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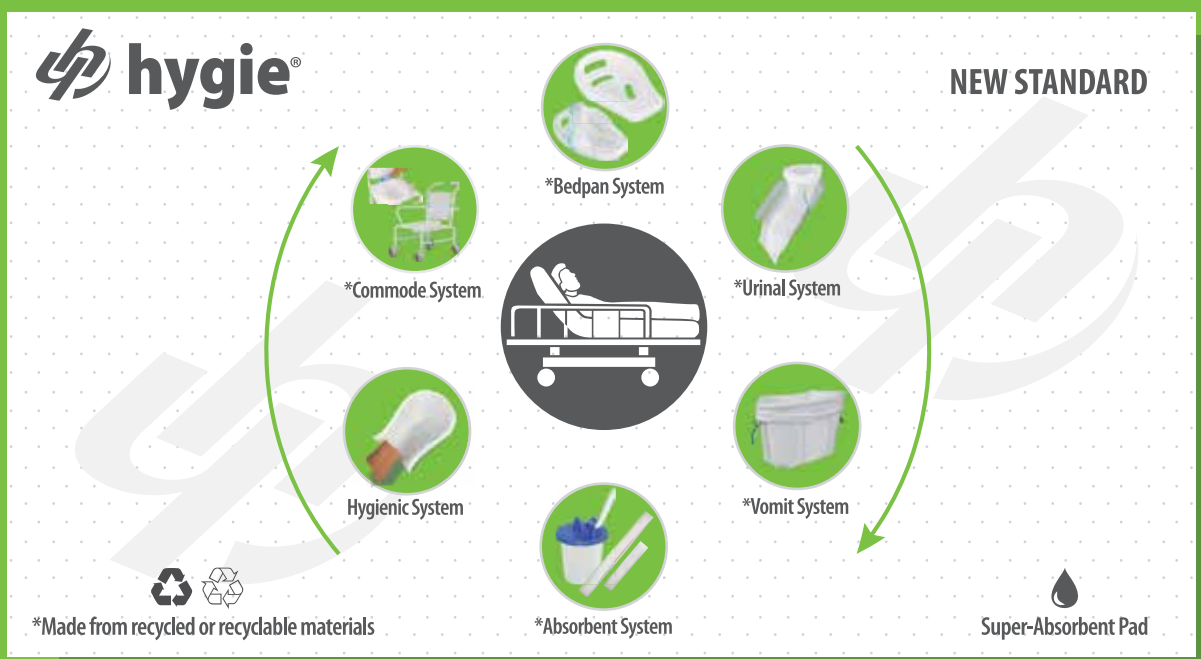

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Chingiz Amirov, MPH, MSc QIPS, CIC, FAPIC
Director, Infection Prevention and Control
Baycrest Health Sciences
3560 Bathurst Street
Toronto, Ontario M6A 2E1
Tel: 416-785-2500 Ext. 2981 Fax: 416-785-2503
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PUBLISHER
Craig Kelman & Associates

3rd Floor, 2020 Portage Avenue
Winnipeg, MB R3J 0K4
Tel: (204) 985-9780 Fax: (204) 985-9795
www.kelman.ca E-mail: info@kelman.ca

EDITOR - Craig Kelman/Andrée-Anne Boisvert
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RE: *Clostridium difficile* infection in Alberta's long-term care facilities

Lesley A. McLeod, MSc, CIC, Provincial Infection Control Coordinator – Patient Safety Unit, Saskatchewan Health Authority

Having spent a lot of time in the pursuit of accurate and timely data on the incidence of CDI in all healthcare facilities, including long-term care (LTC), we were very interested to read Jenine Leal's excellent article in the Summer 2017 issue of *The Canadian Journal of Infection Control* (*CJIC*) entitled '*Clostridium difficile* infection in Alberta's long-term care facilities.' While we agree with the content and conclusions presented in the article and welcome how this data contributes to a greater understanding of the burden of CDI within LTC, we simply wanted to make a correction to a statement made by the authors that CDI surveillance has not been documented in any other province in Canada.

Since 2012, Saskatchewan has had a provincial *Clostridium difficile* infection (CDI) surveillance program. The development and evolution of the program has certainly been a work in progress, requiring a lot of effort to overcome various challenges. Although the current program was revised in 2016 to include healthcare-associated CDI with onset in the community, surveillance, including residents in long-term care (LTC) facilities, has been in place since the program's inception. Details about Saskatchewan's CDI surveillance program were published in the spring 2017 issue of *CJIC* (*https://ipac-canada.org/photos/custom/CJIC/IPAC_Spring2017_McLeod.pdf*) and presented at the IPAC conference in Niagara Falls, ON (2016). Annual reports of Saskatchewan's CDI surveillance program are published on a publicly accessible website (*www.ehealthsask.ca/services/resources/Pages/Communicable-Disease.aspx*) and include rates for all healthcare-associated (HA) cases of CDI reported in Saskatchewan.

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[1] The PLASMAIR™ Decontamination System Is Protective Against Invasive Aspergillosis in Neutropenic Patients Fernandez-Gerlinger MP, et al. Infect Control & Hosp Epidemiol 2016, Vol 37, N°7. 845-851.

ORIGINAL ARTICLE

A cohort study of factors associated with LTBI treatment initiation and completion in Hamilton, Ontario, Canada

Deborah A. Milinkovic, MA;[1, 2] Stephen Birch, PhD;[1, 2] Fran Scott, PhD;[1, 2] K. Bruce Newbold, PhD;[3] Jessica Hopkins, MD;[1, 5] Beverley M. Essue, PhD[1, 2, 4]

[1] *Department of Health Research Methods, Evidence, and Impact, McMaster University, Hamilton, Ontario, Canada*
[2] *Centre for Health Economics and Policy Analysis, McMaster University, Hamilton, Ontario, Canada*
[3] *School of Geography and Earth Sciences (SGES), McMaster University, Hamilton, Ontario, Canada*
[4] *University of Sydney, Sydney, Australia*
[5] *Region of Peel Public Health, Mississauga, Ontario, Canada*

Corresponding author:
Deborah Milinkovic, Centre for Health Economics and Policy Analysis, CRL 2nd Floor, McMaster University, 1280 Main Street West, Hamilton, Ontario, Canada, L8S 4M4
Email: milinkda@mcmaster.ca

ABSTRACT

The Public Health Agency of Canada attributes the majority of active Tuberculosis (TB) cases in Canada to the reactivation of Latent Tuberculosis Infection (LTBI) post immigration. Since 70% of recent migrants to Canada originate from TB endemic regions of which PHAC anticipates 50% have LTBI, LTBI management and control is of growing importance in Canada. LTBI treatment is provided without cost to clients through Public Health Departments but treatment initiation and completion is suboptimal. The objective of the study was to identify the socio-economic characteristics, including those related to immigration, that are associated with LTBI treatment initiation and completion among the LTBI foreign-born population in Hamilton, Ontario, an important immigrant and refugee resettlement community.

Method: A retrospective population cohort of all LTBI cases reported between January 2, 2009 to December 23, 2014. Multivariable probit and oprobit regression analysis was used and the results tested using sensitivity analyses.

Results: Among 1,960 cases that are foreign-born, the LTBI treatment initiation rate was 22% and the unconditional completion rate 13%. LTBI medical screening at point of entry into Canada was strongly associated with initiation and completion of LTBI treatment ($p<.01$). Relative to young adults (aged 18-30 years), middle-aged adults (aged 31-49 years) were less likely to complete LTBI treatment ($p<.05$) and children (aged <18 years) were more likely to initiate treatment ($p<.01$) but not more likely to complete treatment. Having been born in a TB-endemic country and having immigrated within the past five years were not associated with treatment initiation or completion.

Conclusion: The low rates of treatment initiation and completion in this population highlight a need for better strategies to improve use of LTBI treatment by foreign-born populations. Attempts to pursue such improvements through development of evidence-based policies for LTBI management are limited by incomplete reporting on key characteristics such as risk factors and demographic information.

KEY WORDS:
Emigrants and immigrants; latent tuberculosis; bacterial infections; medication adherence

INTRODUCTION

Worldwide, tuberculosis (TB) is the number one infectious disease killer, responsible for 3.2 million deaths in 2015 (WHO, 2017b), but in Canada, like other high-income countries, TB is relatively uncommon[1]. Migrants account for 65% of all active TB cases in Canada (Greenaway et al., 2011) and the majority of these active TB cases have been attributed to the reactivation of Latent Tuberculosis Infection (LTBI), inactive TB, post immigration (Public Health Agency of Canada, 2014; Varughese, Langlois-Klassen, Long, & Li, 2014).

Canada welcomes around 300,000 refugees and immigrants annually, with around 70% originating from endemic TB zones (Public Health Agency of Canada, 2015). To protect Canadians from TB and other communicable diseases and ensure health care for migrants, Immigration, Refugees and Citizenship Canada (IRCC) requires migrants seeking to remain in Canada for longer than six months to undergo medical screening for active TB, including a chest x-ray (Box 1). The chest x-ray can identify active and past incidences of pulmonary TB due to scarring on the lungs. If evidence of infection is found, further

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

Contributions and statement: The study was conceived, designed and managed by DM, SB, JH, FS, BN and BE. DM led the analysis of the data in consultation with the other authors and wrote the first draft of the paper. All authors provided critical feedback and comments on the paper, contributed to the writing, and approved the final draft.

[1] Canada reports 1,600 new cases of TB annually.

BOX 1: Overview of processes for detection and treatment of LTBI in Ontario

TB is a reportable condition in Ontario, however LTBI is not explicitly indicated. This can result in inconsistencies in the reporting of LTBI cases and relevant risk factors.

There are five ways in which LTBI can be detected:

a) *Immigration medical exam*: A medical exam is required for all migrants to Canada who intend to remain in the country for greater than six months. Includes a chest x-ray to rule out active TB.
b) *Contacts of active TB cases*: Public Health recommends certain contacts of individuals with active TB be tested.
c) *Occupation and education requirements:* Training programs, volunteer placements and some professions require applicants to receive screening and/or diagnostic testing to confirm they do not have active TB.
d) *Adhoc provider screening*: Some providers routinely test patients who are from or who travel regularly to TB endemic countries.
e) *Incidental finding*: Individuals may receive a chest x-ray for other reasons (e.g. to diagnose heart failure).

In all cases, testing is aimed at detecting active TB. If LTBI is detected, individuals are referred to their local public health unit or health provider to discuss treatment options. Information, including known risk factors on all detected cases of LTBI should be reported to the local public health unit for follow up.

Treatment is provided free. Some health units dispense medications via pharmacies as well as directly through health care providers. There can be out-of-pocket costs associated with testing (i.e. depending on whether the TST or IGRA test is used), and routine monitoring (i.e. liver tests). This varies by jurisdiction and provider.

testing will be conducted to determine whether the infection is active or stable. Active cases must be treated prior to entering Canada (Citizenship and Immigration Canada, 2013). Any close contacts of the active TB case will receive a tuberculin skin test (TST) and if found to be positive for LTBI but not TB, be required to report to public health within 30 days for medical surveillance (Citizenship and Immigration Canada, 2013; Government of Canada, 2013). It is estimated around 50% of current immigrants to Canada have LTBI (Public Health Agency of Canada, 2014) but the majority pass through to Canada undetected.

Individuals with LTBI are estimated to have a 5-10% lifetime risk of developing active TB with the greatest risk occurring within the first two to five years post exposure to Mycobacterium tuberculosis (Greenaway et al., 2011; Hirsch-Moverman, Daftary, Franks, & Colson, 2008; Public Health Agency of Canada, 2014; WHO, 2017a). Treatment for LTBI can mitigate the risk of TB reactivation and is therefore offered to the recipients without cost at point of delivery; however, LTBI treatment initiation and completion is suboptimal (Hirsch-Moverman et al., 2008; Kane et al., 2013; Lui, Birch, Newbold, & Essue, 2017; Sandgren et al., 2016). A physician and patient's decision to engage in treatment can be influenced by many factors besides direct cost such as medical contraindications, socio-economic factors, culture, language, lifestyle choices, fear of side effects, health knowledge, treatment duration and healthcare access (Greenaway et al., 2011; Lui et al., 2017; WHO, 2014).

The aim of this study was to identify the socio-economic factors, including those relating to the immigration process, that are associated with LTBI treatment initiation and completion among the LTBI foreign-born in Hamilton, Ontario, an important immigrant and refugee resettlement community. The results will be of interest to public health jurisdictions with large migrant populations.

METHODS

Study population, design, and data

We analyzed data from a retrospective population cohort of all LTBI cases, both foreign-born and domestic, reported to the Hamilton Public Health Services (HPHS) between January 2, 2009 and December 23, 2014. Data were from the integrated Public Health Information System (iPHIS), which is an information system used for reporting case information for all provincially and nationally reportable communicable diseases. The database contains information on age, sex, country of birth, origin (Canadian-born, Foreign-born), date the individual was entered into the database, time since immigration, means of identification as LTBI, the first three digits in the postal code (forward sortation area, FSA) at time of LTBI diagnosis, whether medication was dispensed, and whether treatment was completed. While these fields are contained in iPHIS, reporting data for each of the fields is not mandatory. Hamilton is located approximately 60 kilometres from Toronto. In 2016 the population was 536,917, with a total immigrant population of 130,365 (24.3%); 13,150 of whom arrived between 2011 and 2016 (Statistics Canada, 2018). Recent immigrants (past 5 years) mostly originate from Asia (7,555), with over 1,000 from each of India, Iraq, Syria, and the Philippines (Statistics Canada, 2018). Hamilton is also the destination for a large number of refugees, and has been designated as a settlement centre. The study was approved by the Hamilton Integrated Research Ethic Board.

Outcome variables

The two dependent variables for the analysis were a) initiation of treatment (defined as dispensed LTBI medication) and b) completion of treatment (defined as completed the course of medication as prescribed by the clinician). The conditional completion rate is the proportion that completed medication given that treatment was initiated.

Dispensed medication was used as a proxy for initiation of treatment. This captures most individuals who initiate treatment, as it is unlikely that an individual would opt to

receive medication through an alternative source since the medication is available free of charge through the public health department.

Completion of treatment was analysed using a binary measure derived from data entered into the database by a public health nurse based on the notes of the treating clinicians. We coded treatment as completed if the nurse entered 'completed as recommended' or 'completed satisfactory'. We coded treatment as incomplete if the nurse entered 'incomplete,' 'non-compliance,' 'other' or 'unknown.'

Covariates

The following explanatory variables were included in the analysis: age, sex, origin (foreign-born, domestic), TB-endemic country of birth, time since immigration, income, identified with LTBI through immigration medical screening program.

The variable 'country of birth' was used to derive a variable to identify individuals who were born in a WHO identified TB endemic country (WHO, 2012). Country of birth was used as a proxy for country of immigration because the country of immigration variable was incomplete. The date the individual was entered into the database was considered the episode start date. Time since immigration was derived by subtracting the immigration date from the episode start date. Since the greatest risk of reactivation of TB is in the first five years after exposure and greater risk may be associated with higher rates of initiation and completion of LTBI treatment, the variable was dichotomized to identify those who had immigrated less than six years before the episode start date. Because different life stages may result in different healthcare seeking behaviours, the age variable was coded into five groups, <18 years, 18-30 years (young adults), 31-49 years (middle age), 50-64 years (older adults), and >64 years (seniors). The youngest adult age group was the reference category. The episode start date was the date the individual was entered into the database.

We created a proxy for socio-economic status using the median individual income variable from Canada's 2006 FSA-level census[2]. Since the average family size in the City of Hamilton (Statistics Canada, 2007) was three, the SES variable used in this analysis was a binary variable that uses the before tax LICO (Low Income Cut-Off) threshold for a family of three ($31,801 rounded to $32,000), which is similar in value to the median individual income of immigrants in Hamilton aged 25-54 years with no university education ($32,350) (Social Planning and Research Council of Hamilton, 2009; Wayland, 2010). We opted to use median individual income at the FSA-level rather than economic family income because the HPHS database did not contain information on the family status of the individual (i.e. single, married, married with child). (See Appendix A at *https://ipac-canada.org/cjic-abstracts-online-journal-2.php*.)

ANALYSIS

Probit multivariable regression analysis was used to explore the relationship between both initiation and completion, and the covariates listed above. Cases were omitted from the regression analysis if country of origin was missing. A secondary analysis investigated the association between individual characteristics and those individuals lost to follow-up.

