW behaviours is challenging and fails to yield useful insights for teaching and learning. DBR is an effective and innovative research methodology for studying educational interventions for the purpose of practice change, thus offering a systematic alternative approach to experimental research methods. This study demonstrates a successful use of DBR to design and study teaching and learning in the contextual complexity of healthcare. As a change methodology, DBR is well-suited for inquiry beyond the evaluation of teaching and learning environments. DBR offers a new philosophical research perspective for studying change and innovation in complex contexts.

Adoption of a DBR methodology in healthcare will require a philosophical shift in research agendas. Traditional, reductionist research methods that focus on prediction and control are ill-suited for creating and studying change in complex and authentic learning systems. DBR uniquely balances rigor from research with relevance in the field by drawing continually on both theory and practice throughout the research process to inform the design and implementation of sustainable solutions to practice problems. Adoption of a DBR approach focused on creating change will open the door to new discoveries for IPAC educational research designed to promote IPAC HCW practice change.

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QI IN IPAC

The frequency and reasons for central line accesses in critical care units

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ABSTRACT

Background: A quality improvement initiative sought to understand opportunities to reduce central line utilization. This pilot study assessed the most common reasons for and rates of line access.

Methods: 15 nurses across three critical care settings tracked accesses of central venous catheters and peripherally inserted central catheters.

Results: The results from 119 shifts showed that lines are accessed on average seven times per shift. The most common reason for access was medication delivery. Blood collections were 22% of accesses (medication delivery was 51% of accesses).

Conclusions: These results show opportunities to reduce reliance on central lines by moving blood collections to an alternative method.

KEYWORDS

Central line; critical care; study; practice; infection

INTRODUCTION

Improved procedures from the Society for Healthcare Epidemiology of America, the Association for Professionals in Infection Control, and the Centers for Disease Control and Prevention [1, 2] on central line insertion and maintenance have reduced central line-associated blood stream infections (CLABSI). The reduction of central line utilization, however, has been more resistant to change: central line utilization has increased over time [3]. A reason for this resistance is that while it is accepted that infection rates are strongly correlated to the number of line days and line touches [4], central lines provide reliable patient access, particularly for blood collections in otherwise difficult venous access patients [5].

To understand possible levers to reduce central line utilization, we performed a pilot study in various critical care units to define the most common reasons for central line access and how they relate to patient treatment. The goal was to approximate the percentage of line uses that could be avoided or switched to other, less risky vascular access devices with changes in practice or policy. The results may be used to inform the protocol design of a broader study on the effect of hospital policy changes to central line access practices.

METHODS

The study was evaluated by the University Hospital of Cleveland Medical Center (UHCMC) Investigational Review Board and exempted from review. The study was deemed to be observational for quality assurance purposes and no patient identifying data was collected.

The cardiac intensive care unit (CICU), the surgical intensive care unit (SICU), and the medical intensive care unit (MICU) were chosen for the study because of the high percentage of patients with indwelling central lines. Five nurses were chosen in each of the critical care units (a total of 15 nurses in all) to participate in the study by their nurse managers based on interest in the study. Each nurse was asked to track line access data for all the patients they cared for who had an internal jugular or subclavian central venous catheter (CVC) or a peripherally inserted central catheter (PICC) for up to ten shifts. Data collection included the type of central line, the patient's primary diagnosis, the time of each access, the number of accesses, and the reason for access. Data was gathered prospectively in real time on paper worksheets and was later collected and tabulated by a single researcher.

RESULTS

The average daily census (ADC) of the critical care units at the UHCMC are:

CICU ADC: 15
MICU ADC: 19
SICU ADC: 17

Over the first three months of 2017, >20% of patients in the three units had central line access, representing a total of 993 line days. A total of 119 day-time and night-time shifts' worth of data from 14 nurses were gathered, representing nine shifts per nurse on average. Data from five shifts was excluded because of catheter type; an additional five shifts were excluded because the care was delivered in a non-critical care unit. There were more observations in the SICU and CVC lines were four times more common as PICC lines (99 vs 24).