The model was fitted using all available and relevant variables. Variables that did not contribute to the model were backwards eliminated using the joint F-test and the Likelihood Ratio Test.

Because several variables were aggregated at the FSA level, where possible, models were fitted using bootstrapping and robust cluster errors at the FSA. Clustering the errors at the FSA level controlled for intergroup correlation – individuals that live near each other may be similar in unobservable ways, while bootstrapping should help control for the potential of model misspecification due to small sample size (Ong, 2014). The data were analyzed using Stata 14.

RESULTS

Descriptive analysis

The data were pooled for the 5 years of the study period. The full sample consisted of 3,036 LTBI cases, of which 1,970 were reported as foreign-born. Of the 780 who were dispensed medication, our proxy for initiation, 441 were reported as foreign-born. However, the foreign-born is likely under-reported since the origin variable (foreign-born versus Canadian-born) is missing for 33% of the full sample and 40% of those dispensed medication (see Table 1). Those of unknown origin tended to be older than foreign-born (>50 years, 33% vs 20%, respectively). The treatment initiation rate in the full sample is 25.7% whereas the initiation rate is marginally lower among the foreign-born at 22.4%.

TABLE 1: Sample distribution by birth country

	Full Sample	Sub-sample (dispensed med)
ORIGIN	n(%)	n(%)
Canadian Born	74 (2.4)	27 (3.5)
Foreign Born	1,970 (64.9)	441 (56.5)
Unknown	992 (32.7)	312 (40.0)
Total	**3,036 (100)**	**780 (100)**

*Canadian-born non-Aboriginal and Canadian-born Aboriginal were combined due to the small number of Aboriginal Canadians in the sample.

The binary completion variable was missing for 9% of the sample (41 of 441 who were foreign-born and dispensed medication) (see Table 2).

[2] We use the 2006 Census because researchers have voiced concerns around data quality due to the voluntary nature of the 2011 long-form census. Prior to 2011, the Canadian long-form census and the short-form census were mandatory. The concern with the voluntary nature of the census is that those who are most likely to benefit from social programs are the least likely to participate. As a result, they would be under-represented in the data. Since the first year of this study is 2009, the 2006 Census should be reasonably reflective of the time-period of this study.

TABLE 2: Characteristics of Foreign-Born Persons with Latent Tuberculosis Infection Who Initiated and Completed Treatment; Hamilton, Canada 2009 – 2014

	Sample	Initiation		Sample	Completion		
	N	NO	YES	N	NO	YES	Missing
		n (%)	n (%)		n (%)	n (%)	n (%)
Age<18 yrs	93	56 (60)	37 (40)	37	10 (29)	25 (72)	2 (5)
18-30 yrs	703	572 (81)	131 (19)	131	48 (40)	71 (60)	12 (9)
31-49 yrs	786	607 (77)	179 (23)	179	49 (31)	109 (69)	21 (12)
50-64 yrs	227	160 (70)	67 (30)	67	12 (19)	52 (81)	3 (4)
>64 yrs	161	134 (83)	27 (17)	27	3 (31)	21 (82)	3 (11)
Total	**1,970**	1529 (78)	441	**400**	122 (31)	278 (70)	41 (9)
Missing				41			
Pearson chi2(4) = 31.5295 Pr = 0.000				Pearson chi2(8) = 17.3842 Pr = 0.026			
Male	875	692 (79)	183 (21)	183	56 (35)	106 (65)	21 (11)
Female	1,095	837 (76)	258 (24)	258	66 (28)	172 (72)	20 (8)
Total	**1,970**	1529 (78)	441 (22)	**400**	122 (31)	278 (70)	41 (9)
Missing				41			
Pearson chi2(1) = 1.9619 Pr = 0.161				Pearson chi2(2) = 3.8700 Pr = 0.144			
Immigrated five years ago or less							
No	820	650 (79)	170 (21)	170	40 (26)	113 (74)	17 (10)
Yes	591	446 (75)	145 (25)	145	47 (35)	86 (65)	12 (8)
Total	**1,411**	1096 (78)	315 (22)	**315**	87 (30)	199 (70)	29 (9)
Missing	559	433 (77)	126 (23)	126	35 (28)	79 (63)	12 (10)
Pearson chi2(1) = 2.8645 Pr = 0.091				Pearson chi2(4) = 3.1332 Pr = 0.536			
Born in TB endemic country							
No	1,080	846 (78)	234 (22)	234	70 (33)	141 (67)	23(10)
Yes	826	639 (77)	187 (23)	187	49 (28)	124 (72)	14 (7)
Total	1,906	1485 (78)	421 (22)	**421**	119 (31)	265 (69)	37 (9)
Missing	64	44 (69)	20 (31)	20	3 (15)	13 (65)	12 (10)
Pearson chi2(1) = 0.2572 Pr = 0.612				Pearson chi2(4) = 5.5439 Pr = 0.236			
FSA income less than or equal to $35,000							
No	185	152 (82)	33 (18)	33	12 (41)	17 (59)	4 (12)
Yes	1,770	1365 (77)	405 (23)	405	108 (29)	260 (71)	37 (9)
Total	1,955	1517 78)	438 (22)	**397**	120 (30)	277 (70)	41 (10)
Missing	15	12 (80)	3 (20)	44	2 (67)	1 (33)	0 (0)
Pearson chi2(1) = 2.4508 Pr = 0.117				Pearson chi2(4) = 4.4728 Pr = 0.346			
LTBI identified by immigration screening							
No	1,822	1449 (80)	373 (20)	340	114 (34)	226 (66)	33 (9)
Yes	128	66 (52)	62 (48)	54	7 (13)	47 (87)	8 (13)
Total	1,950	1515 (78)	435 (22)	**394**	121 (28)	273 (63)	41 (9)
Missing	20	14 (70)	6 (30)	47	1 (17)	5 (83)	0 (0)
Pearson chi2(1) = 53.9680 Pr = 0.000				Pearson chi2(4) = 11.2603 Pr = 0.024			

The chi square test for treatment initiation and individual characteristics suggests an association between initiation and age, and initiation and identification of LTBI through immigration screening (see Table 2). Of the 1,970 foreign born individuals, 7% were identified with LTBI through immigration screening, which is consistent with the national average (Greenaway et al., 2011).

REGRESSION RESULTS

Children (age <18 years) were more likely to initiate treatment than all other age groups (OR 2.8, p<.01). Individuals identified through immigration medical screening programs were more likely to initiate and complete treatment relative to the reference group individuals not identified at immigration (OR 3.2 and 5.2, p<.01, respectively) (see Table 3).

Relative to young adults (aged 18-30 years), immigrants aged 31-49 and 50-64 were less likely to complete treatment (OR .53 and .33, P<.05). Females were more likely to complete treatment (OR 1.8, p<.05) and those with low income (FSA income proxy <CDN$32,000) were less likely to complete treatment (OR .38, p<.05).

For 'Lost to follow up' individuals identified with LTBI through immigration medical screening and female sex were less likely to be lost to follow-up (OR .08, p<.01 and OR .47, p<.05, respectively).

We conducted several robustness checks including alternative models such as a self-reported completion variable, the Heckman selection model and the generalized linear model as well as recoded some variables. The results reported here were robust to model specification and recoding. (See Appendix B at *https://ipac-canada.org/cjic-abstracts-online-journal-2.php*.)

DISCUSSION

LTBI treatment would reduce the number of active TB cases, yet the observed initiation and completion rates for LTBI treatment have been universally suboptimal (Hirsch-Moverman

TABLE 3: Regression results for the final three models with the factors explaining a) treatment initiation, b) treatment completion, and c) lost to follow up in this study population

	A Treatment initiation	B Treatment completion	C Lost to follow up
VARIABLES	**OR (95% CI)**	**OR (95% CI)**	**OR (95% CI)**
Under 18 yrs	2.812*** (1.449 - 5.456)	1.965 (0.753 - 5.128)	0.863 (0.263 - 2.833)
31 to 49 yrs (ref)	0.767 (0.495 - 1.188)	0.537** (0.310 - 0.931)	2.676* (0.948 - 7.554)
50 to 64 yrs	0.960 (0.663 - 1.389)	0.331** (0.126 - 0.871)	2.715 (0.749 - 9.847)
Over 64 yrs	0.966 (0.485 - 1.924)	1.871 (0.196 - 17.87)	1.403 (0.113 - 17.42)
Female	1.302* (0.960 - 1.766)	1.793** (1.134 - 2.834)	0.467** (0.249 - 0.876)
High TB birth country	0.967 (0.690 - 1.356)	1.525 (0.897 - 2.591)	0.849 (0.426 - 1.692)
Immigrated <6yrs	0.964 (0.679 - 1.368)	0.579 (0.271 - 1.237)	1.074 (0.415 - 2.776)
FSA income =<$32,000	1.299 (0.848 - 1.991)	0.376** (0.161 - 0.880)	1.092 (0.406 - 2.936)
Identified by immigration	3.166*** (1.994 - 5.026)	5.217*** (2.426 - 11.22)	0.0808*** (0.0164 - 0.399)
Observations	1,357	276	276
Pseudo R-squared	0.0316	0.109	0.105

*** p<0.01, ** p<0.05, * p<0.1

While the main analysis used probit modelling, the results are reported as Odds Ratios for ease of interpretation. 95% confidence intervals are in parentheses. Model A and B were bootstrapped with robust clustered errors at the FSA-level. Model C used robust cluster errors at the FSA-level. See the online supplement for full details of each model. (*https://ipac-canada.org/cjic-abstracts-online-journal-2.php*)

et al., 2008; Kane et al., 2013; Lui et al., 2017; Sandgren et al., 2016). We found an initiation rate (defined as dispensed medication) for LTBI treatment between 22%, a conditional completion rate (conditioned on starting treatment) of 59%, and an unconditional completion rate of 13%. Other public health regions elsewhere in Ontario have reported higher initiation rates (42%) but similar completion rates (Nguyen & Frenette, 2012). A Quebec study that used a similar definition of initiation (dispensed medication) reported a conditional completion rate of 31.3% (Rivest, Street, & Allard, 2013).

We also found that, controlling for multiple factors, immigrant children were more likely to initiate LTBI treatment relative to young adults (18-30 years) but not more likely to complete the treatment. Since children under five years of age are at greater risk of developing TB and at greater risk of complications including mortality, the initiation results were as expected for this age group (Lonnroth et al., 2015; Public Health Agency of Canada, 2014). However, despite being well tolerated by children, poor completion rates for the nine-month INH protocol has been documented (A. Cruz & Starke, 2014; A. T. Cruz, Ahmed, Mandalakas, & Starke, 2013).

Other studies have found inconsistent results for age and completion. Bieberly and Ali (2008) found greater rates of non-completion for ages 19-35, while Trauer and Krause (2011) found greater failure to complete treatment among older age groups. Li et al. (2010) report greater completion rates after age 35, while other studies report no effect of age on completion (Ailinger, Black, Nguyen, & Lasus, 2007; Shieh et al., 2006).

The inconsistency for age and completion may be due to how various studies defined age. Some studies used a pivotal age point, 35 years of age; whereas we considered differences in initiation and completion at different stages of adulthood. For example, relative to younger adults, middle-age adults (age 31 to 49) may face greater opportunity costs due to family responsibilities, child care needs and workplace insecurity, which could make it more difficult for them to keep the frequent medical appointments (every six weeks). Adults aged 50 years and older face a greater risk of hepatoxicity due to LTBI treatment (Greenaway et al., 2011; Public Health Agency of Canada, 2014), which might make them less likely to be recommended treatment and therefore less likely to initiate treatment and more likely to discontinue treatment due to medical complications. Finally, those 65 years and older have likely left the workforce and have reduced family responsibilities, leaving them more able to initiate and adhere to treatment. Older adults in Canada also have greater access to medical coverage for prescription drugs and other health care services, which could facilitate the decision to seek LTBI treatment. As anticipated, we found a strong, robust and negative association with middle age (31 to 49 years) and completion relative to younger adults (18 to 30 years).

We also found that foreign-born women were more likely to complete LTBI treatment and less likely to be lost to follow-up than foreign-born males. These results are consistent with some LTBI literature (Rogo et al., 2017; Trauer & Krause, 2011) but inconsistent with other literature that found a negative association (Kan, Kalin, & Bruchfeld, 2013; Lui et al., 2017; Rivest et al., 2013). Other studies found no effect of sex on completion (Ailinger et al., 2007; Shieh et al., 2006).

The strongest and perhaps most compelling result is the strong and robust relationship between each dependent variable (initiation, completion, and lost to follow-up) and identification through immigration screening. We cannot conclude, however, that improved immigration screening would increase initiation and completion rates or reduce the numbers lost to follow-up because there could be unobservable differences between the people identified through immigration screening and those who are not. IRCC identifies opportunistically either by finding evidence of past TB infection on the chest x-ray or through TST testing of close contacts of active TB cases. For these individuals, the knowledge of being recently exposed to TB or seeing visible evidence of a past TB infection on the chest x-ray may make them more receptive to LTBI treatment. However, for the majority of migrants from TB endemic countries, LTBI has become normalized and LTBI is not typically treated in the source country. Although Canada may be inadvertently reinforcing the message that LTBI is a low priority health concern by not specifically screening for it, a change in IRCC screening policy may not have any impact on a group that views LTBI as normal. In addition, there is anecdotal evidence that some individuals may intentionally conceal evidence of TB exposure or other health issues during the immigration medical screening process. While this viewpoint has not been documented in the published literature, it is an area worthy of further investigation given that only 1-3% of active TB cases and 3-5% of LTBI cases (Greenaway et al., 2011; Khan et al., 2015) are identified through immigration screening, prompting calls for changes to IRCC screening policy (Khan et al., 2015; Varughese et al., 2014).

Identifying the extent of the data gaps in the Public Health administrative data is another important contribution of this study (Essue et al., 2018). LTBI is not a mandatory reportable condition in Canada and so vital information on known risk factors and demographic information is not consistently available, which hinders efforts to develop evidence-informed policy. For example, a Swedish study on LTBI completion rates observed a high failure rate among migrants from specific countries (Kan et al., 2013). In our dataset, over 35% of observations were missing for country of origin. Data gaps like this result in missed opportunities to ensure that the current strategies are well targeted and reaching the groups who would benefit most from LTBI treatment.

LIMITATIONS

The dataset had a high proportion of missing observations for some key explanatory variables such as country of birth and immigration country. Ideally, we would like to use immigration country as a proxy for high TB risk; but due to data limitations we relied on country of birth. Country of birth has some potential shortcomings because an individual's birth country could be a low TB risk country while the country immigrated from could be a high TB risk country. In addition, the origin (foreign-born, Canadian-born) was missing for 40% of the sample. However, as

a robustness check, we recoded the missing observations for birth country to foreign-born and found that the results were generally consistent. A notable exception was the strong and positive association between aged 50-64 years and lost to follow-up. Observations were also missing for almost a third of the ordinal dependent variable and nearly a tenth of the binary dependent variable. However, the results remained consistent across models irrespective of differences in the proportion of missing observations. Nonetheless, the high proportion of missing observations for country of birth and completion variables along with observable differences between the known and unknown origin groups suggests that the results may not be generalizable.

In addition, some of the bootstrapped probit models encountered problems with the number of replicates that could not be estimated – most likely due to the small number of positive results associated with some variables. Where we encountered problems with bootstrapping, we took our inference from the model with the largest standard errors. This did not alter our findings.

We were unable to control for underlying medical conditions and/or health status as this information was either incomplete or not available. Finally, the finding that lower income is associated with lower likelihood of completing treatment should be interpreted with caution as we used a neighbourhood proxy for income and it is possible that other characteristics of the individual or neighbourhood could explain this relationship.

CONCLUSION

The main contribution of this study is the finding that immigrants in Hamilton, Ontario identified with LTBI at the point of entry into Canada, relative to those identified through other means, were more likely to be receptive to LTBI treatment initiation and completion, an important component of TB control. We have also demonstrated that more consistent and comprehensive data could reveal valuable and actionable insights into population characteristics that are associated with treatment completion.

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ORIGINAL ARTICLE

An exploration of IPAC educational intervention research: What do we mean by education?