FIGURE 1: Comparison line access by line type.
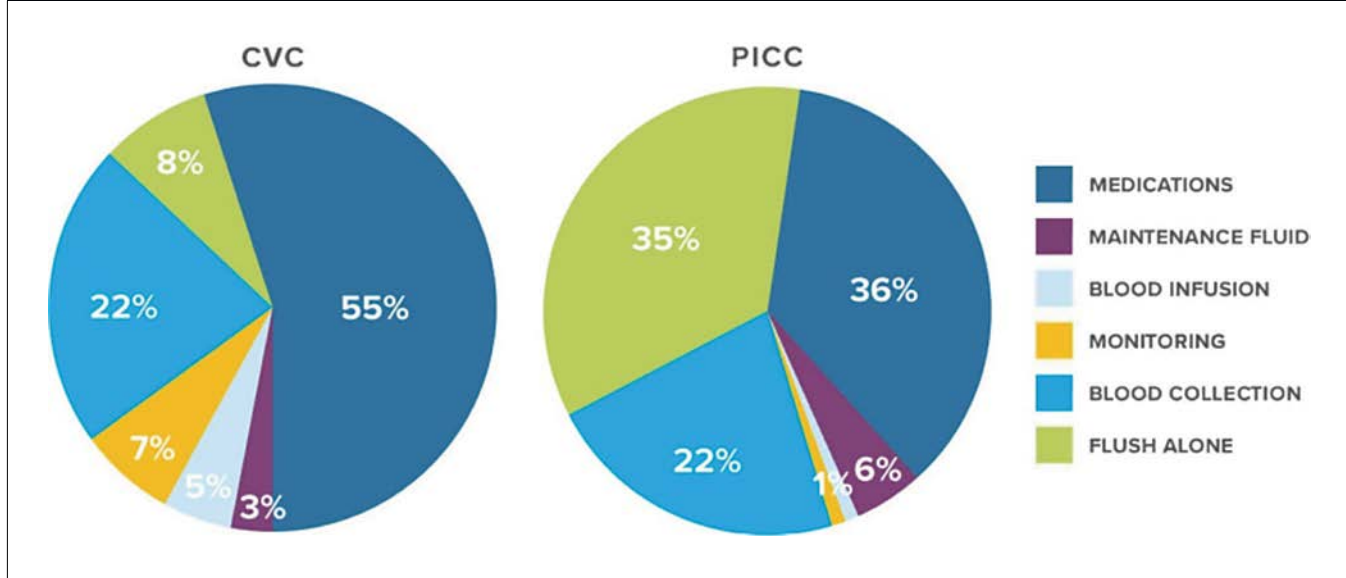
FIGURE 2: Count and type of access in average shift.
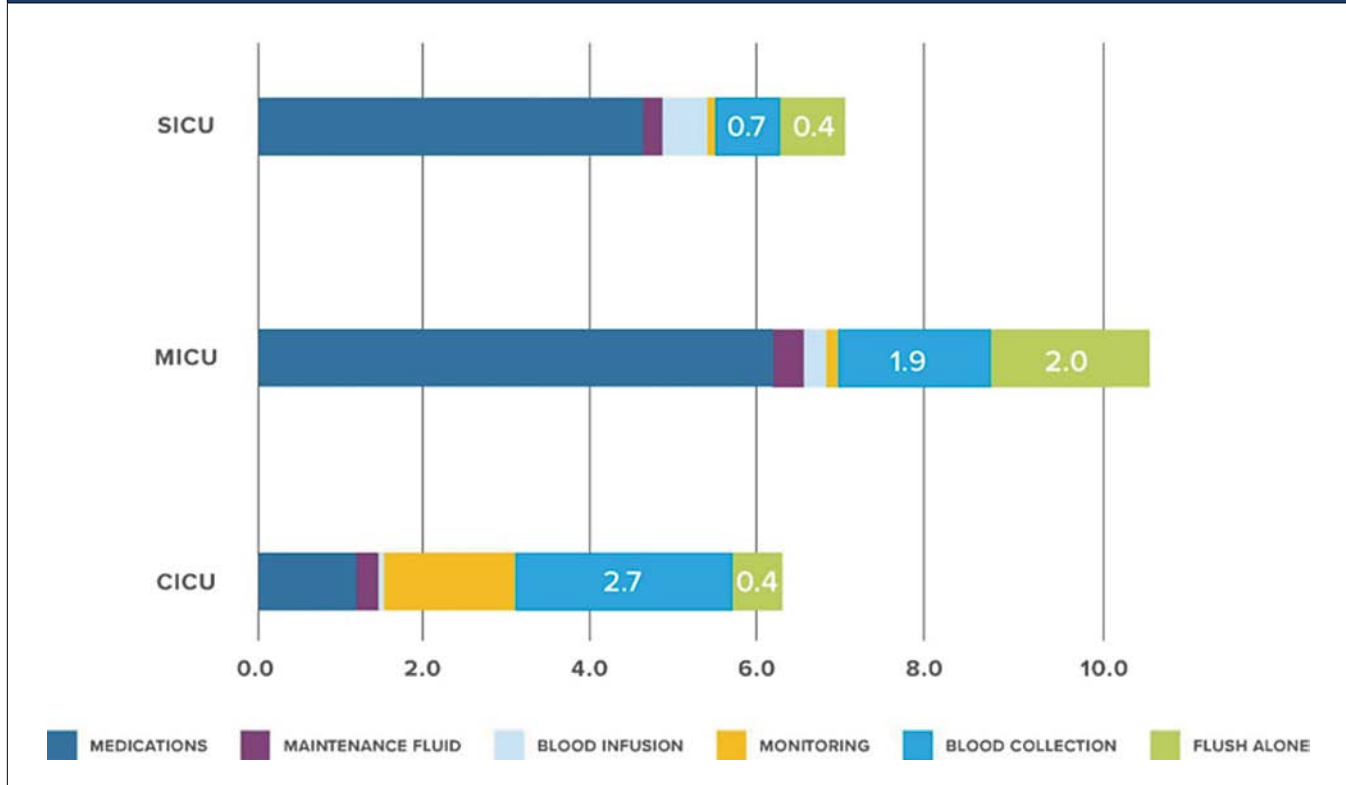
Overall, the most common reason for line access was to deliver a medication (including flushes following delivery), which accounted for 51% of all accesses. Blood collections, including flushes following the collections, represented 22% of accesses; flushes alone represented another 12% of accesses. The number of unique accesses or connections to a line for maintenance fluids is small at 3%, likely because the lines remain running for several hours without disconnection (see full breakout in Figure 1).

The usage of central lines for blood collections was not driven by the type of line (Figure 1). PICC lines were used for blood collections nearly as frequently as CVC lines. CVC and PICC lines were otherwise accessed differently: PICC lines were not used for cardiac monitoring and were more likely to have maintenance flushes. Overall, access rates were similar for the line types (CVC: 8 accesses/shift vs PICC: 6 accesses/shift).