Gwyneth L. Meyers, PhD;[1] Michele Jacobsen, PhD;[2] Elizabeth Henderson, PhD[3]

[1] *Senior Clinical Practice Coordinator IPC, Alberta Health Services*
[2] *Professor and Vice Dean, Werklund School of Education, University of Calgary*
[3] *Professor, Department of Community Health Sciences, University of Calgary; Senior Advisor, IPC Surveillance and Standards, Alberta Health Services*

Corresponding author:
Gwyneth L. Meyers, PhD
Infection Prevention and Control Rm 3683A
Peter Lougheed Centre
3500 26 Ave N.E.
Calgary, Alberta T1Y 6J4
Telephone: 403-943-4157
Email: gwyneth.meyers@ahs.ca

ABSTRACT

Background: Education is considered an important component of Infection Prevention and Control (IPAC) practice. A shift has occurred from exploring how education plays a role in changing healthcare provider infection control practices to increased interest in the use of multimodal interventions. However, several comprehensive systematic literature reviews have identified theoretical, conceptual and methodological challenges in IPAC educational intervention research.

Methods: To gain deeper insight into the challenges, a qualitative review was conducted using a content analysis of 122 papers published between 1989 and 2017.

Results: IPAC educational practice and research is predominantly informed by the traditional educational paradigm of knowledge acquisition, with a commitment to quantitative research methodologies that treat education as a static tool. Limited attention is given to educational theories, teaching and learning concepts and instructional design processes.

Conclusions: IPAC educational practice is constrained by implicit philosophical assumptions about education as information delivery. This paper proposes a paradigm shift from transmission educational practices to those more attuned to the concepts of teaching and learning. By making this shift, IPAC can begin to address the challenges identified in the literature and explore educational theories, contemporary active and engaged teaching and learning processes, instructional design frameworks, and using innovative educational research methodologies.

KEYWORDS:
Infection prevention and control; education; teaching and learning

INTRODUCTION

Education is considered an important component of Infection Prevention and Control (IPAC) practice. Infection Control Professionals (ICPs) describe their role as educators to be central to their practice because it is embedded in every aspect of their consultative role in promoting IPAC practice and patient safety [1]. However, the limited conceptualization of education in IPAC research and practice has led to undervaluing education's role in and contribution to facilitating behaviour change. This paper is the first in a series of four that explore IPAC educational research and practice and the need to build ICP educational expertise by focusing on teaching and learning processes to explore the full value and potential of IPAC education.

Recommendations have been made to move toward the use of multimodal interventions, shifting focus away from reliance on education to incorporating the use of bundles, utilizing aspects of social science and health behaviour models [2, 3, 4]. However, in multimodal approaches, education is integrated primarily to promote knowledge acquisition, without paying critical attention to what IPAC means by education, how it is applied, and how and what healthcare providers learn as a result of education [4]. A shift away from using education to promote behaviour change may be premature. Six systematic literature reviews examining IPAC educational intervention studies identified three areas of concern linked to the lack of success: 1) minimal attention is given to *a priori* pedagogical assumptions informing IPAC educational intervention research; 2) limited consideration is given to education as a construct; and 3) significant methodological challenges exist with the application of experimental research designs, the quality of data collected and the resulting inconclusive findings [5, 6, 7, 8, 9, 10].

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The central goal of education is to facilitate learning. Etienne Wenger, founder of "Communities of Practice," contends that "our perspectives on learning matter: what we think about learning influences where we recognize learning, as well as what we do when we decide we must do something about it – as individuals, as communities, and as organizations" [11, p. 4]. The concept and process of learning has been largely overlooked in IPAC educational intervention research. Limited attention is given to questions about where and how learning occurs, and the role learning plays in influencing beliefs, attitudes, motivations and behaviour change at individual, community and organizational levels. IPAC is hindered by a circumscribed conceptualization and practice of education in our research. This paper proposes a paradigm shift from IPAC's existing view of education to more contemporary conceptualizations of teaching and learning.

MATERIALS AND METHODS

To gain deeper insight into how education is conceptualized and applied in IPAC educational intervention research, a content analysis, involving a qualitative thematic exploration of text using a broad interpretive approach to summarize important facets of the materials being analysed, was used to review 122 research papers published between 1989 and 2017 [12]. Text from each paper was systematically reviewed and coded into the categories described in Table 1. The coding scheme was informed by the principles of grounded theory [13]. Categories, created in advance by the researcher, were based on the IPAC educational literature and pedagogical concepts from the Learning Sciences, a multidisciplinary field focused on the study of learning processes and the design and implementation of effective learning environments [14].

Selection criteria

The 122 papers were selected from a review of 280 papers that were either referenced in the six systematic literature reviews of IPAC educational research, or identified in a literature search of papers published between 2012 and 2017. Combinations of the key words 'education', 'teaching', 'training', 'professional development', 'instruction', 'in-service', 'curriculum', 'infection prevention and control', 'healthcare personnel', 'healthcare providers', 'healthcare professionals', and 'healthcare workers' were searched for in PubMed, Medline and CINAHL databases to find relevant publications. Papers were excluded if education was not identified as an intervention in the study, the paper was not available in English, or it was an abstract. (See Appendix A *https://ipac-canada.org/cjic-abstracts-online-journal-2.php*.)

RESULTS

Research design

The majority (106/122, 86%) of papers employed quantitative research methods; experimental or quasi-experimental research designs were the most common (82/106, 77%), such as before/after studies. As an intervention variable in these studies, education was generally treated as a static tool congruent with traditional reductionist research philosophy. Despite being a core variable in these designs, limited attention was given to the concept of education, its meaning, utility or boundaries as a construct. Most studies focused on the clinical problems they were trying to impact and on measurable outcomes, and gave limited consideration to how the educational intervention might address those problems and facilitate the achievement of outcomes. Only one study utilized an educational research methodology, Action Research, to study teaching and learning of IPAC principles.

Categorizing types of interventions

Categorization of educational interventions proved challenging due to the heterogeneity in terminology used in the papers. Without a clear conceptual framework, there was ambiguity around what was considered an educational strategy in a study. Consequently, various strategies were inconsistently applied. For example, it was often unclear if posters were designed and implemented as a social marketing intervention to create awareness and provide behavioural cues, or whether these were designed to deliver explicit declared knowledge. Similarly, it was often unclear if feedback was used as an approach to practice improvement, or as a motivational tool to create social awareness and pressure to facilitate cultural or behavioural change.

Over the two decades in which the 122 papers were published, two events impacted the types of educational interventions being researched. The first was an increased interest in using multimodal approaches [15, 16]. The second and more predominant was the proliferation of Internet and digital technologies impacting teaching and learning [17]. In response, the types of educational interventions and strategies were grouped into three periods based on the decade of publication: prior to 2000, between 2000–2009, and 2010–2017 (see Tables 2 and 3).

Overall, multimodal interventions were the dominant type reported in the studies (48/122, 39%). The exploration of single interventions has been increasing and constitutes 48% of educational interventions since 2010, perhaps due to increased focus on online and simulation strategies. Most papers exploring simulation were published after 2013 and focused on teaching in post-secondary institutions, or on organisation disaster planning and preparation for Ebola. Studies of online learning generally focused on its efficacy in delivering information compared to face-to-face education. Despite being described as interactive, most online education still followed a passive content delivery format.

Education theory, learning concepts, and instructional design

Education theories, learning concepts, and instructional design constitute underlying conceptual foundations of educational research and inform the choice of research questions, methodology, design of an intervention, as well as the intended outcomes. In reviewing the studies, each of these three categories was given a broad definition so that coding might be

TABLE 1: A summary of categories used for coding in the content analysis

Categories	Description
1. **Type of Intervention**	Based on purpose or use of the education, number, and type of educational interventions identified in the study
a. Single	a. One type of educational intervention being used/explored
b. Multi-educational	b. More than one type of educational intervention being used
c. Multimodal with education	c. The use of multiple types of interventions, including education as at least one type of intervention
d. Comparison of methods	d. Two or more types of educational approaches being compared to each other
2. Theory	Any generalized thinking providing an explanatory framework informing the educational intervention or research
a. Formal Theory	a. Any education, learning or instructional design theory
b. Principles/ideas	b. Concepts providing a framework used to make predictions, explain education, or inform understanding of the education intervention
c. Assumptions	c. Assumptions (explicit or implicit) regarding the education intervention and learning outcomes
3. Learning	Use of the term learning particularly in relation to acquiring, modifying or reinforcing knowledge, behaviours, skills and values
a. Description	a. Any description or discussion of learning regarding the intervention
b. Aspects of Learning	b. Any discussion of learning domains, assessment, transfer or process
4. Instructional Design	Any discussion of a systematic process or learning and design theory, in part or in whole, for educational strategies and materials used to support either instruction or learning
a. Assessment	a. Assessment of instructor or learner needs
b. Design	b. Design/creation of elements that will be used
c. Development	c. Development of activities and resources that will be used
d. Implementation	d. Implementation/pilot testing and roll out of activities
e. Evaluation	e. Evaluation of materials – did they achieve the learning or instructional intent
5. Learning Ecology	An ecology that explores the relationships between instructor, learner, content, activities and environment
	Any discussion related to:
a. Learners	a. Learners (students, healthcare staff)
b. Teachers	b. Teachers (instructors, educators, Infection Control Professionals)
c. Content	c. Educational content and domain knowledge, skills, procedures
d. Strategies	d. Types of educational activities, tools, aids and resources used
e. Environment	e. The context in which the educational intervention is offered and the type of learning environment in which it occurs (e.g., online, practice setting, classroom)

TABLE 2: Types of educational interventions grouped by year published

Type of Educational Intervention[a]	Year Article Published			Total
	< 2000 N=11	2000-2009 N=65	2010-2017 N=46	All Years N=122
Single Education	1 (9%)	17 (26%)	22 (48%)	40 (33%)
Multi-education	7 (64%)	11(17%)	11 (24%)	29 (24%)
Multimodal with education	3 (27%)	33(51%)	12 (26%)	48 (39%)
Comparison of methods	0	4 (6%)	1 (2%)	5 (4%)

[a] Definitions for the various types of interventions are provided in Table 1.

as inclusive as possible. Almost three quarters (88/122, 72%) of the papers made no reference to any of the three categories, and only 10 studies (8%) discussed all three. Appendix B summarizes those studies which dealt even minimally with these educational concepts. (See Appendix B at *https://ipac-canada.org/cjic-abstracts-online-journal-2.php*.) Studies that made reference to all three categories were often exploring educational approaches such as online learning, simulation, and novel interventions like the use of peers, role models or musical parodies. Discussion in each of the three categories varied, ranging from cursory to an in-depth exploration of either the theoretical framework, learning concepts or design of an intervention.

Theory

In only 20% of the studies (24/122), the chosen interventions were intentionally informed by a theoretical framework, philosophy or explicit assumptions grounded in a variety of educational, behavioural or organizational change theories and models. In only one study the described educational theory intentionally informed the choice of research methodology.

For those studies providing a cursory discussion of the theoretical or conceptual frameworks, the focus tended to be on a description of 'what', rather than on an exploration of 'how' or 'why' the theory informed the research. Minimal attention was paid to how the theoretical framework supported the choice of educational intervention or facilitated learning, or why that intervention might achieve the intended research outcomes. Studies that provided more detailed theoretical discussions focused on the 'how' of the learning process, that is, by what means the educational strategies might impact learning. These studies moved beyond treating educational activities as static intervention tools and attended to aspects of teaching and learning strategies that were more likely to facilitate knowledge acquisition, learning, and the transfer of new knowledge and skills into practice.

Learning

Only 15% of studies discussed concepts related to teaching and learning (18/122). While some explored the affordances and hindrances of the strategies in facilitating learning, studies that attended to the 'how' of the learning process focused on concepts such as learning by doing, interactivity, problem-solving, critique, coaching and reflection. They discussed how these concepts facilitated learning and how they could be used to achieve learning outcomes. However, most of the discussion about learning provided a description of teaching and learning concepts rather than how these concepts might be applied to facilitate teaching and learning, and how that new learning might transfer into practice and influence behaviour change.

Simply describing teaching and learning concepts leaves as implicit the process by which those concepts might achieve the desired educational outcomes. The reason for their application and the implications of their use varied across the studies, and remained unclear. As an example, in the studies

TABLE 3: Educational strategies used in interventions grouped year published

Tool or Teaching Strategy	Year Articles Published			Total
	< 2000 N=11	2000-2009 N=65	2010-2017 N=46	All Years N=122
Lecture/training	7 (63%)	31 (48%)	21 (45%)	59 (48%)
Demonstration	5 (45%)	9 (14%)	8 (17%)	22 (18%)
Video	3 (27%)	7 (11%)	4 (8%)	14 (11%)
Poster	4 (36%)	19 (29%)	7 (15%)	30 (25%)
Feedback	5 (45%)	10 (15%)	7 (15%)	22 (18%)
Documents (brochure, policy, articles)	4 (36%)	13 (20%)	6 (13%)	23 (19%)
Online learning	0	10 (15%)	13 (28%)	23 (19%)
Simulation	0	1 (2%)	10 (22%)	11 (9%)
Other (e.g., games, role models, screensavers, musical parody)	4 (36%)	12 (18%)	4 (8%)	20 (16%)
Not described	0	9 (14%)	2 (4%)	11 (9%)

'interactivity' could mean interactions between learners and technology, groups interacting collaboratively through activity and discussion, or individuals interacting with game content. As the purpose for interactivity was not explicit, the intended impact on the learning process and outcomes was unclear. Sometimes, interactivity engaged the learner in passive or lower order learning processes, rather than higher order thinking such as critical evaluation and reflection, which can result in deeper learning.

Instructional design

Instructional design is the systematic development of educational strategies to facilitate high-quality teaching and effective learning experiences. Given limited attention to learning processes, it was not surprising that discussion focused on the research design. Discussion about the design of the educational interventions was identified in only 18% of the studies (22/122).

As with theory and learning, these discussions mostly provided a description of the educational strategies in the materials and methods sections, consistent with treating education as a tool. In a few studies, the educational theory informed the design of teaching and learning strategies. Three studies provided an in-depth discussion of the design of the educational intervention, two of which used the ADDIE instructional design model, (Assessment, Design, Development, Implementation and Evaluation).

The ecology of learning (learners, teachers, content, strategies and environment)

An ecological perspective of the learning environment considers the context in which the learning occurs. From this perspective, learning is a complex, dynamic process that occurs across interactions between learners, teachers, content, strategies and environment in which the teaching and learning occurs. Given limited emphasis on the learning process, limited attention was also given to learning ecology. In almost all the studies reviewed, components of the learning ecology were simply listed or briefly described in the studies' materials and methods section.

Educational strategies were provided as a list in almost all of the studies (120/122, 98%), the most frequent being formal or informal lectures, in-services, rounds and workshops (59/122, 48%). The next most frequently listed component was the domain content topic addressed in the education (116/122, 95%), and a general listing of the type of learners who received the intervention (115/122, 94%). Little information was provided regarding learner needs, experience, engagement, motivation or roles. Only one third of the studies identified the teacher or instructor. Even then, there was limited discussion regarding teachers' pedagogical expertise, involvement in the design of the educational strategies, or their teaching approach.

The least addressed aspect of the learning ecology was the environment in which the learning occurred. Only 7% of the studies explored the impact of context on learning (9/122), by discussing the social and cultural perspectives in clinical or other learning environments, the interactions and relationships between learners, the activities, technology or the teachers involved. Discussion of the learning environment was most likely to occur in studies that explored less traditional approaches such as online learning, simulation or the use of peer groups.

DISCUSSION

A central goal of education is to provide learning experiences that can be transferred or modified from the context in which learning occurs to another context where it can be applied [18]. The process of learning is complex and dynamic, and involves the development of knowledge and abilities, and also of emotions, attitudes and sociality [19]. Because of this complexity, clarity is needed about what is meant by education; assumptions need to be explicit and research grounded in theoretical frameworks. *A priori* epistemological assumptions influence both the theoretical framework informing the research, and the choice of educational and research designs [20].

Theoretical and design frameworks provide a foundation from which the research questions, methodology, interventions and outcomes can be systematically and intentionally threaded together.

The findings from this content analysis demonstrate that limited attention is given in IPAC education research to the complex and dynamic nature of the teaching and learning processes involved. This often results in implicit and unexamined educational assumptions informing the educational approaches used in that research. The approaches tend to follow a teaching as telling paradigm, focused on information delivery by knowledgeable experts to individual learners. The problem is that the educational strategies employed in information giving processes tend to engage lower order cognitive activities such as remembering and understanding, and facilitate passive learning that is less than ideal for producing behaviour change [17]. These approaches tend to result in what is considered de-contextualized knowledge that does not necessarily prepare the learner for their workplace practice, nor assist them in knowing how to apply or modify acquired knowledge in each new situation they face [17, 21].

How knowledge is acquired and transferred or fails to transfer into practice has long been regarded as one of the most important problems in learning. Translating knowledge of best practice based on research findings into healthcare clinical practice has been described as a slow and inconsistent process that requires focused effort [22, 23]. Interventional frameworks from the fields of Knowledge Translation and Implementation Science have been developed to address this know-do gap in healthcare [24, 25]. The empirical approach to knowledge creation and transfer into practice limits how the links between knowledge and action are studied as there are many ways of conceptualizing how knowledge is acquired. These include

knowledge being created, constructed, embodied, performed and collectively negotiated, all of which impact how knowledge manifests in practice [26]. The concepts of transfer, knowledge and learning are complex and multidimensional [19, 27]. Narrow perspectives of both education and knowledge result in undervaluing the role of educational processes in change interventions and of educators in facilitating behaviour change.

Longstanding educational approaches of knowledge acquisition, such as knowledge is a collection of facts and procedures that are transmitted to learners by content experts and that learners are vessels waiting to be filled, are grounded in traditional assumptions of teaching and learning from the 19th and 20th centuries [14, 28]. These assumptions treat knowledge as stable and education as a tool. From this perspective, knowledge and educational interventions are commensurate with classical experimental research methods treating education and knowledge as intervention variables to identify 'cause and effect' relationships in controlled environments. While such classical research designs do offer powerful methods, the research approach is not a scientifically sensitive method for understanding the dynamic relationships amongst teachers and learners in the contextual complexity of healthcare settings. There is a need for newer and broader methodological approaches to support research on education and change in complex healthcare settings [29, 30, 31].

Research from the Learning Sciences performed in response to the emergence of digital technologies, the Internet and the knowledge era is expanding and shifting our understanding of knowledge, teaching, and learning [32, 33]. In her article *Teaching in a Digital World*, Jacobsen clearly articulates these shifts [34]. She points out that knowledge is built and socially constructed through collaborative discussion and interactions with others around activities and through problem-solving within those activities. Contemporary teaching requires active and engaged designs that facilitate rich learning experiences. Finally, formal learning is an actively structured and engaged process that involves the development of deep understanding through meaning-making and interpretation.

Study limitations

A possible limitation of this content analysis is that the research team's professional experiences in the IPAC profession are likely to influence interpretation of the data and findings. While this affords both sensitivity and insight into the subject, it could also introduce bias. Therefore, the research team followed systematic coding processes, and obtained external feedback regarding findings by individuals outside the project. Another limitation of this analysis was the focus on educational intervention research studies. Other interesting and innovative research is emerging that explores IPAC educational practice and different forms of knowing. Nichols and Badger explored the role that tacit knowledge plays in nursing IPAC practice and behaviour [35]. More recently, Slyne et al. explored the manner in which experience enhanced the implementation of nursing infection control knowledge in practice [36]. Such studies suggest that a paradigm shift regarding the teaching and learning of IPAC concepts and practice is beginning to occur.

CONCLUSIONS

This first paper in a series of four is a call to action for a paradigm shift in how IPAC as a profession thinks about education, teaching and learning. A critical appraisal is needed regarding the role and value of education in IPAC intervention research. Effective education calls for more active, engaged, and collaborative, interest-based teaching and learning relationships. Making a shift of this magnitude will take time and support. The subsequent papers in this series will provide tangible steps toward making this shift. In response to the need for innovative research methodologies that attend to the design and study of effective teaching and learning environments, the second paper will explore the application of a Design-Based Research (DBR) methodology that focuses on changing ICP educational practices and building their educational expertise. Papers three and four will discuss findings from the DBR study. Paper three will look at the complexities, value and challenges of ICP educational practice beyond educational intervention research settings. Paper four will describe a professional development framework that uses contemporary teaching and learning strategies to build ICP educational expertise. By building such expertise the relevance of education can be revaluated and IPAC educational research can be opened to new discoveries and advances in teaching and learning practices to improve our ability to effect behaviour change.

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ORIGINAL ARTICLE

Epidemiology of patients hospitalized with *Clostridium difficile* infection: A comparative analysis of community-associated and healthcare-associated *Clostridium difficile* infections

Maryam Salaripour, MSc, MPH, PhD;[1] Jennie Johnstone, MD, PhD, FRCPC;[2,3,5] Michael Gardam, MSc, MD, CM, MSc, FRCPC[1,4,5]

[1]*School of Health Policy and Management, York University, Toronto, ON*
[2]*Public Health Ontario, Toronto, ON*
[3]*St. Joseph's Health Centre, Toronto, ON*
[4]*Humber River Hospital, Toronto, ON*
[5]*Department of Medicine, University of Toronto, ON*

Corresponding author:
Maryam Salaripour, MSC, MPH, PhD, School of Health Policy and Management, York University, Room 409 HNES Building, 4700 Keele Street, Toronto, ON M3J 1P3
Email: msalaripour@hotmail.com; msalarip@yorku.ca

Alternate correspondence to:
Dr. Michael Gardam, MSc, MD, CM, MSc, FRCPC, Chief of Staff, Humber River Hospital, 1235 Wilson Avenue, Toronto, ON M3M 0B2
Email: mgardam@hrh.ca

ABSTRACT

Objectives: To compare the epidemiology of hospitalized patients with community-acquired *Clostridium difficile* infections (CA-CDI) and those with healthcare-associated *Clostridium difficile* infections (HA-CDI).

Design: A retrospective case series analysis was conducted.

Setting: Niagara Health System, a multi-site hospital amalgamation in the Niagara Region, Ontario, Canada.

Participants: Hospitalized patients with confirmed CA-CDI and HA-CDI between September 2011 and December 2013.

Methods: Patients with *Clostridium difficile* infections (CDI) were identified through surveillance and laboratory testing, then stratified in two groups: CA-CDIs and HA-CDIs. Data were obtained from the Infection Prevention and Control (IPAC) surveillance database and the Decision Support database. Nonparametric descriptive statistics were applied to compare the characteristics of patients with CA-CDI and HA-CDI.

Results: Of 628 hospitalized patients identified with CDI, 315 (50.2%) had CA-CDI and 313 (49.8%) had HA-CDI. Compared to patients with HA-CDI, patients with CA-CDI were younger (median age 72 years, interquartile range [IQR] 26, versus 77 years, IQR 18; $p<.001$), had less exposure to antibiotics (52% versus 83%, $p<.001$), and used fewer proton pump inhibitors (PPI) (30% versus 52%, $p<.001$). Gender proportions were similarly distributed between the two groups (58% of CA-CDI and 55% of HA-CDI were female, $p=.38$). There were differences in the proportion of comorbidities between CA-CDI and HA-CDI as follows: presence of an inflammatory bowel disease (18% of CA-CDI versus 40% of HA-CDI, $p<.001$) and surgery in the past three months (13% of CA-CDI versus 23% of HA-CDI; $p<.001$).

Conclusion: CA-CDI must be considered as a potential diagnosis in patients admitted to hospital with diarrhea, even in the absence of conventional CDI risk factors.

KEYWORDS:
Epidemiology; *Clostridium difficile*; infections; community-acquired

INTRODUCTION

The incidence and severity of healthcare-associated *Clostridium difficile* infections (HA-CDI) have been increasing since the emergence and the epidemic spread of the invasive strain BI/NAP1/027 (Khanna & Pardi, 2010; Khanna et al, 2013; Barbut & Petit, 2001; Freeman et al., 2010). Concern is also growing that *Clostridium difficile* (*C. difficile*), historically considered a healthcare-associated infection, is increasingly a cause of diarrhea in the community, causing community-associated *Clostridium difficile* infections (CA-CDI) (Khanna & Pardi, 2010; Khanna et al., 2012). Although many studies have explored the increasing burden of HA-CDI, more research is required to fully understand the epidemiology of patients hospitalized with CA-CDI (Levy et al., 2015; Dumyati et al., 2012).

In the summer of 2011, the Niagara Health System (NHS) in Ontario experienced an unusual increase in hospitalized HA-CDI and CA-CDI cases, combined with multiple HA-CDI outbreaks that were reported to the local public health department. To this end, this paper describes the clinical characteristics and the epidemiology of patients admitted to NHS hospitals with CA-CDI and compares them to the epidemiology of patients admitted with HA-CDI during the same period.

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METHODS

Setting

NHS is a large, multi-site hospital network in the Niagara Region in Ontario, Canada. The region has 12 municipalities and a population of 427,421 (Statistics Canada, 2016). NHS consists of six hospital sites providing a wide range of healthcare services. The subjects of this study were hospitalized patients confirmed to have *Clostridium difficile* infections (CDI). During the study period, NHS hospitals experienced a significantly higher than usual number of cases and clusters of CDI.

Study period and study design

In a case-series retrospective study of consecutive patients admitted to all NHS hospitals with confirmed CDI between September 2011 and the end of December 2013, we analysed the patients' demographic information, comorbidities, antibiotic history, and presence of conventional risk factors for CDI. Table 1 lists the evidence-based covariates evaluated in this study, and their implications.

Case identification, data sources, and privacy

Case definitions used in this study for CDI, HA-CDI, and CA-CDI are listed in Table 2. Hospitalized patients suspected as having CDI were identified by active daily surveillance using a standardized (NHS) surveillance tool based on signs and symptoms manifestation, followed by positive laboratory testing. Final case confirmation was done after positive laboratory toxin testing and case review by an infectious diseases physician and the Infection Prevention and Control (IPAC) personnel at NHS hospitals.

Data for this study were electronically obtained from IPAC surveillance databases and the administrative databases from NHS hospitals. The surveillance, clinical information, and demographics files for the study period from NHS hospitals were combined, creating one large file that was reviewed by a member of the Decision Support Department for completeness of data elements. Deficiencies in demographics and clinical or surveillance information were reviewed on a case-by-case basis. In cases of missing information, the electronic record of the patient was matched with the paper records, using name, admission date, and the site-specific medical records number. Missing information was

TABLE 1: List of selected independent covariates, supporting rational and implications based on a review of the literature

Supporting Literature: Author and Study Year	Predisposing Risk Factor	Justification and Implications
Demographics and patient characteristics		
Pépin & Valiquette et al., 2005 Barbut & Petit, 2001 Southern & Rahmani et al., 2005 Brown et al.,1990	Age≧65 years	Increased incidence explained by old age comorbidities Increased risk: OR* 114.1 (CI** 95%) 1.4–141
Aronsson & Mollby et al., 1985 CDC, 2008, Lessa & Mu et al., 2014	Being female	Increased incidence due to healthcare-seeking behaviour or changing diapers Increased incidence: RR♣1.9 (CI 95%) 1.5-2.5
Comorbidities and clinical history		
Thibault et al.,1991 Gupta & Khanna, 2014	Inflammatory Bowel Disease	Disease flare ups may lead to colonization Increased risk: OR 4.7 (CI 95%) 1–21
Brown et al.,1990	Gastrointestinal surgery	Intestinal stasis may predispose to CDI Increased risk: OR 23.2 (CI 95%) 2.1–255
Fekety & McFarland et al., 1997 Modena & Gollamoudi et al., 2006	History of CDI	Failure of treatment due to other antibiotics Reported in up to 20% of cases
Medication use		
Aronsson & Mollby et al., 1985 Bauer & Veenendaal et al., 2009 Southern & Rahmani et al., 2010 Baxter & Ray et al., 2008 Deshpande et al., 2013 Wren & Ahmed et al., 2005	Use of antimicrobial agents	Increased incidence as a result of imbalance of normal flora of the intestines Increased risk: OR 6.91 (95% CI) 4.17-11.44
Batajoo & Weber et al., 2015 McFarland et al.,1990	Use of laxatives or stool softeners	Positive result on CDI testing Increased risk: OR 3.26 (CI 95%) 1.51–7.02
Dial & Alrasadi et al., 2004 Deshpande & Pant et al., 2012	Use of PPI	Increased risk due to reduced gastric acid Increased Risk: OR 2.7 (CI 95%) 1.4–5.2

* OR: Odds Ratio ** CI: Confidence Interval ♣ RR: Relative risk

TABLE 2: NHS definitions of CDI, HA-CDI and CA-CDI used between September 2011 and December 2013 for surveillance and case identification.

CDI definition	
• A patient with diarrhea with laboratory confirmation of a positive toxin assay (A/B) for *Clostridium difficile*, or • Visualization of pseudomembranes on sigmoidoscopy, or • Colonoscopy, or histological/pathological diagnosis of pseudomembranous colitis.	
Definition of HA-CDIs	**Definition of CA-CDIs**
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: • He or she does not present with CDI upon admission, but shows 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: • The symptoms of CDI *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.

then retrieved from the paper copies of the surveillance forms and medical records. Ultimately, a complete-case analysis (CCA) method that is a recommended statistical approach to analyse datasets with data missing completely at random (MCAR) was used (Stern et al., 2009). A de-identified data set was used for final analysis of this study's objectives.

Laboratory methods and testing for CDI

From September 2011 to April 2012, NHS sent CDI samples for diagnostic testing to a nearby academic centre that used an in-house developed Polymerase-Chain Reaction (PCR) method using the BD GeneOhm™ Cdiff Assay, with a sensitivity and specificity of 93.8% and 95.5% respectively (BD Diagnostics GSCI. BD GeneOhm™ Cdiff Assay, 2010). From April 2012 to December 2013, NHS sent samples to an external commercial laboratory that used BD MAX™ Cdiff, a Nucleic Acid Amplification Test (NAAT) with a sensitivity of 96.3% and a specificity of 92.4% (Dalpke, Hofko, Zorn, & Zimmerman, 2013).

Statistical analysis

Descriptive statistics for age are presented using the median value (and interquartile range [IQR]) (Moore & McCabe, 2003). Significance in the difference between the age median for HA-CDI and CA-CDI cases was evaluated using the Mann-Whitney U test (Pagano & Gauvreau, 2000). Categorical covariates, including gender, age≧65, previous CDI (previous is defined as eight weeks before the onset of CDI symptoms), previous surgery (past three months), previous (8-12 weeks prior to admission) laxative use, proton pump inhibitor (PPI) or antibiotic use, and previous inflammatory bowel disease were dichotomized and presented as proportions. Differences in proportions of all covariates were tested using Chi-Square. In the event of missing data, complete-case analysis was conducted. Data were analyzed using SPSS software, version 21.0 (IBM Corp., Armonk, NY).

Ethical considerations

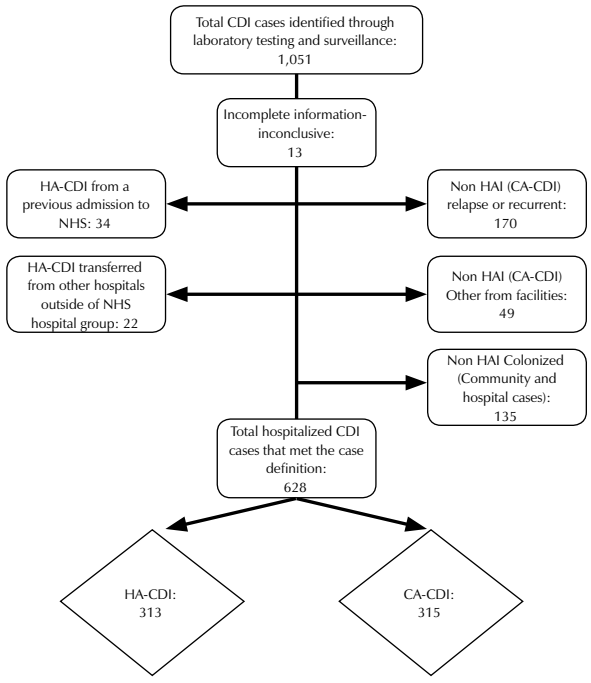
The protocol for this study was approved by York University's Research Ethics Board and the Niagara Health Service's Research Ethics Board. De-identified data were retrospectively accessed from hospital administrative databases; therefore, the requirement for informed consent was waived.

RESULTS

Surveillance and classification of cases

During the study period, 1,051 cases of CDI were identified with laboratory testing and confirmed through surveillance that did not include colonized HA-CDI patients. Overall, 423 cases were eliminated from further analysis (colonized hospital and community cases, transferred and previously positive patients), leaving 628 cases that fulfilled the criteria for case definitions for CA-CDI and HA-CDI. Breakdown of patient classification and the criteria of the eligible and ineligible cases is presented in Figure 1.