The patient's diagnosis was included in the study but did not provide differentiating analysis information. The patient unit, as a proxy for patient disease, did seem to affect the rate of line utilization for blood collections. The CICU had the highest rate, followed by the MICU and the SICU (Figure 2).

DISCUSSION

PICC lines are typically used if the patient requires prolonged IV therapy, often in the form of antibiotics, Total Parenteral Nutrition (TPN), or infusates, which are too caustic for peripheral infusion. CVCs are used for resuscitation efforts, often including vasopressors, large fluid or blood administration, cardiac monitoring, blood draws, and central venous oxygen saturation (SvO2) measurements. CVCs also are preferred in critically ill patients since they typically have more lumens, larger bore, and faster flow rates into the central circulation. Both CVC and PICC lines are placed by a subset of specially trained nurse practitioners, physician assistants, residents, and attending physicians.

Beginning in 2014, the UHCMC adopted the CLABSI best practice bundles set forth by the Joint Commission. The insertion bundle includes proper hand hygiene; use of full barrier precautions, including personal protective equipment (sterile gown, sterile gloves, and large sterile drapes); and optimal site placement. All patients in the critical care areas are bathed daily with chlorhexidine. Line maintenance includes daily review and monitoring. The CLABSI target for each of the critical care units is a rate of 1.29 per 1,000 catheter line days.

All three critical care units at the UHCMC have been meeting or besting target CLABSI rates and quality monitoring shows strong adherence to policies on line insertion. However, as part of continual improvement, the institution sought to understand avenues to further reduce CVC utilization by reducing CVC line days and the number of CVC accesses. This pilot study was designed as a first step in understanding how often lines are accessed and the most common reasons for those accesses.

The results show that over one-fifth of all central line accesses are for blood collections, which do not have to be performed through a central line. Central line infections were initially understood to be caused by bacterial migration from the insertion site; however, they are now thought to be caused by the ingress of bacteria from one of the catheter's connection ports as the line dwell increases [6]. Therefore, the common avenues to CLABSI reduction are employing sterile insertion techniques, ensuring proper disinfection prior to each access, and line removal at the earliest occasion [7].

One limitation of this study is that each nurse only completed up to ten shift observations, which may not be enough to capture the full variability of patient care progression. There is also potential recall bias whenever using self-reporting data. Even though the data was captured in real time, a single visit to the bedside might include several procedures, thereby clouding even recent memory of the interaction.

A 242-bed community hospital in eastern Pennsylvania with a 14-bed ICU reported in 2011 on a practice bundle change of "no blood draw from a central line without physician order" [7]. The practice change was enacted following a discussion by a multidisciplinary team that included physicians, nurses, infection preventionists, and quality managers to reduce the CLABSI rate by lowering line accesses. The authors noted that the overall CLABSI rates trended downward over the 22-month period of evaluation after the practice bundle change. Though not noted by the authors, of further interest is that total central line days also decreased with a negative trend in the central line utilization ratio.

This pilot study and the finding that over 20% of central line accesses across three critical care units were for blood collections suggest that banning blood collections from central lines at our hospital could significantly reduce central line accesses. A further analysis of how access rates and reasons for access change over the dwell of the line could inform potential policy shifts to reduce line utilization.

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CONCISE REPORT

Usefulness of an antibiotic prescription-based healthcare-associated infection surveillance program in an ICU setting

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ABSTRACT
We evaluated the accuracy of the use of an antibiotic prescription-based (APB) case-finding program to identify healthcare-associated infections (HAIs) by carrying out a retrospective review of all patient records in the adult ICU in a tertiary care Finnish teaching hospital in one year. The concordance between the program and our retrospective review was 91.7%. Of all prescribed antibiotics, 12.4% were for HAIs. The case-finding program produces large amounts of data, only a small fraction of which is useful for estimating the incidence of HAIs. Case-finding needs automatic data processing using multiple sources of information.

INTRODUCTION
Surveillance is an essential element in preventing healthcare-associated infections (HAIs) [1]. However, surveillance of HAIs using conventional (symptom-based and lab result-based) methods leads to under-reporting [2]. Therefore, electronic surveillance systems using multiple sources of information have been developed [3]. Hospitals using automated surveillance have been effective in implementing evidence-based practices to prevent HAIs [4].

The search for HAI cases was performed by the Hospital Antibiotic and Infection Monitoring System (SAI) (Neotide, Finland), an antibiotic prescription-based (APB) case-finding program. At the beginning of antibiotic treatment, the program requires that the physician indicate whether the antibiotic was started for an ICU-related HAI (ICU-HAI), for a HAI from healthcare treatment received outside the ICU (H-HAI), for a community-acquired infection (CAI), or for prophylaxis (PR). HAI cases were then reviewed by an infection control nurse (ICN) and the cases were recorded into the SAI system, which was linked to electronic patient databases.

The aim of this study was to assess the accuracy of the electronic HAI case-finding system in the ICU of a tertiary-care Finnish teaching hospital. The study was approved by the Ethics Committee of the University of Turku.