FIGURE 1: Decision process flowchart describing the case inclusion and exclusion procedure among 1,051 cases that had toxin positive C. difficile test results



Demographics, clinical characteristics, and comorbidities

Out of the 628 patients, 315 (50.2%) cases were categorized as CA-CDI and 313 (49.8%) as HA-CDI. The median age of CA-CDI patients (72 years, IQR 26) was lower than that of the HA-CDI group (77 years, IQR 18, $p<.001$). The proportion of patients aged ≧65 was 60% for CA-CDI and 79% for HA-CDI ($p<.001$). There were no differences in gender proportions between the two groups, where 58% of the CA-CDI cases were female and 55% of HA-CDI cases were female ($p=0.38$).

Report on CDI risk factors

Approximately half of patients with CA-CDI used antimicrobials prior to the onset of their CDI; the proportion was higher in patients with HA-CDI. Cephalosporins and fluoroquinolones were used more than other antimicrobials in both groups, but were prescribed less often for patients with CA-CDI during the eight to 12 weeks prior to the onset of their CDI infection when compared to HA-CDI patients. Similarly, a smaller proportion of CA-CDI compared to HA-CDI cases used PPI and laxatives. Patients with a previous inflammatory bowel disease and those who had had a previous surgery were proportionally lower amongst patients with CA-CDI versus those with HA-CDI. Fewer CA-CDI cases had no history of CDI compared to HA-CDI cases.

The comparison of patient characteristics and the risk factors for hospitalized patients with CA-CDI and HA-CDI is presented in Table 3 in more detail. Table 4 lists the proportion of antimicrobials used prior to the onset of CA-CDI and HA-CDI.

CDI treatment

Of the patients with CA-CDI (n=315), 218 (69%) had a record of antibiotic treatment after their CDI infection was confirmed; of these, 54 patients (54/218=24%) were treated with vancomycin and 150 patients (150/218=69%) received metronidazole. Of the patients with HA-CDI (n=313), 251 (80%) had a record of antibiotic treatment post-infection; of these, 74 (74/251=29%) were treated with vancomycin and 159 (159/251=63%) received metronidazole.

TABLE 3: Patient characteristics and risk factors: A univariate analysis of patients with CA-CDI and HA-CDI for hospitalized patients in NHS hospitals between September 2011and December 2013

Characteristics and Risk Factors	CA-CDI (n=315) (50.2%)	HA-CDI (n=313) (49.8%)	p-value
Demographics			
Age, median	72 (IQR=26)	77 (IQR=18)	<.001
Age ≧ 65	190 (60%)	247 (79%)	<.001
Female	183 (58%)	170 (55%)	.38
Comorbidities and clinical history			
History of an inflammatory bowel disease			
Yes	56 (18%)	125 (40%)	<.001
No	49 (16%)	29 (9%)	
Not documented	210 (66%)	159 (51%)	
Previous surgery			
Yes	41 (13%)	71 (23%)	
No	92 (29%)	100 (32%)	<.001
Not documented	182 (58%)	142 (45%)	
History of previous CDI			
Yes	12 (5%)	15 (5%)	
No	100 (32%)	140 (45%)	.002
Not documented	203 (63%)	158 (50%)	
Medication use			
Previous exposure to antimicrobials			
Yes	163 (52%)	259 (83%)	<.001
No	152 (48%)	54 (17%)	
Not documented	N/A	N/A	
Protein Pump Inhibitor (PPI) use			
Yes	93 (30%)	163 (52%)	<.001
No	58 (18%)	45 (14%)	
Not documented	164 (52%)	105 (34%)	
Previous laxative use			
Yes	26 (8%)	98 (31%)	
No	71 (22%)	56 (18%)	<.001
Not documented	217 (70%)	159 (51%)	

DISCUSSION

This retrospective case-series study compared the epidemiology of patients hospitalized with CA-CDI with that of those with HA-CDI. The study found that hospitalized CA-CDI patients accounted for slightly more than half of all hospitalized CDI cases; they were younger than HA-CDI patients and, overall, had a lower proportion of established CDI risk factors.

In this study, CA-CDI patients comprised a substantially larger proportion of the total hospitalized patients with CDI than has been reported elsewhere. A North Carolina study reported patients with CA-CDI represented 20% of all hospitalized CDI patients, while another American study reported 40% and a Swedish study reported 22%-28% (Kutty et al., 2010; Khanna, Pardi, Aronson, Kammer, & Baddour, 2012; Karlstrom, Fryklun, Tullus, & Burman, 1998; Norén et al., 2004). One potential explanation could be the rural nature of the Niagara Region and the role of the environment in harboring *C. difficile* spores. Natural sources of surface water, which are common in the Niagara Region, have been known to harbor *C. difficile*, as well as dried airborne debris that can carry spores (Al Saif & Brazier, 1996; Lin, Wade, & Hilborn, 2015). *C. difficile,* including the invasive strain PCR Ribotype 027, has also been isolated from dairy calves, beef calves, and adult cattle (Rodriguez-Palacios, Staempfli, Duffield, & Weese, 2007; Weese, Avery, Rousseau, & Reid-Smith, 2009; Weese, Reid-Smith, Avery, & Rousseau, 2010).

The median age of CA-CDI patients was significantly lower than that of patients with HA-CDI, a finding consistent with those of other studies (CDC, 2006; Fellmeth, Yarlagadda, & Lyer, 2010). However, our CA-CDI median age was notably higher than that reported elsewhere (72 versus ~50 years) (Dumyati et al., 2012; Khanna et al., 2012). A study with a similar environmental background in England reported that almost all cases of CA-CDI occurred in individuals younger than 65 (Fellmeth et al., 2010). Similarly, studies from rural areas in

TABLE 4: Types of antimicrobials and the proportion of patients receiving antimicrobial agents prior to the onset of CDI, stratified by CA-CDI and HA-CDI

	Patients who received antimicrobials prior to the onset of CDI		
	CA-CDI (n= 315)	**HA-CDI (n=313)**	***p* value**
Number of patients that used at least one antimicrobial during the past 8 to12 weeks preceding the onset of CDI *	163 (52%)	259 (83%)	<.001
Cephalosporins	83 (83/163) (51%)	174 (174/259) (67%)	<.001
Fluoroquinolones	61 (61/163) (37%)	146 (146/259) (56%)	<.001
Clindamycin	9 (9/163) (6%)	11 (11/259) (4%)	.55
Vancomycin	7 (7/163) (4%)	37 (37/259) (14%)	<.001
Macrolides	14 (14/163) (9%)	23 (23/259) (9%)	.92
Sulfonamides	4 (4/163) (2%)	13 (13/259) (5%)	.20
Others	93 (93/163) (57%)	229 (229/259) (88%)	<.001

*Some patients received more than one antimicrobial prior to onset of their symptoms.

the US found that only 30% of CA-CDI cases were older than 65 (CDC, 2006; Khanna et al., 2012; Gupta & Khanna, 2014). These differences might be explained by the relatively higher population-level median age in the Niagara Region (median age 44.4 years in the 2011 census, compared with 39.9 years for the south of England, reported in 2014) (Statistics Canada, 2016). However, other age-related dynamics that could have attributed to a transient epidemic activity should be studied.

Our finding of a uniform distribution of CDI in males and females does not follow the pattern reported elsewhere. Almost all studies of CA-CDI report a higher proportion of women with CA-CDI (Khanna et al., 2012; Gupta & Khanna, 2014). Some studies have considered this could be a result of more antibiotic exposure due to more healthcare-seeking behaviour by women, or as a result of exposure while changing diapers (Khanna et al., 2012; Gupta & Khanna, 2014; Leffler & Lamont, 2011). The equal proportions of male and female CA-CDI infections could not be explained by differences in the population construct, as a comparison of the population pyramids of the Niagara Region and those in Connecticut and Monroe County in the US reveals similar proportions of men and women (Statistics Canada, 2016; United States Census, 2016). Other environmental factors or sources of exposure, such as occupation, must be explored to understand this difference.

While exposure to antimicrobial agents is known to be a key risk factor for HA-CDI, a recent study reported less of an association with CA-CDI (Kutty et al., 2010). In a case control study of antibiotic utilization, Wilcox et al. indicated that approximately 50% of the CA-CDI cases in their study used antibiotics prior to the onset of their infection (Wilcox, Mooney, Bendall, Settle, & Fawley, 2008). Similarly, fewer patients with CA-CDI received PPI when compared to patients with HA-CDI; this is similar to a case-control study of antimicrobial-naïve CA-CDIs that found only 50% of patients with CA-CDI had received PPI (Freedberg & Abrams, 2013). Our findings also confirmed previous studies, in that CA-CDI in NHS had had lower proportions of previous inflammatory bowel disease and surgery compared to HA-CDI (Barbut & Petit, 2001; Pépin, Valiquette, & Cossette, 2005). Our results suggest the risk factors for CA-CDI are different than for HA-CDI and should be explored further. Epidemiological studies can lead to root causes of fundamental differences between the risk factors contributing to CA-CDI and HA-CDI.

Although the convenience of a sizable data set was one of the advantages of this study, our surveillance and demographics reports were missing some data elements. Despite our best efforts to complete missing data (previous medical history or previous medication used) that existed in our data set, there were still a notable number of missing data elements that couldn't be retrieved from electronic databases or patient records that could introduce bias due to the missing outcome data (Wood & White, 2004; Stern et al., 2009). In addition, the use of hospital-based administrative data reduced the generalizability of our findings to non-hospitalized CA-CDI cases.

CA-CDI is emerging as an important cause of diarrhea in patients without healthcare exposure; it accounted for half of all hospitalized cases of CDI in our study. CA-CDI affects a younger, healthier population and can occur, even in the absence of the risk factors traditionally associated with this infection seen in HA-CDI cases. Lack of the conventional risk factors suggests the possibility of novel community reservoirs. Comprehensive surveillance and more research on CA-CDI is required to understand the scope of this infection, to determine additional or different risk factors in the community, and to devise preventive measures that enable and inform clinical and public health policies and practices.

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ORIGINAL ARTICLE

Skin preparation in the hand surgery clinic: A survey of Canadian plastic surgeons and a pilot study of a new technique

Brittany A. Best, BSc (Kin), MSc;[1] Timothy J. Best, MD, MSc, FRCSC[2]

[1] *Department of Physiology, King's College London, London, UK*
[2] *Section of Surgery, Division of Clinical Sciences, Northern Ontario School of Medicine, Sault Ste. Marie, ON, Canada*

Corresponding author:
Timothy J. Best, MD, MSc, FRCSC
504-421 Bay Street
Sault Ste. Marie, ON P6A 1X3 Canada
705-256-6012 (tel) 705-256-7228 (fax)
tjb@bestsurg.com

ABSTRACT

Background: Preparation of a patient's skin by application of an antiseptic solution is performed prior to hand surgery as a standard procedure; this study surveyed current practice and examined conversion to a new technique.

Methods: Part 1: an electronic survey was sent to members of the Canadian Society of Plastic Surgeons; Part 2: the current standard technique of nurse-applied antiseptic solution (Povidone 10% w/v (Lernapharm Inc, Saint-Laurent, QC, Canada); Part 3: patients applied their own antiseptic solution (Avagard™ CHG - (Chlorhexidine Gluconate 1% Solution and Ethyl Alcohol 61%, w/w) 3M London, ON, Canada) under nursing supervision; time to complete, cost estimates, and infection rates were compared. Study participants for parts 2 and 3 included a consecutive sample of patients presenting for hand surgery.

Results: 32% of Canadian Plastic Surgeons responded to the survey. 81% did not require patients to wash their hands; 82% indicated that the surgeon applied the prep solution; 78% utilized alcohol/chlorhexidine; 82% used a prep kit; no respondents used a technique of patient-applied solution.

In the clinical study, 21 patients underwent the standard technique, 24 patients utilized the patient-applied technique. The standard technique averaged 131 seconds, the modified technique 47 seconds, significantly quicker ($p<0.0001$). No surgical site infections occurred in either group.

Conclusions: Changing technique resulted in a significant time savings, allowing for 1 additional procedure to be performed in an average clinic day. Processing and waste from use of the prep kits was eliminated, institutional costs were marginally decreased, and the rate of surgical site infections was not altered.

KEYWORDS:
Surgery; ambulatory clinic; skin preparation

INTRODUCTION

The objective of the preparation of a patient's skin prior to surgery is to reduce the incidence of surgical site infections (SSIs). This is thought to be achieved by reducing the bacterial burden resident on the patient's skin prior to making a surgical incision. Two cornerstones of this preparation include a pre-operative wash with soap or an antiseptic agent, and the application of an antiseptic solution to the patient's skin by a member of the healthcare team. Although the effectiveness of the pre-operative wash is not without controversy, it is recommended to be performed prior to the making of a surgical incision by many organizations, including the Canadian Patient Safety Institute [1]. At our institution, Sault Area Hospital (SAH) in Sault Ste. Marie, ON, Canada, washing with soap followed by the application of an antiseptic solution by a nurse is the current standard of care prior to the performance of outpatient hand surgery.

As the efficacy of the pre-operative wash is unclear [2], the first objective of this study was to determine current skin preparation techniques in use in Canadian ambulatory clinics performing hand surgery. The second and third parts of this study were designed as a proof of concept study; the purpose was to observe parameters of the current technique of nurse-applied antiseptic solution used at our institution, followed by observing the same parameters with changing to a patient-applied antiseptic solution.

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Conflicts of interest: The other authors declare that they have no conflict of interest.
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Previous presentation: These data were presented at the Northern Ontario School of Medicine's Northern Health Research Conference, Sault Ste. Marie, Canada on June 24, 2016, and the British Society for Surgery of the Hand Spring Scientific Meeting, Bath, United Kingdom on April 28, 2017.

We investigated if the change in technique conferred any advantages and whether or not it adversely affected SSI incidence.

METHODS

All parts of this research study were approved by the Joint Group Health Centre/Sault Area Hospital Research Ethics Board, in accordance with the Tri-Council Policy Statement 2 issued by the Panel for Research Ethics for the Government of Canada.

Part 1

An electronic survey was sent out via email to all members of the Canadian Society of Plastic Surgeons in 2015, followed up by two further invitations to participate at 1 week and 1 month. The survey was designed to sample current patient skin preparation practices by Canadian plastic surgeons in the ambulatory care hand clinic. Surgeons were requested to answer 4 questions pertaining to their practice in the ambulatory hand clinic (Appendix A).

Part 2

This portion of the study was performed in the ambulatory hand surgery clinic of our community hospital, SAH in Sault Ste. Marie, Ontario Canada. We utilized a quasi-experimental design in which patients presenting on days 1 and 2 were enrolled in Part 2, and patients presenting on days 3 and 4 were enrolled in Part 3. Potential participants were all patients presenting to the clinic for surgery on the study days; all patients were scheduled to receive either carpal tunnel release or stenosing flexor tenosynovitis release surgery. Inclusion criteria were fluency in the English language, being physically able to participate in the study (i.e., possessing 2 functional hands) and possessing competence to follow instructions from the nurse. Exclusion criteria were a history of diabetes mellitus or any immunocompromising illness. Every patient attending clinic on the study days was screened for eligibility, and all eligible patients were invited to participate. Informed consent was obtained from all individual participants included in the study.

Skin preparation was twofold. First, all patients washed their hands with soap and water. Second, the operative hand was held out over a side table by the patient, and the surgical nurse assistant applied povidone 10% w/v prep solution (Lernapharm Inc, Saint-Laurent, QC, Canada) using the standard prep kit supplied by the hospital's sterile processing department, with the povidone solution poured into a sterile medicine cup provided in the kit. The solution was painted onto the patient's skin to just proximal to the wrist, then sterile towels were applied to create the sterile field for surgery. The time for the second part of the procedure was recorded by the research assistant observing from a sitting position at the side of the room. Start time was determined as the time the nurse assistant commenced opening the prep kit; stop time was determined as the time when the sterile towel application was completed.