METHODS
In this study, the accuracy of the APB program was retrospectively evaluated by an infection control researcher who reviewed electronic records of patients admitted to the ICU in 2015. The incidence of HAIs was defined by the number of initiated antibiotics for HAIs per 1,000 patient days. The number of HAIs was expressed in absolute numbers; the proportion of HAIs per all discharged patients and patient days; and the number of central line-associated bloodstream infections (CLABSI), catheter-associated urinary tract infections (CAUTI), and ICU-acquired pneumonia per 1,000 device days. The agreement between cases (ICU-HAI, H-HAI, CAI, and PR), APB cases, and cases after the researcher's retrospective inspection were examined by percentage and Cohen's kappa. All statistical tests were performed using JMP® Pro 13.1.0.

RESULTS
This study was conducted in a mixed adult ICU with 25 beds, 1,736 admitted patients, and 5,707 patient days in 2015.

Antibiotics were started 1,425 times. ICU-HAIs represented 10% of antibiotics, H-HAIs represented 2.5%, CAIs represented 27.2%, and PR represented 60.4%. The incidence of ICU-HAIs was 24.9 per 1,000 patient days.

After retrospective review of electronic patient files, antibiotics were found to be started 1,444 times. Here, 12.4% of antibiotic treatments were started for ICU-HAIs, 5.5% for H-HAIs, 26.6% for CAIs, and 56.8% for PR. The incidence of ICU-HAIs was 31.4 per 1,000 patient days.

The agreement between registered cases and cases after retrospective inspection by the researcher was 91.7% (1,266/1,380). The Cohen's kappa statistic was 0.86, with a 95% confidence interval (0.82-0.87). The most common CAI was pneumonia. Antibiotic treatments for PR were started in 10.4% of cases. The most common ICU-HAI was pneumonia in 49 cases.

DISCUSSION

The accuracy of the application of the APB program to ICU-HAIs in our ICU was good. In 15% of cases, physicians did not record the reason for initiating antibiotics. Sometimes it may be challenging for a physician to decide the cause of infection at the beginning of ICU care. Furthermore, physicians do not usually return to answer questions they initially skipped.

The agreed incidence of ICU-HAIs was lower than those reported in previous publications [5]. Pneumonia was the most common HAI; ICU-acquired pneumonia was higher than European HAI surveillance of ICUs (8.6 vs 6 per 1,000 patient days) [6]. Otherwise, incidences of BSIs and CAUTIs were considerably lower (0.7 vs. 1.7 and 0.2 vs 1.1 per 1,000 patient days) than previously reported.

The antibiotic-initiated case identification program also reveals antibiotic consumption not related to any infection (PR).

FIGURE 1: Antibiotic prescription and APB case-finding surveillance by indication and HAI type (CAI, H-HAI, ICU-HAI, and PR).

Registration of the reason for antibiotics in the ICU

Physician: Prescribes antibiotics.

Physician: Registers the reason for antibiotics.

ICN: Verifies the cases and changes the origin of cases if necessary.

1,425 started antibiotics for 1,212 patients:
ICU-HAI: N = 142
H-HAI: N = 36
CAI: N = 387
PR: N = 860

Research Process

All patients treated in the ICU: N = 1736.

Researcher: Verifies all initiated antibiotic cases in the ICU.

1,444 started antibiotics for 1,238 patients:
ICU-HAI: N = 179
H-HAI: N = 79
CAI: N = 384
PR: N = 802

Agreed
ICU-HAI: N = 120
H-HAI : N = 30
CAI: N = 342
PR: N = 774

TABLE 1: Reason for antibiotic initiation in the ICU and the agreement between APB case-finding cases and cases after retrospective inspection.			
Characteristics of antibiotic treatment initiation	Surgical patients: 41.4% Medical patients: 58.6% BSI: 3.6% (63/1,736) Pneumonia: 11.4% (198/1,736)		
Characteristics of antibiotic treatments initiated for ICU-HAIs	Surgical patients: 54.4% Medical patients: 45.6% 21 antibiotics/1,000 patient days 0.8 CLABSI/1,000 CVC days 15.2 ICU-acquired pneumonia/1,000 ventilator days 1.4 CDI/1,000 patient days 0.2 CAUTI/1,000 urinary catheter days		
Agreement between APB cases and cases after retrospective inspection		Percentage	Cohen's kappa	95% confidence interval
	ICU-HAI	79%	0.82	0.77-0.87
	H-HAI	52%	0.66	0.54-0.77
	CAI	90%	0.87	0.83-0.90
	PR	98%	0.88	0.86-0.91

LEGEND
Bloodstream infection (BSI)
Catheter-associated urinary tract infection (CAUTI)
Central line-associated bloodstream infection (CLABSI)
Central venous catheter (CVC)
Clostridium difficile infection (CDI)
Community-acquired infection (CAI)
Healthcare-associated infections from healthcare treatment received outside the ICU (H-HAI)
ICU-related infections (ICU-HAI)
Prophylaxis (PR)

If that much of all antibiotic consumption (10%) is clinically relevant and ecologically sustainable, it should be discussed by intensive care specialists, surgeons, and infection control specialists.

There were some limitations in our study. Only 5% of the data were analyzed by three evaluators; the rest was analyzed by one. The evaluators were all infection control professionals but there is nonetheless the possibility of subjectivity.

The antibiotic-initiated case-finding program helps evaluate the use of antibiotics in the ICU. However, it also produces a huge amount of data, of which only a small fraction helped accurately record the incidence of HAIs. Moreover, as has been reported [7], verifying the accuracy of our HAI surveillance program is time-consuming. There is a need for more automatic case-finding data processing using multiple sources of information. Automated text mining would help minimize that workload.

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EMERGING TECHNOLOGIES

Uncovering the rates of damaged patient bed and stretcher mattresses in Canadian acute care hospitals

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ABSTRACT

Background: Cleaning and disinfection prevent the spread of healthcare-associated infections. Damaged surfaces, such as mattresses, cannot be properly cleaned and may harbour pathogens that pose a risk for cross-contamination. The U.S. Food & Drug Administration has expressed concern that damaged mattresses may be widespread and recommends that mattresses be regularly inspected for damage.

Methods and materials: A novel process was developed to assess the integrity of bed and stretcher mattresses throughout a healthcare facility. Between 2014 and 2017, five Mattress Integrity Assessment projects were conducted at Canadian acute care hospitals. All inspected mattresses were categorized based on the presence of damage. Damaged mattresses were either immediately repaired with a medical surface repair patch or tagged for replacement in accordance with a defined protocol. Data was collected, including photographs of damage and repairs.

Results and discussion: A total of 2,561 patient mattresses were assessed for damage. 32.5% (833/2,561) were damaged, of which 55.6% (463/833) were repaired and 44.4% (370/833) were recommended to be replaced. Stretcher mattresses had higher damage rates than patient beds.

Conclusion: The findings confirm that damaged patient mattresses are widespread in Canadian acute care hospitals, posing a risk for cross-contamination. Staff may be unaware of the potential risks, and frequent inspection is required to ensure mattress damage is repaired or replaced.

KEYWORDS
Bed; stretcher; mattress; damage; assessment; inspection; repair; patch

INTRODUCTION

Cleaning and disinfecting patient care areas is essential to preventing healthcare-acquired infections [1-5]. In addition, all furnishings and equipment, such as mattresses, should be regularly inspected to ensure they are safe and properly maintained [6]. Damaged surfaces cannot be properly cleaned and pose a safety risk by harbouring and transmitting pathogens. When the integrity of a mattress cover is compromised, fluids may penetrate the inner core.

In April 2013, the U.S. Food & Drug Administration (FDA) issued a Safety Communication to alert healthcare providers, facility staff, and caregivers that damaged or worn mattress covers can allow blood and body fluids to penetrate inside the mattress, posing a risk for cross-contamination and infection to patients [7]. There have been cited incidents of patient exposure to body fluids from another patient when fluid leaked upon compression of a contaminated mattress. From 2011 to 2016, the FDA received over 700 reports associated with bed and stretcher mattress covers failing to prevent blood and body fluids from leaking into the mattress [8]. In November 2017, the non-profit organization Emergency Care Research Institute (ECRI) included damaged patient mattress covers in the top ten health technology hazards for 2018 [9].

An outer mattress cover is meant to provide a barrier to the inner core while maintaining a level of moisture vapour permeability to help reduce heat and moisture surrounding the patient (microclimate), thereby reducing the risk of skin breakdown [10]. A wide variety of medical mattresses are

available on the market, but they are generally either foam-filled (sometimes with a gel layer) or air-filled, with covers made of polyurethane, vinyl, or coated nylon. Medical mattress covers may lose their effectiveness over time and the expected service life varies from manufacturer to manufacturer, ranging anywhere from one to seven years. In addition, the expected life of a mattress cover may differ from that of the mattress itself.

Fluid ingress may occur if mattress covers become worn or damaged. Damage may result from physical causes (punctures, scratches, cuts, or rips in the fabric), chemical causes (frequent cleaning with chemical disinfectants, use of harsh cleaners without rinsing or laundering procedures), or breakdown from aging over time. The medical literature shows that damaged mattresses can be a source of contamination during infection outbreaks and enhanced cleaning and restoration of the mattresses resulted in termination of the outbreaks [11-14].

One study at a hospital in the United States revealed that over 26% of adult patient mattresses had occult damage to the interior of the mattress cover [15]. The FDA has expressed concern that fluid ingress from worn or damaged medical bed mattress covers may be widespread and largely under-recognized by healthcare providers and facility staff.

Bed and stretcher mattresses are often overlooked as a low-priority asset and are not commonly owned by a consistent department. Facility staff may be unaware of mattress integrity because mattresses are typically covered by bed linens. Great cultural differences exist between facilities and even between departments as it relates to the importance of addressing this problem.

An adhesive patch for the repair of damaged mattress covers was introduced to the healthcare market in 2014. This product is registered with Health Canada and the FDA as a Class 1 medical device, is impervious to fluids, is durable in a healthcare environment, and has been shown to be equivalent to the mattress surface in terms of microbial growth before and after terminal cleaning [14]. The patch is applied by a peel-and-stick method and is manufactured with medical-grade biocompatible materials.

The replacement costs of bed and stretcher mattresses range from a few hundred to thousands of dollars, depending on the mattress type, brand, and composition. Some bed mattresses have replaceable covers but this is uncommon with stretcher mattresses, as they generally do not have zippered openings. The medical device that repairs mattress covers is available in three sizes and costs tens of dollars per patch. Significant cost savings may be realized if damaged mattress covers can be repaired instead of replaced.

The purpose of this study was to determine the extent of damaged patient mattresses in Canadian acute care hospitals.

METHODS

A novel process was developed to assess the integrity of bed and stretcher mattresses in healthcare facilities. A Mattress Integrity Assessment (MIA) involves proactive inspection of patient bed and stretcher mattresses throughout the facility following defined bedside inspection protocols [16]. Mattresses in all participating clinical areas were assessed for any signs of damage and immediately repaired with the Health Canada and FDA Class 1 medical device according to product guidelines or tagged for

replacement. Following inspection, each bed or stretcher was labelled with a colour-coded sticker for tracking purposes.