Part 3

This portion of the study was conducted in the exact same setting of the community hospital ambulatory hand surgery clinic, with the exact same nursing staff. Patients were screened for participation and informed consent obtained in the same fashion as Part 2. The first stage of the patient washing their hands with soap and water was repeated - the second stage was altered to a patient-applied hand antiseptic solution. Specifically, the patient was instructed how to apply the solution (Avagard™ CHG - (Chlorhexidine Gluconate 1% Solution and Ethyl Alcohol 61%, w/w) 3M London, ON, Canada) by the clinic nurse, who proceeded to observe the patient apply 1 pump (2 mL) of the solution from the hands-free applicator, and coached them on application to all surfaces of their operative hand by their contralateral hand, up to the wrist. The nurse then applied sterile towels to create the sterile field for surgery. The time for Part 3 was defined as starting when the clinic nurse commenced explanation of the procedure to the study patient, and ended when the sterile towel application was completed. Recording by the research assistant was in identical fashion to Part 2.

All patients in Parts 2 and 3 of the study were followed and assessed for SSI according to the Center for Disease Control standard Surgical Site Infection criteria for 30 days [3]. This was done in person by the senior author (TJB) at day 14 or 15; at that visit, the signs and symptoms of infection were reviewed with the patients, and they were requested to contact the surgeon if any of those developed up to day 30.

RESULTS

Part 1

32% of the surveyed members of the Canadian Society of Plastic Surgeons responded with a completed survey (n = 130) (Figures 1-4).

FIGURE 1: Survey response from Question 1: Are patients required to wash their hands prior to the procedure?

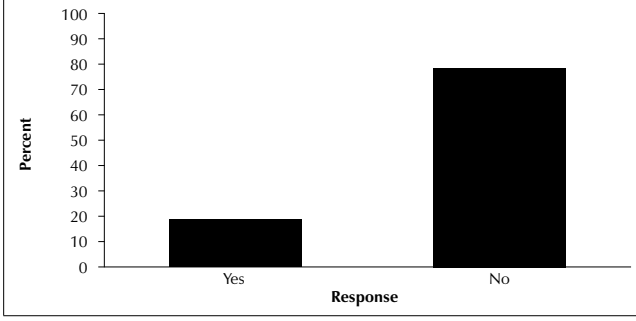


FIGURE 2: Survey response from Question 2: Who applies the skin prep solution?

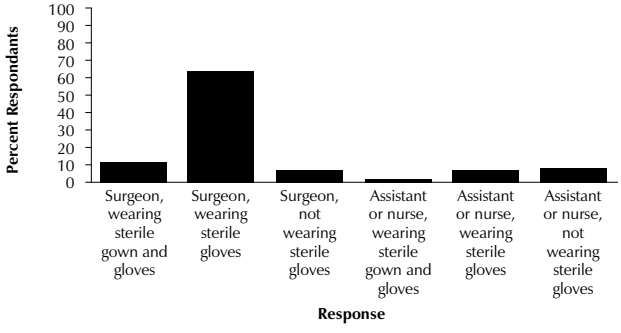
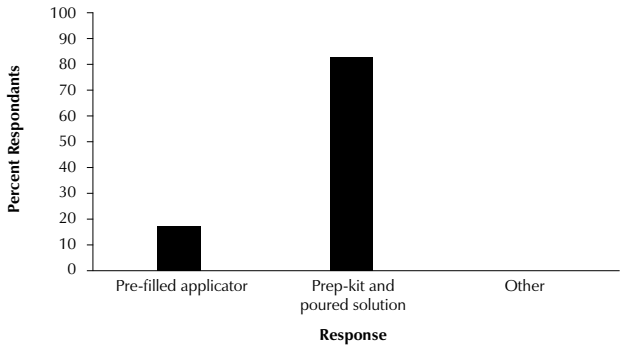


FIGURE 3: Survey response from Question 3: What skin prep solution is routinely used?

FIGURE 4: Survey response from Question 4: What type of product do you use?



Parts 2 and 3

Patients were enrolled in the study over 4 consecutive days of hand surgery clinic. All patients meeting the inclusion criteria were offered participation in the study, and all eligible patients over those 4 days decided to participate. 21 patients were enrolled in Group 1 over days 1 and 2, 24 patients were enrolled in Group 2 over days 3 and 4 (Table 1). No patients were taking any immunosuppressive therapy.

TABLE 1: Time to complete pre-surgical hand preparation.

	Group 1	Group 2
Number	21	24
Mean Time (s)	130.9 +/- 46.2	46.7 +/- 17.2

DISCUSSION

Results from the survey of members of the Canadian Society of Plastic Surgeons revealed that the majority (82%) of respondents did not require their patients to wash their hands prior to the procedure (Figure 1). This does not follow the recommendations of the Canadian Patient Safety Institute (CPSI) to include a "pre-op wash with soap or antiseptic agent" [1]. It is not clear if this was an accurate representation, or if a greater percentage of patients did wash their hands than was reported but the surgeons involved were unaware of that practice (perhaps handwashing occurred as part of the admission process but the surgeon was unaware). A 2015 Cochrane Review concluded there was no evidence to support this practice [2]. Nevertheless, it raises the possibility that there is the opportunity to increase compliance with the CPSI recommendations to include a "pre-op wash with soap or antiseptic agent" to potentially reduce the incidence of SSIs in this setting [1].

Most survey respondents indicated that the prep solution application was performed by the surgeon wearing sterile gloves (Figure 2). Both the Canadian and American Operating Room Nurses Associations publish guidelines on this issue, directing that application of the antiseptic solution for surgical skin preparation be done by "non-scrubbed personnel" [4, 5]. However, no literature support for this recommendation is found in their publications, nor could the authors find a similar recommendation in any of the cited references in this publication. It is unclear if compliance with this guideline would reduce the incidence of SSIs in this setting.

The agent used for the prep solution was an alcohol/chlorhexidine solution for 78% of survey respondents (Figure 3). The CPSI does not specify the exact agent for "skin cleansing", i.e. the skin prep [1]. The Society for Healthcare Epidemiology of America gives firmer recommendations with respect to agent to use, noting high quality evidence exists for the use of alcohol, but conflicting evidence exists on whether combining alcohol with povidone-iodine or chlorhexidine is better [6]. The 2015 Cochrane Review on the topic notes 1 poor quality study reporting lower infection rates following clean surgery when chlorhexidine-alcohol was used for skin prep as opposed to alcohol-based povidone iodine, so no conclusion on which agent was recommended for routine use was reached [7]. Most recently, the World Health Organization issued Global Guidelines for the Prevention of Surgical Site Infection and stated that "despite current knowledge of the antimicrobial activity of many antiseptic agents and application techniques, it remains unclear what is the best approach to surgical site preparation" [8]. In summary, current recommendations cited conclude at this time that both chlorhexidine-alcohol and povidone-alcohol are effective surgical site prep solutions in the prevention of SSIs.

The final survey question explored materials used for the application of the prep solution. 82% of surgeons utilized a prep kit and poured solution, and none reported patients self-applying prep solution to their skin (Figure 4).

The clinical portion of this study (Parts 2 and 3) examined the current practice for hand skin preparation prior to surgery at a Canadian community hospital, and compared it to modifying to a patient-applied technique of skin preparation. The study design was a non-randomized interventional clinical trial. These were outpatient surgeries with primary wound closure, classified as clean wounds by the CDC [7]. There are 2 methods available to healthcare personnel to apply antiseptic solution to patients either using a commercially prepared package, which comes sterilized from the manufacturer in a sealed plastic wrap, or using a hospital prepared reusable kit with sterile disposable gauze or cotton balls added to absorb the solution and apply it to the patient's skin. In Part 2, of this study, nurses utilized standard

prep kits provided by our hospital, prepared in the sterile-processing department, including sterile disposable gauze.

For Part 3 (patient-applied hand antisepsis) we chose to use Avagard™ a solution of Chlorhexidine Gluconate 1% Solution and Ethyl Alcohol 61% in an emollient base (3M London, ON, Canada). Although designed for use by surgical personnel rather than for patients, we chose this product for this off-label usage as it is easy to use, was readily available in our clinics, and in its literature reports "over 98% kill of harmful bacteria in 15 seconds" [9]. With respect to the emollient, we did not see any adverse effects on the patient's skin or the surgical wounds, either at the time of surgery or in the follow-up 30 days. It is possible that some patients will experience an irritant or allergic reaction to the product, but that was not seen in this small pilot study. Surveillance for such reactions would be required in clinical use of the product in this application.

Switching from a nurse-applied solution to a patient applied hand rub saved an average of 84.25 seconds per case in this study, a significant time reduction ($p<0.0001$). In the SAH clinic, an average of 16 procedures are performed in a 6 hour day (22.5 min per procedure), resulting in a cumulative time saving of 22.5 minutes – hence allowing 1 more procedure per clinic day to be performed, without extending clinic hours.

It was difficult to determine a true measure of the financial savings switching methods represented, as the hospital was not able to determine a calculation of the cost of preparing, delivering, and reprocessing the prep kits. For this analysis, we substituted the cost of disposable prep kits (our hospital cost $2.33 each). The cost of the two solutions per procedure was 12.5 cents for Avagard™ and 23.4 cents for povidone, giving a material cost savings of $2.45 per case (all costs in Canadian dollars). This represented a small financial savings of marginal significance; perhaps more importantly it meant no cost increase was incurred by switching to the new method. However, more significant savings were found in the reduction of the medical waste, the elimination of the central supply processing of the kits, and eradicating the need to supply and stock the prep kits in the clinic. Lastly, when asked after study completion for comments on the new procedure, the clinic nurses noted contentment with eliminating the 'somewhat tedious' process of skin preparation by their painting of the hand skin (especially all surfaces of the fingers) with antiseptic solution. Nonetheless, they also noted that due either to language, cognitive or physical barriers, some patients will not be able to comply with effectively completing a self-applied surgical skin preparation procedure and the standard procedure needs to remain available for those patients.

Some limitations of this study are that it was not blinded and did not include a control group. Surgery was limited to carpal tunnel release or stenosing flexor tenosynovitis release surgery, performed by a single practitioner. Although no SSIs were noted in either group, or any adverse effect of utilizing the chlorhexidine gluconate/ethyl alcohol with emollient, this proof of concept pre-post study will need to be followed by a larger study to be sure this change in process does not lead to adverse events and that efficiencies are realized.

APPENDIX A:
Ambulatory hand clinic skin prep survey questions.

1. ***Are patients required to wash their hands prior to the procedure?***
   - ◯ Yes
   - ◯ No

2. ***Who applies the skin prep solution?***
   - ◯ Surgeon, wearing sterile gown and gloves
   - ◯ Surgeon, wearing sterile gloves
   - ◯ Surgeon, not wearing sterile gloves
   - ◯ Assistant or nurse, wearing sterile gown and gloves
   - ◯ Assistant or nurse, wearing sterile gloves
   - ◯ Assistant or nurse, not wearing sterile gloves

3. ***What skin prep solution is routinely used?***
   - ◯ Povidone (Iodine)
   - ◯ Chlorhexidine/Alcohol
   - ◯ Other (please specify)

4. ***What type of product do you use?***
   - ◯ Pre-filled applicator
   - ◯ Prep-kit and poured solution
   - ◯ Other

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ORIGINAL ARTICLE

Evidence-based awareness generation improves infection control practices in Neonatal Intensive Care Units at secondary-level government hospitals in Central India

Anudita Bhargava, MD, PDCC, PhD;[1] Ajay Trakroo;[2] Debabrata Dash, MD;[1] R. Prasanna;[3] Ritu Pandey, MSc[1]

1 All India Institute of Medical Sciences, Raipur
2 UNICEF, Chhattisgarh
3 Health Services, Chhattisgarh

Corresponding author:
Dr. Anudita Bhargava, Additional Professor, Department of Microbiology, All India Institute of Medical Sciences, Raipur – 492099, Chhattisgarh, India
Telephone: 91-851-888-1903
Email: anuditabhargava@gmail.com; dr_anuditas@yahoo.co.in

ABSTRACT

Background: Healthcare-associated infections are preventable yet a significant cause of neonatal mortality. Neonatal Intensive Care Units (NICU) are established in resource poor settings in India to reduce the neonatal mortality rate. However, inadequate infection control practices (ICP) at these NICUs may defeat its purpose. A study was designed to conduct an environmental microbiological surveillance of the NICUs to identify the infectious microbes and to use the results as an evidence to generate awareness among the NICU team members to improve ICP.

Methods: Environmental swabs were collected in pairs (before and after cleaning) from the NICUs in three rounds of sampling and were subjected to culture.

Results: Of the 1,284 swabs collected, 29.7% showed positive bacterial or fungal growth. Among the positive cultures 37% had known pathogens. Commonest were *Pseudomonas spp.* and *Acinetobacter spp.* followed by enteric bacilli. 15% of the non-fermenting gram-negative bacilli and 43% of coliforms were Multi Drug Resistant (MDR). The reports with possible solutions were shared with the respective NICU and a significant reduction in bio-load between pre and post-cleaning swabs ($p<.001$) were noted. Significant reduction ($p<.001$) in bio-load was recorded in the swabs collected in rounds two and three.

Conclusion: Environmental Microbiological Surveillance of intensive healthcare setting and sharing of the reports with possible solutions specific to the recorded findings, found to be an effective tool in motivating the NICU team members for improved ICP.

KEYWORDS:
NICU; infection control practices; surveillance; awareness

INTRODUCTION

Special New-born Care Unit is a facility established in some states of India with relatively higher infant mortality rate. These units are equivalent to Neonatal Intensive Care Units (NICU, in their objectives and functioning. Therefore, they would be referred as NICU in this article. Regionalized neonatal/perinatal care with good network at various levels is emerging as an effective strategy to manage neonatal disease burden [1, 2].

Therefore, the State of Chhattisgarh (a state in Central India) has also established 16 functional NICUs, one each at 15 district hospitals (secondary-level healthcare facility), and one at a medical college, with support from UNICEF. However, the presence of Hospital Acquired Infections (HAI) and emergence of drug resistance microbes at these NICUs has challenged its gains and positive contributions. The presence of HAI is attributed to inadequate infection control practices (ICPs) whereas the unmonitored and lack of evidence-based use of antibiotics is causing the emergence of drug resistance microbes.

The efforts were thus made to identify the gaps in the knowledge and practices regarding standard ICPs. The requirement of training in standard ICPs and sub-optimum ICPs across all levels of team members was a major gap identified from the discussions with the NICU team members.

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Contributions: AB & AT conceptualized the study. AB, DD & RP1 performed and analyzed the laboratory work. RP2 provided administrative support. AB & DD wrote the manuscript. RP1 – Ritu Pandey, RP2 – R. Prasanna.

Among many published studies reporting the importance and role of NICUs in India in facilitating quality neonatal care [3-5], none were found to have delved into the hospital associated infections and infection control practices. A study thus was planned with 13 NICUs that were fully functional by then. As a first step, the study focused on microbiological environmental surveillance of NICUs, to generate and demonstrate the existence of microbes in the NICU environment; and the need for initiation and maintenance of adequate ICPs. This article discusses the results of the Microbiological Environmental Surveillance and its impact on ICPs.

METHODS

The study was conducted from February 2017 through August 2017 at the Department of Microbiology of All India Institute of Medical Sciences (AIIMS), Raipur, a tertiary level healthcare center-cum teaching institute, located at Raipur, the capital city of the State of Chhattisgarh. The study was approved by the institutional ethics committee.

The study started in February 2017 with a workshop for two days, which was attended by the Pediatrician-in-charge and the Chief Staff Nurse from each of the 13 NICUs. The hands-on sessions for various infection control practices were organized on the first day of the workshop. Day two was dedicated to sample collection, its packing and transportation to the laboratory.

Microbiological environmental samples from 13 NICUs were collected from high touch areas and patient care items by swabbing. Commercially available sterile swabs (Himedia, Mumbai) were used for the purpose. The surfaces swabbed included nursing station, cradle bar/frame, phototherapy hood, warmer basinet, suction tube, suction jar, oxygen humidifier, oxygen concentrator, oxygen hood, ventilator tubing, C-PAP instrument, ambu-bag, nebulizer mask, infusion pump, intravenous stand, water tap handle, door handle, medicine trolley, procedure trolley, and computer keyboard.

Through the period of the study three rounds of sample collection were undertaken. In each round the samples from every NICU was collected once. The duration between two rounds of sample collection at any of the participating NICU varied between 20 to 25 days. In each round of sample collection, following were collected:

a) A pair of surface swabs from each site – one pre-cleaning and another after 30 minutes of cleaning procedure.
b) Samples of disinfectant being used at the time of sample collection.

The collected samples were then transported (as per standard protocol) to the Department of Microbiology of AIIMS, Raipur by specially trained team members [6].

The swabs were cultured on Blood agar and MacConkey agar, incubated at 37°C for 18-24 hours. The results were categorized as: no growth (NG), growth of contaminants (C) or growth of pathogenic bacteria (P).

The pathogenic bacteria were identified to the species level by standard laboratory protocol. For all identified pathogenic bacteria antibiotic sensitivity test (AST) was conducted as per CLSI guidelines [7, 8].

The antibiotic sensitivity pattern was recorded. The MDR organisms thus identified were stocked for future studies.

The disinfectant was tested by in-use test [9].

Statistical analysis

Statistical analysis was done by applying chi-square test using on-line statistics calculator "open epi". The p-value less than 0.01 (1%) was considered as statistically significant [10].

RESULTS

Among the total 1,284 swabs cultured, 381 (29.7%) showed positive bacterial/fungal growth. Out of these 381, 141 (37%) grew pathogenic bacteria while 240 (67%) were contaminants (Non-pathogenic) or environmental saprophytes. Mixed growth was noted in 33 (8.6%) samples.

Among the 1,284 swabs, 655 were collected prior to cleaning while 629 were post-cleaning swabs (Table 1). Nearly 30% of the samples showed growth of microorganisms. This comprised 19% non-pathogenic bacteria/fungus and 11% pathogenic bacteria.

The number of pre-cleaning swabs showing no-growth (NG) were 52%, 59%, and 71% in the first, second and third round of sampling, respectively. The number of post-cleaning swabs showing no-growth was 78% in the first round of sampling, 81% in the second and 82% in the third round of sampling.

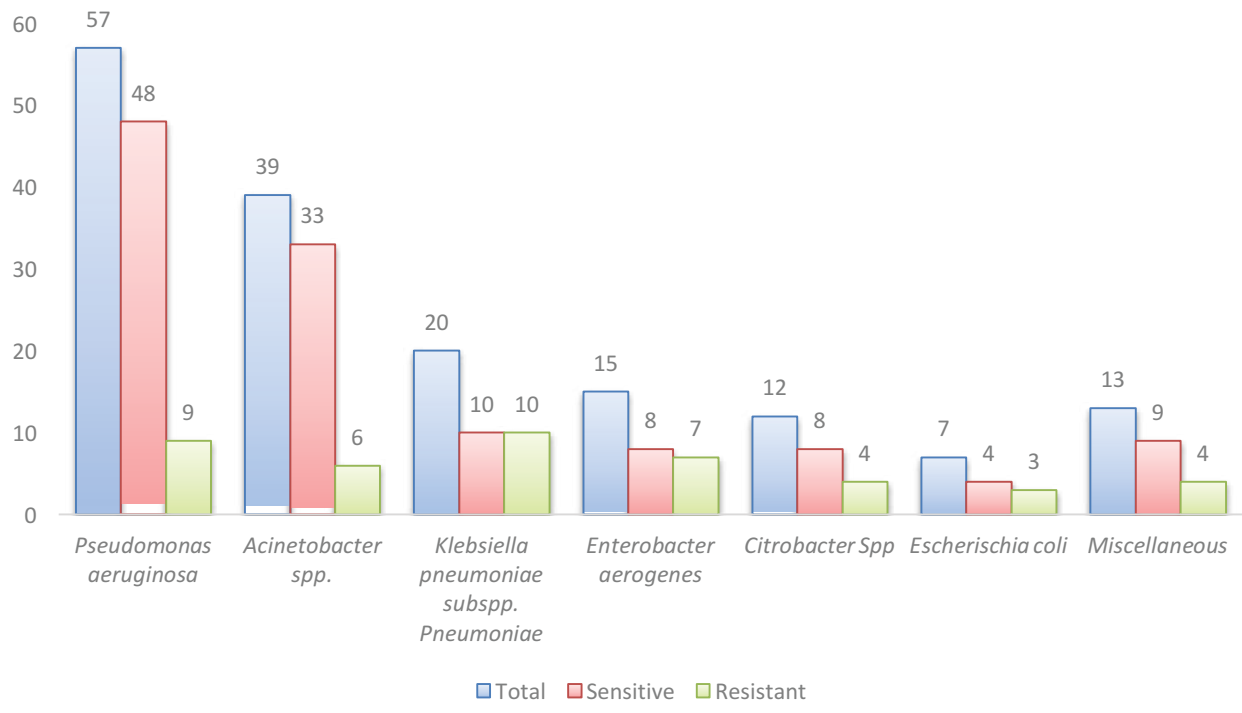
The number of pre-cleaning swabs showing growth decreased from 48% in the first round of sampling to 41% in the second and 29% in the third round of sampling. Growth in post-cleaning swabs decreased from 22% in the first round to 18% in the third round of sampling.

There was statistically significant difference in the results of the pre-cleaning swab cultures of the three rounds of sampling. There was, however, no significant difference in the results of the post-cleaning swab cultures in all three rounds of sampling (chi-square =1.141).

TABLE 1: Observation of surface swab cultures from NICUs of Central India

Swabs	Total	No growth		Pathogen		Contaminants	
		N	%	N	%	N	%
Pre-cleaning random swabs	655	396	60.4	95	14.5	164	25.2
Post-cleaning swabs	629	507	80.6	46	7.3	76	12.1
Total	**1284**	**903**	**70.3**	**141**	**10.9**	**240**	**18.7**

FIGURE 1: Spectrum of pathogenic bacteria and their antibiotic susceptibility pattern



A total of five swabs showed the growth of *Candida albicans*.

Majority of contaminants were Coagulase-negative Staphylococcus (CoNS).

The spectrum of microorganisms isolated were approximately similar for all NICUs.

The chi-square value of difference in NG samples between pre-cleaning and post-cleaning swabs was 30.98, 28.16, and 6.02 in the first, second and third rounds of sampling, respectively.

Among the patient care items, respiratory equipment including suction tube and suction jar, followed by oxygen concentrator showed maximum bioburden of both contaminants and pathogenic bacteria. The nursing station, medicine trolley, followed by procedure trolley and computer keyboard had the highest bioburden among the non-patient care high touch surfaces of the environment.

A predominance of gram negative bacilli was noted in the analysis of the spectrum of bacteria isolated from different sites. Among gram negative bacilli non-fermenters *Pseudomonas aeruginosa* and *Acinetobacter spp.* were the commonest, followed by the members of enterobacteriacae family. Among the family of enterobacteriacae, maximum were *Klebsiella pneumoniae subspp. pneumoniae,* followed by *Enterobacter aerogenes, Citrobacter spp*. and *Escherischia coli* (Fig. 1).

The analysis of antibacterial sensitivity pattern of the pathogenic bacteria revealed that 25.6% of the isolates were Multi-Drug Resistant (MDR), i.e., showing resistance to three or more than three classes of antimicrobial agents (Fig.1).

Further evaluation of the organism-wise antibiotic sensitivity pattern indicated that 15% of the non-fermenting gram negative bacteria were MDR, whereas 43% of the gram negative bacilli belonging to Enterobacteriacae family were MDR (Fig.1).

Of the disinfectants used at the NICUs, 87% were found to be acceptable, while 13% were unacceptable.

DISCUSSION

Neonates are vulnerable to various infections due to their weak immune system and this vulnerability depends on the maturity status of the neonate, birth weight, maternal health etc. The NICUs are therefore set up at district and block levels in resource poor settings of India, to provide specialized care to an increasing load of newborns due to a rise in institutional delivery and referrals under Integrated Management of Childhood Illness (IMNCI). Such regionalized neonatal care units with good network at various levels are emerging as an effective strategy to manage neonatal disease [1, 2]. Additionally, where advanced care units do not exist, the secondary level units can help lower NMR significantly [11, 12]. Towards mid-2016, 13 NICUs became functional in the state of Chhattisgarh.

It is thus important that the environment inside the NICU has minimum bioburden, which can be attained only by following standard infection control practices. Inadequate infection control practices make NICUs vulnerable to various hospital-acquired infections (HAIs).

During past years, several studies have been published to evaluate the impact of these NICUs. A study by Neogi et al. observed that aseptic practices critically determine the outcome of treatment a newborn received in the NICU [3].

In a review of 125 articles, Srivastava and Shetty emphasized the importance of raising awareness among the team members regarding infection control practices, especially in resource poor settings [13]. The NICUs in the present study are also located in resource poor settings with inadequate awareness regarding infection control practices among the team members and use of antibiotics as the only weapon to combat infections.

In the Indian context, the authors could not find any study that used laboratory-based evidence to indicate the presence of micro-organisms (bioburden) in the NICU and the impact of good ICPs in reducing it. The present study was planned according to the CDC recommended situations-research and quality assurance to evaluate the effect of infection control practices and commissioning newly established special care areas like NICUs [14, 15, 16, 17].

In the present study, about one third of the high touch surface swabs showed presence of either contaminants or pathogenic bacteria. A total of 11% of the swabs showed growth of pathogenic bacteria, among which 25.6% were MDR organisms. Isolation of such a high number of MDR bacteria was a cause of serious concern since they could be potential source of HAI to the neonates.

Among the pathogenic bacteria reported there was a preponderance of gram negative bacilli comprising non-fermenters like *Pseudomonas aeruginosa*, *Acinetobacter species* and members of enterobacteriaceae family, including *Klebsiella pneumoniae subspp. pneumoniae, Escherischia coli, Enterobacter spp.* and *Citrobacter spp.* etc. A review of 125 HAI related studies in India reported that gram positive cocci, viruses and fungi were predominant pathogens found from the advanced units, whereas gram-negative enteric rods, non-fermenting gram negative rods and fungi were commonly reported in patient samples collected from resource-limited settings [13]. These findings can be related to the presented study since these NICUs are also located in resource poor settings and showed predominance of non-fermenting gram-negative rods and enteric bacilli in the environment, which may be a potential source of HAIs among the neonates.

Another study by Pawa et al. from North India observed MDR *Klebsiella spp*. (68%) as the commonest pathogen (causing nosocomial septicemia and pneumonia), followed by *Pseudomonas aeruginosa* (13%) [18].

In a study from South India by Kamath et al., Extended Spectrum Beta Lactamase (ESBL) producing *Klebsiella spp.* was observed as the commonest nosocomial pathogen, followed by Methicillin Resistant *Staphylococcus aureus* (MRSA) [19].

Coagulase Negative Staphylococcus (CoNS) constituted the majority of contaminants. These bacteria can also act as a pathogen in neonates. Earlier studies established that 8-24% of CoNS isolated from blood were true pathogen. There is also a substantial body of evidence to demonstrate increasing antibiotic resistance by CoNS among neonates [20, 21, 22]. Thus isolation of large number of CoNS from the NICU environment reported in the present study is highly significant as it can be a potential pathogen, and secondly its widespread presence in the environment indicates suboptimum ICPs, especially poor hand hygiene among the team members.

The reported study observed that the growth of microorganisms decreased in the samples collected in the second and third round. During the first round of sampling, 48% of the swabs collected prior to cleaning showed bacterial growth. It reduced to 40% in the second round of sampling, and to 28% in the third round. The observed reduction in bacterial growth in the second and third rounds was statistically significant ($\chi^2 = 16.55$; $p < .001$).

The authors of the study prepared customized instructions as per the WHO and CDC guidelines to improve infection control practices for each NICU separately, which dealt specifically with the deficit/s found in each NICU's surveillance report. These customized instructions were not only based on the laboratory test results, but also on the resources that the NICUs had: e.g., which disinfectant or decontaminant was available, availability of PPE (Personal protective equipment), availability and skill of human resources and the work-load in each NICU. The team members at every NICU followed the ICP related specific instructions shared with them, which helped significantly in reducing the bioburden, thereby reducing the probability of HAIs in the respective units.

Significant reduction in the bioburden was also recorded in the post cleaning swabs as compared to swabs collected prior to cleaning. This was a consistent phenomenon across three rounds of sample collection. In the first and second rounds of sampling the difference between the pre and post-cleaning swab cultures were statistically significant with χ^2 values of 30.98 and 28.16 respectively. In the third round of sampling the difference in bioburden between pre and post-cleaning swabs reduced substantially. It indicates that the efforts of the NICU team members improved towards maintaining cleanliness consistently as per standard ICP protocol, resulting in reduced difference in bioburden in pre and post-cleaning swabs.

The equipment showing highest bioburden included suction tubing and suction jar followed by phototherapy hood, warmer basinet, other respiratory care items such as oxygen concentrator, oxygen humidifier, C-pap and oxygen hood, etc. Considering it as a potential source of infection to the neonates admitted in the unit, authors provided specific cleaning instructions to the NICU team members. By the third round of sampling, significant reduction in bioburden was also reported in the swabs collected from the surfaces of the NICU equipment. Among the non-patient items, highest bioburden was observed from nursing station and medicine trolley. Approximately 72% of swabs collected in the third round did not show any bacterial growth. It indicates improvement and consistency in the infection control practices followed for cleaning of equipment and non-patient care items in line with the specific suggestions made by the authors.

An earlier study by Gupta et al. has found that in the NICU, baby placements, resuscitation equipment, and cleansing

solutions are significantly associated with HAI [23]. It is similar to the findings of the present study, which has also observed heavy contamination of respiratory care equipment with various microbes including MDR bacteria.

With regard to the presence of microbes reported in samples from inanimate environment and fomites, it is of importance to refer to a study by Brito et al., which concluded that lower sink: cot ratio (poor hand washing facility) and higher monthly admission rate resulted in higher rates of HAI [24].

The aim of the present study is to conduct an environmental microbiological surveillance of the NICUs to identify the infectious microbes and their niches and to use the results as evidence to generate awareness among the NICU team members to improve infection control practices, which was successfully attained.

Limitations of the study

The authors of the study depended on NICU team members for sample collection and its packing, while transportation from the NICUs to the microbiology laboratory at AIIMS Raipur was supported by a logistical partner.

CONCLUSION

Environmental Microbiological Surveillance of a new intensive healthcare setting would be an effective tool in motivating the team members for better infection control practices, thereby helping in reducing HAI and thus morbidity and mortality among neonates admitted in such units. The Environmental Microbiological Surveillance is also helpful in identifying the MDR microorganisms present in the healthcare environment and prevent its spread to the vulnerable neonates, well in time.

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QI IN IPAC

Reduction of *C. difficile* standardized infection ratio by limiting testing in patients with low probability of infection

Morgan Block, PMP, CSSGB, CPHQ; Chris Henderson, MT(ASCP)SM, CIC; Doramarie Arocha, PhD, CIC, FAPIC; Mary-Grace Reed, RN; James Foster, PMP; Tsedey Melaku, RN; Carol Croft, MD;[1] Julie Trivedi, MD;[1] Francesca Lee, MD[1]

[1] *Senior author*

ABSTRACT

Background: *Clostridium difficile* is a spore-forming, anaerobic gram-positive bacillus that is a major cause of healthcare-associated infections. *C. difficile* can be transmitted from symptomatic individuals as well as from asymptomatic carriers, however, compliance with recommended precautions can minimize the risk of transmission. Testing of patients with a low probability of *C. difficile* Infection (CDI), based on the presence or absence of risk factors and symptoms, can result in the identification of asymptomatic carriers. This can lead to 1) the unnecessary institution of contact isolation; 2) unnecessary administration of antibiotics for the treatment of *C. difficile*; and 3) an increased length of stay, all of which contribute towards increased healthcare-related expenditures on an individual and system wide level. In order to reduce the amount of unnecessary testing and subsequent treatment of patients colonized, but not infected with *C. difficile*, a "C. diff SWAT team" was created.

Methods: Starting January 2015, all orders for *C. difficile* toxin B gene (PCR) at Clements University Hospital (CUH) placed or collected while in an inpatient location were considered. CUH is a 460-bed acute care hospital associated with the University of Texas Southwestern Medical School. The following measures were monitored using individual-moving range control charts (XmR):

Outcomes measures: (1) National Healthcare Safety Network (NHSN) *C. difficile* hospital-onset standardized infection ratio (SIR) and (2) inpatient facility *C. difficile* healthcare facility-onset incidence rate per 10,000 patient days.

Process measures: (1) percentage of *C. difficile* testing ordered when laxatives were given within the prior 48 hours, (2) percentage of *C. difficile* samples ordered on day 1-3 but collected on hospital day 4 or greater, and (3) percentage of samples collected greater than 24 hours after the order was placed.

Balances measures: Total community-onset *C. difficile*.