TABLE 1: Mattress inspection categories.	
Colour Code	**Mattress Status**
Green	Mattress had no visible damage.
Yellow	Mattress had minor damage that was suitable for repair using the Health Canada and FDA registered medical surface repair patch.
Pink	Mattress had damage that was not repairable with the repair patch and required replacement when possible.
Red	Mattress showed signs of fluid ingress or severe damage, requiring immediate removal from service.

As beds and stretchers are often moved throughout a facility, inspection results were recorded for the first location in which the bed or stretcher appeared, and not repeated if the same bed or stretcher was found on another unit. Projects ranged from two to six days in duration and the number of mattresses that could be inspected each day varied depending on the number and types of clinical units involved, preferred inspection times, number of patients on isolation precautions, and number of Assessment Team members.

Settings
Between December 2014 and June 2017, five MIA projects were conducted at Canadian acute care hospitals in Alberta, Saskatchewan, and Ontario. The hospitals ranged in size from 300 to 1,100 beds. Three were university-affiliated teaching hospitals and all provided a full range of services, including emergency care, medicine, surgery, critical care, maternity, psychiatry, and outpatient services. Three of the projects covered nearly all areas of the hospital and two of the projects were limited in scale, covering only a few pre-selected clinical units.

Planning
Each project was planned in advance with communication and coordination between manufacturer representatives and hospital management. Assessment Team members included manufacturer and distribution representatives and designated staff as chosen by each facility, which included Facilities and Maintenance, Environmental Services, Infection Control (IPC), or Risk Management. A formal presentation to clinical managers in advance was found helpful to ensure input from all areas and to address any questions or concerns. The project dates and scope were determined and a schedule was developed for the Assessment Team to visit each clinical area. A brief hour-long training was conducted with all members of the Assessment Team prior to project initiation in order to ensure consistency of data collection and tracking.

Inspection process
Patient bed and stretcher mattresses throughout each clinical area were manually inspected. Occupied mattresses were inspected when possible, as determined by the registered nurse in charge and

depending on patient acuity. Mattresses on which patients were sleeping or too ill to get out of bed were excluded and inspection was attempted at a later time. Linens were removed so that the mattress covers could be visually assessed on the top and sides. Canadian infection control guidelines (Infection Protection and Control Canada) were followed, including hand hygiene and the use of clean gloves with each bed or stretcher. Appropriate personal protective equipment was used to inspect the vacated beds of any patients on contact precautions, with the approval of IPC and the registered nurse in charge. Assessment of each mattress included looking for any potential signs of fluid ingress (staining or warping), physical damage (punctures, scratches, tears, cuts, damaged seams or zippers), chemical damage (bleaching, staining, cracking, delamination), or other abnormalities such as sagging, which may indicate that the inner foam is no longer supportive or that an air bladder has deflated. Any mattress with visible signs of fluid ingress was immediately tagged as "red" according to mattress inspection protocols.

Recording

All inspection findings and interventions were recorded via either a manual spreadsheet or phone-based survey app. Recorded data included the date, location (clinical area/room), mattress type (bed, stretcher, or other), make, model, year (if available), and a description of any damage. Photographs were taken of all damage and before-and-after photos were taken of all repairs. Colour-coded labels were dated and applied to the foot of each bed or stretcher to indicate that it had been inspected and to reflect the inspection findings as intact (green), repaired (yellow), or requiring replacement (pink or red).

Data analysis

After completion of the inspection process at each site, the findings were tabulated to identify the overall rate of mattress damage, frequency and types of damage, differences among the various clinical areas, and to help identify any mattress damage trends observed by the Assessment Team. Data analysis at each hospital was meant to be specific and relevant to that facility; however, the overall information obtained from these projects provides a snapshot of the state of patient mattresses in Canadian hospitals.

Presentation

Following each MIA project, a written report or presentation was provided to hospital management. The reports included an overall summary of the damage, repairs, replacements required, and other relevant observations. Photographs were included to illustrate the types of mattress damage found and all repairs performed with the repair patch. As capital funding for mattress replacement may not be sufficient to cover the total need, any mattresses tagged "red" were identified as the priority for immediate replacement. Staff engagement in the MIA project varied greatly, signaling cultural differences between hospital sites.

RESULTS

The pooled number of inspected beds and stretchers across the five hospitals was 2,561. Overall, there were 833 damaged mattresses, representing a damage rate of 32.5% (833/2,561). Of the damaged mattresses, 55.6% (463/833) were repaired with a medical device according to product guidelines and specific protocols approved by each hospital. The remaining 44.4% (370/833) were not suitable for repair and were recommended for replacement.

Reasons for not repairing a mattress cover included signs of fluid ingress, damage that was too large to cover with a single patch, more than three to six areas of damage, or if damage was located on a three-dimensional corner where the patch could not be applied properly.

The rates of mattress damage at each hospital ranged from 20.8% to 44.7%, but there was greater variation in the severity of damage. In the hospital with the newest beds, the vast majority of the damage was caught early and was repairable with the repair patch (95.8% repair rate), while beds at another site were older and too damaged to be saved (34.3% repair rate).

Stretchers had the same or higher rates of damage than beds. This is most likely because they generally have thinner mattresses, are frequently moved around the facility, and are cleaned more often than beds. Four out of five hospitals had mattresses that were classified as "red," posing the highest risk to patients.

TABLE 2: Damaged bed and stretcher mattresses by site.						
	Hospital A	Hospital B	Hospital C	Hospital D	Hospital E	Combined
Beds:						
Number	817	349	264	94	246	**1,770**
Intact	626	198	160	52	203	**1,239**
Damaged	191	149	104	42	43	**529**
Damage rate	23.4%	42.7%	39.4%	44.7%	17.5%	**29.9%**

	Hospital A	Hospital B	Hospital C	Hospital D	Hospital E	Combined
Stretchers:						
Number	321	118	72	65	215	**791**
Intact	182	67	39	36	162	**486**
Damaged	138	51	33	29	53	**304**
Damage rate	43.0%	43.2%	45.8%	44.6%	24.7%	**38.4%**

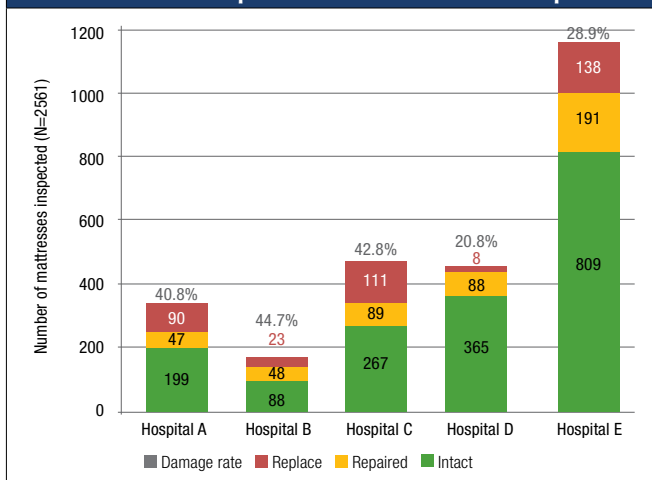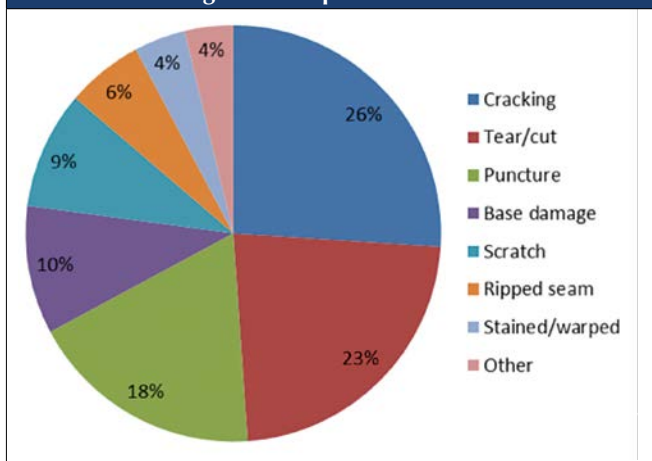FIGURE 1: Status of patient mattresses in five hospitals.

FIGURE 2: Damage rates of patient beds vs stretchers.

Types of damage

Beds and stretchers are physically damaged from everyday use, transportation through hallways and elevators, contact with sharp objects, or by placing equipment on top of the mattress. Tears and rips are generally ragged in nature, while cuts are clean-edged from a sharp object. Punctures are small holes in the mattress cover that may be the result of hazardous sharp objects such as syringes or catheters or innocuous objects such as jewellery or pens. Scratches involve partial depth damage to the mattress cover, usually as a result of dragging equipment across the surface. Combined, all types of physical damage represented approximately 68% of damage, while 32% of damage appeared to be from chemical causes.

Cracking of the mattress cover occurs from repeated and prolonged contact with chemical disinfectants, especially if the linens are replaced before the mattress cover is fully dry. Cracking may begin in a small area, such as a fold in the mattress cover at the pivot point when the head of the bed is raised. Once cracking starts, it may become extensive and eventually progress to the point of destruction of the polyurethane cover (delamination).

Two of the hospitals had extensive cracking damage, with more than 80 inpatient beds combined showing severe delamination and obvious signs of fluid ingress and contamination. Nearly 15% (122/833) of mattresses had more than one type of damage.

FIGURE 3: Types and frequency of mattress damage.
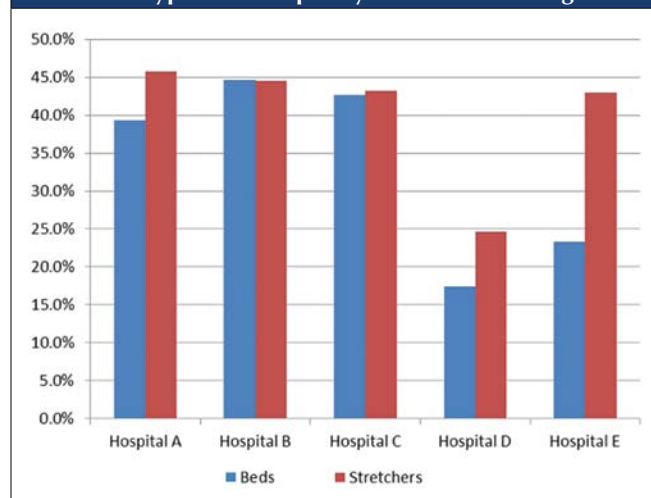
DISCUSSION

Five MIA projects confirmed that damaged mattresses are common in Canadian acute care hospitals, as over 32% of those inspected had visible damage. Damaged surfaces cannot be properly cleaned and pose a risk of harbouring and transferring pathogens to subsequent occupants. Any patient with diarrhea or incontinence would be lying on a source of contamination, and any damage to the mattress underneath may become a reservoir.

Stretchers, which are most commonly used in the Operating Room (OR) and the Emergency Department (ED), had higher rates of damage than beds. Stretchers from the OR are used to transport surgical patients to and from other departments, and this movement could potentially increase the risk of transferring pathogens from one area of the hospital to another. Patients coming into the ED may be very ill or harbour as-yet undiagnosed infections and the ED stretcher may be their first significant point of contact upon admission.

There are several reasons why damaged mattresses are so prevalent. With competing capital wish lists, beds are often a low priority compared to new technologies. Mattresses are often kept in use far beyond the recommended lifespan because there is simply not enough money to keep replacing them.

Mattresses are usually covered by linens and, once covered, they may be "out of sight, out of mind." Cleaning checklists often list bed rails, bed controls, and bathrooms as the priority, but may not list the mattress even though the mattress has one of the highest touch points in the patient environment [17].

The National Health Service in the United Kingdom has made six- to twelve-month mattress inspections mandatory [18-20]. Hospitals in the United States are cited for damaged surfaces and even penalized for any preventable healthcare-acquired infections [21], yet scheduled mattress inspections are rarely performed in the U.S. or Canada. Unfortunately, damage begets damage. When staff see damaged soft surfaces as commonplace, it becomes the

norm and contributes to a culture of apathy. Terminal cleaners often see damage when they are cleaning the mattress but do not report it because they either see it as normal or find it too time-consuming to fill out a maintenance requisition. Front-line staff believe it is up to maintenance staff to track and repair equipment and maintenance staff do not see the damage unless someone tells them – and the vicious cycle continues.

Throughout the MIA process, there were notable differences in occupational cultures between hospitals, clinical units, and individuals. Some people were passionate about addressing this problem, while others were not, but the majority of staff was simply not aware that damaged mattresses pose an infection risk to patients.

Implementing a mattress inspection and repair program is critical to patient safety and reducing the infection risk that damaged mattresses pose. Senior management needs to be committed and assist in engaging three key stakeholder groups, identified as Damage Monitors, Damage Fixers, and Damage Champions. The Damage Monitors consist of all staff that come into contact with bed and stretcher mattresses daily, such as Portering, Environmental Services, Nursing, and Physicians. This group's key responsibility is to look out for damaged mattresses and to report them immediately upon discovery. The Damage Fixers consist of a subset of individuals who have been trained in the mattress assessment process described above and decide when a mattress can be repaired or when it needs to be replaced. These individuals must have access to the adhesive patch and replacement mattresses to complete the assessment in a timely manner, and to reduce the likelihood of damaged mattresses circulating undetected. The Damage Fixers may be individuals from Facilities or Maintenance; however, they could be from another department, such as Nursing. Finally, the Damage Champion may be an individual from Infection Prevention and Control or Risk Management who takes ownership of this program to ensure that it operates successfully and that there is an effective communication channel between Damage Monitors and Damage Fixers. Communication may include a dedicated phone line or email address, or may be part of an existing facilities reporting software. Damage Monitors would also conduct routine bed and stretcher mattress integrity audits to ensure the program is running smoothly.

CONCLUSION

MIA projects at five hospitals suggest that one in three Canadian patients is lying on a damaged mattress. Damaged mattresses cannot be properly cleaned and pose a risk of cross-contamination and potential infection. More education is required to increase clinician and staff awareness that damaged mattresses are not acceptable and need to be repaired or replaced. MIA projects may be helpful to find and address mattress damage and repair minor damage before it becomes extensive. Operationalizing a stretcher and bed mattress surveillance program in healthcare facilities is critical to resolving this problem and enhancing patient safety.

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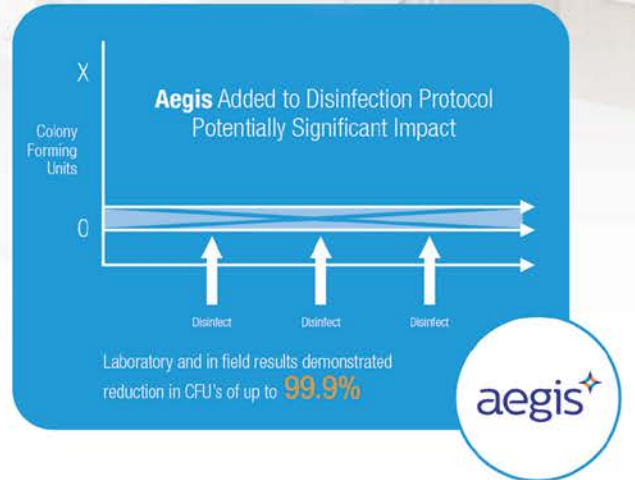
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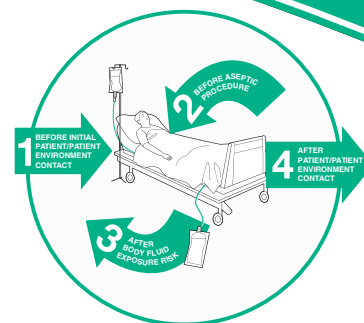
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