Results: Both the process measures and the NHSN *C. difficile* hospital onset rate per 10,000 days demonstrate statistically significant shifts on the control charts. Overall, the SIR in 2015 quarter Q1-Q3 was 1.20 (107/89.38), and from initiation of the project through 2017 Q2, the SIR is 0.87 (151/174.28) ($p = 0.011$).

Conclusion: With the aid of clinical decision support (CDS) and clinical education, the project team was able to successfully hardwire *C. difficile* testing and diagnosis best practice guidelines into the diagnostic pathway and significantly reduce the *C. difficile* SIR and subsequent burden of treatment.

INTRODUCTION

Clostridium difficile is a spore-forming, anaerobic gram-positive bacillus that is a major cause of healthcare-associated infections [1]. Evidence shows that only 1-2% of hospitalized patients may have active *C. difficile* infection (CDI), while up to 20% may actually be colonized with *C. difficile* [3]. The rates of CDI have risen nationally, partly thought to be due to inappropriate testing in patients with a low probability of infection, as well as the use of the PCR (polymerase chain reaction) assay for the toxin B gene. It is a sensitive diagnostic modality able to detect a small amount of genetic material, but cannot distinguish between active infection or colonization. A positive test in an asymptomatic individual would essentially identify patients who are colonized and not infected, which can lead to
1) the unnecessary institution of Contact isolation;
2) unnecessary administration of antibiotics for the treatment of *C. difficile*; and 3) an increased length of stay, all of which contribute to increased healthcare-related expenditures on an individual and system-wide level [3].

Problem description

Inappropriate ordering of *C. difficile* testing with subsequent identification of colonized (rather than infected) patients can harm the patient and the institution in several ways.

1) The administration of antibiotics for the treatment of *C. difficile* is known to disrupt the normal flora of the intestine and, in the case of oral vancomycin, may allow the proliferation of vancomycin-resistant enterococci (VRE) [4].
2) A diagnosis of *C. difficile* based primarily on a positive PCR test can distract clinicians along the diagnostic pathway, delaying the identification of the actual cause of illness and having a negative impact on patient treatment [5].

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3) The judicious use of testing for *C. difficile* can protect the patient from experiencing any feelings of social or physical isolation that can result from being placed in isolation. In our institution, contact precautions for CDI constitutes the use of gloves, gown and subsequent hand washing with soap and water. For example, staff are required to wear personal protective equipment (which would include at the least, an impervious isolation gown and gloves) when entering the rooms of known or suspected *C. difficile* patients to prevent the risk of acquiring and transmitting *C. difficile* spores throughout the hospital environment. The financial cost of contact precautions is due to usage of disposable gowns, gloves and medical equipment, as well as the enhanced cleaning of these rooms with Oxycide and a UV light disinfection system (Xenex). The psychological impact of contact isolation on patients is related to fewer room entries by staff and limited physical interaction with others; this can also consequently impact patient and family satisfaction [6].

Rationale

Diagnostic stewardship refers to choosing the right diagnostic assay for the right reason at the right time for the right patient. Modifying the ways in which tests are ordered, performed and resulted can result in improving the quality of patient care and subsequent clinical outcomes. The diagnostic pathway encompasses the three phases of lab testing: pre-analytic, analytic, and post-analytic. Leveraging efforts to address the pre-analytic phase of care can help prevent the subsequent consequences of inappropriate testing.

The Society for Healthcare Epidemiology of America (SHEA) and Infectious Diseases Society of America (IDSA) joint expert panel established best practice guidelines on the testing and diagnosis of *C. difficile* [7]. Recommendations adopted from SHEA-IDSA are as follows: (1) testing should only be performed on diarrheal stool, and (2) the testing of stool from asymptomatic patients is not advisable [7].

Specific aims

Stewardship of diagnostic testing and "choosing wisely" are important concepts to control cost in care delivery and to avoid unnecessary treatment. Our approach to improve diagnostic stewardship included clinical decision support to guide testing and analytic interventions to improve Best Practice Advisory (BPA) utility. Working as a multidisciplinary team allowed for a diversified perspective and interdepartmental project buy-in. The project team aim was to reduce *C. difficile* SIR from 1.20 to 0.92[1] for Clements University Hospital (CUH).

METHODS

Context

The project was implemented via rapid cycle changes using performance improvement methodologies such as Plan-Do-Study-Act. Each new improvement change was selected by the project team for implementation. Compliance with the change was monitored and infection rates were analyzed for evaluation of efficacy.

All positive *C. difficile* tests in which a stool was collected after hospital day 3 were reviewed thoroughly by the Department of Infection Prevention & Control (IPC). These positive tests were divided into one of two categories (HO vs. HAI). HO cases were defined as a positive PCR test for *C. difficile* toxin, but the positive test was attributed to colonization or infection upon admission. Common HO scenarios included: diarrhea that was attributed to laxative usage without evidence of colitis, history of *C. difficile* colonization, delay in stool being sent to the lab, and inappropriate ordering of testing in patients with less than three watery stools in a 24-hour time period. HAI cases were defined as positive PCR test for *C. difficile* toxin and the patients were truly infected showing signs and symptoms of CDI such as fever, leukocytosis, and abdominal pain.

A multidisciplinary "*C. difficile* SWAT team" was created to address these concerns. The core project team members included representatives from Infection Prevention, Laboratory Services, Nursing, Medical Staff, Quality Analytics, and Performance Improvement. Reporting of progress was presented at periodic intervals to the hospital Performance Improvement Committee, the Medical Executive Committee, and the Hospital Board. Expectations and requirements established by Executive sponsorship were identified at project kickoff and used as a project tollgate to validate quality parameters and customer requirements.

To reduce the incidence of inappropriate ordering, the project team opted to emphasize *C. difficile* diagnosis and rejection guidelines through the use of 1) clinical decision support (CDS) and 2) revised lab policy:

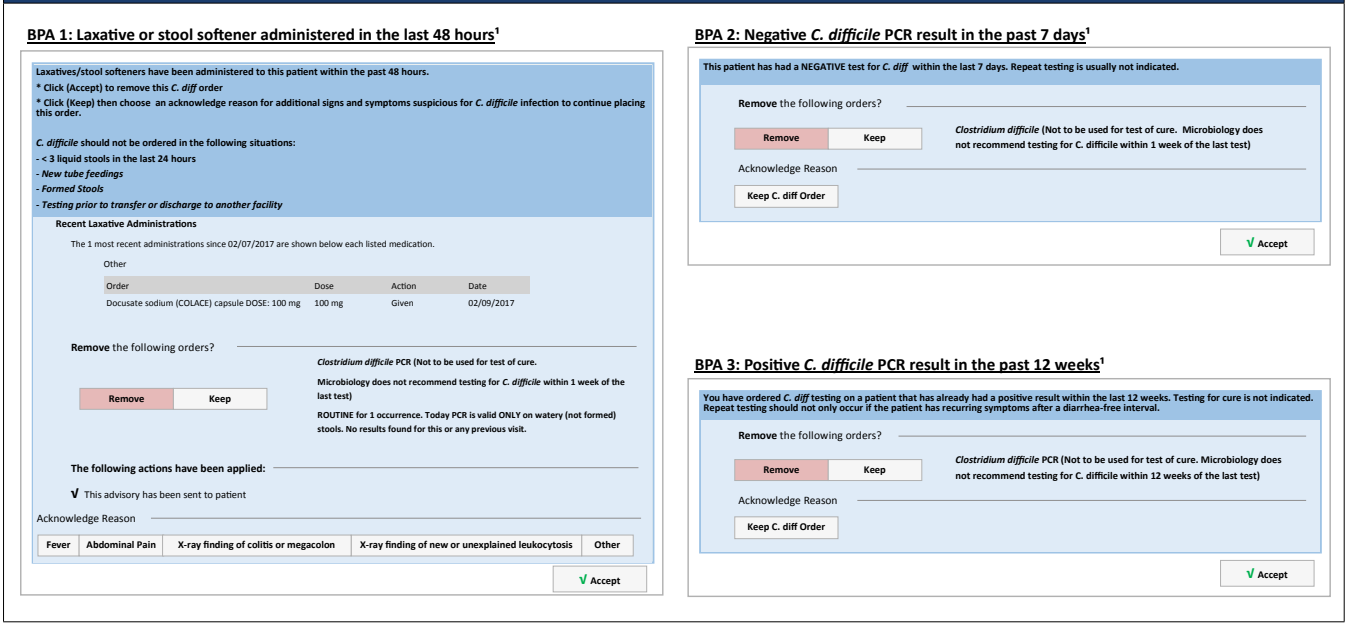
1) CDS design was based on discouraging (a) the testing of patients for whom laxatives, stool softeners or enemas have been administered in the past 48 hours, (b) "test of cure" or ordering test for patients treated for *C. difficile* infection after symptom resolution, or (c) repeat testing within one week of last test due to ongoing concern for CDI. These testing algorithms are founded on best practice and supported by CDS to guide ordering habits. This is preferable to relying on clinical education, which is subject to the deterioration of recall.
2) The Cepheid Xpert *C. difficile/Epi* Assay is a rapid, automated in vitro diagnostic test for detection of toxin producing *C. difficile* directly from unformed stool specimens. If the sample fails to meet specimen requirements (i.e., the specimen does not conform to the container), it would be subject to rejection per lab policy. The lab resolved to emphasize policy as of November 2015.

Interventions

1. *C. difficile* notifications for providers: All Hospital Onset (HO) C. diff Laboratory Identified (LabID) events are reviewed by Infection Prevention and a clinical summary is provided in an email notification.

[1] At project kickoff, 0.92 represented the 50th percentile of facilities reporting.

FIGURE 1: C. difficile Best Practice Advisories*



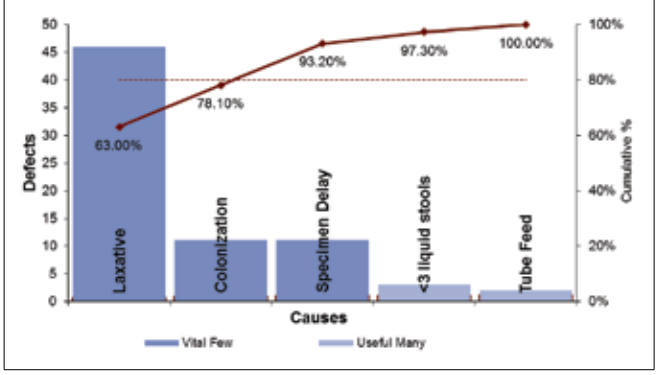
* Figure 1 depicts generic renderings of Best Practice Advisories.

2. Lab rejection of formed stool specimens: The *C. difficile* PCR assay is only intended for use on diarrheic stool samples that conform to the shape of the collection container. Three or more diarrheic stools within a 24-hour time period are required before testing should be considered. The lab is empowered to reject specimens that do not meet the requirements of the test or the clinical criteria for CDI (no diarrhea).
3. *C. difficile* order laxative question: a clinical justification is required if the ordering provider responds affirmatively to the question, "Have laxatives, stool softeners or enemas been administered in the last 48 hours?"
4. Nursing cancellation of *C. difficile* orders after 24 hours: Nurses may discontinue *C. difficile* testing orders if no specimen was collected in the 24 hours after the order was placed and the provider agreed with the cancellation in the text of the original order.
5. Clinical Decision Support using BPAs (Best Practice Advisories):
    1. Laxative or stool softener administered in the last 48 hours (modified from 24 to 48 hours in February 2017) – the BPA will prompt providers entering an order for *C. difficile* PCR when the patient has had a stool softener, laxative, and/or enema administered in the past 48 hours. The provider may either remove or keep the order and provide an explanation in the comments box.
    2. Negative *C. difficile* PCR result in the past seven days – the BPA will prompt providers entering an order for *C. difficile* PCR when the patient has had a negative *C. difficile* PCR result in the past 7 days. The provider may either remove the order or keep the order and provide an explanation in the comments box.
    3. Positive *C. difficile* PCR result in the past 12 weeks – the BPA will prompt providers entering an order for *C. difficile* PCR when the patient has had a positive *C. difficile* PCR result in the past 12 weeks. The provider may either remove the order or keep the order and provide an explanation in the comments box.

Measures

Beginning in January 2015, all *C. difficile* PCR orders placed while in an inpatient location or collected at an inpatient location were considered. Process and outcome measures were tracked using individual-moving range control charts (XmR). In addition, a Pareto chart of frequent causes revealed that laxative use was the most common factor involved (Figure 2).

FIGURE 2: 2016 UTSW HO C. difficile Attribution Types



Process and balance measures were determined based on the National Healthcare Safety Network (NHSN) reporting definition of laboratory-identified CDI event (LabID). At least 12 months of data were collected for each process and outcome measure to establish pre-intervention baselines. The Center for Disease Control (CDC) will factor Community-Onset (CO) *C. difficile* into the risk adjustment calculation of CDI SIR, hence this balance

measure was included to assess the impact of lab's rejection of formed stool samples on the CO count [9]. The project team also used the Pareto chart to analyze aggregate hospital-onset data by attribution type (Figure 2). The Pareto chart guided our efforts to focus on the few causes that produce more than 80% of defects. Optimizing resources proved to be critical in the eventual realization of our project goal.

- Outcomes measure: NHSN *C. difficile* hospital onset standardized infection ratio.[2]
- Outcomes measure: Inpatient facility *C. difficile* healthcare facility-onset incidence rate per 10,000 patient days.
- Process measure #1: the percentage of *C. difficile* testing ordered when laxatives had been given within the prior 48 hours.
- Process measure #2: the percentage of samples collected on hospital day 4 or greater that were ordered on day 1-3.
- Process measure #3: the percentage of samples collected greater than 24 hours after the order.
- Balance measure #1: total community-onset *C. difficile*.

RESULTS

Outcomes measures

The SIR in calendar 2015 Q1 - Q3[3] was 1.20 (107/89.38). From initiation of the project through 2017 Q2, the SIR is 0.87 (151/174.28) ($p = 0.011$) (Table 1; Figure 3). The XmR control charts demonstrated two statistically significant declines in the healthcare facility-onset incidence rate per 10,000 patient days at CUH (Figure 4). The process has demonstrated stability since December 2016.

TABLE 1: Healthcare Facility-Onset Change in Incidence

	Pre-Intervention	Post-Intervention
Observed	107	151
Expected	89.38	174.28
SIR	1.197	0.866

Relative ratio of SIRs (data column 2/data column 1: 0.866/1.97=0.723 (72.3%)
Two-tailed p-value: 0.0114
95% Confidence Interval: 0.565, 0.929

Process measures

Process measure #1 (percent of *C. difficile* orders with laxatives given <48 hours prior to order improved from) improved from its initial baseline average of 26.39% (January – October 2015) to a re-baselined average of 11.24% (February 19 – April 9, 2017). This was confirmed by a signal of process change indicated by 8 consecutive data points below the baseline (February 19 – April 9, 2017). The change was observed 2-8 months following the launch of the *C. difficile* laxatives BPA (September 2016) and the implemented changes to the *C diff BPA* timeframe (February 2017; 24 to 48 hours).

Process measure #2 (the percentage of samples collected on hospital day 4 or greater that were ordered on day 1-3) improved from its initial baseline average of 6.4% (January – December 2015) to 3.4% (January – November 2016). The process change was observed 4 months post the implementation of the nursing cancellation of C. diff orders after 24 hours. The post-intervention group is within expected boundaries, indicating the process is in control.

Process measure #3 (the percentage of samples collected greater than 24 hours after the order) improved from its initial baseline average of 10.9% (January 2015 – March 2016) to 5.8% (April – November 2016). The process change was observed 3 months subsequent to the initiation of nursing cancellation of *C. diff* orders after 24 hours. The post-intervention group performance is being maintained within the control limits.

Balance measures

Balance measure # 1 (total community onset *C. difficile)* declined from its initial baseline average of 30.5 per month (January 2015 – October 2016) to 18.4 per month (November 2016 – October 2017). The decrease correlated with Lab's rejection of formed stool specimens, beginning in November 2016.

Summary

The process measures and the NHSN *C. difficile* hospital-onset rate per 10,000 days demonstrated statistically significant control chart shifts (Figure 2). The CO count decreased substantially and resulted in an SIR average difference of 0.1 – 0.2 but ultimately did not offset the benefits of the lab's rejection of formed stool samples. The project successfully achieved its SIR target as well as the process targets for each of the indicated measures.

DISCUSSION

CDI is a publicly reported hospital acquired infection per the Affordable Care Act's Hospital Acquired Condition (HAC) Reduction Program. Pursuant to HAC, relative institutional performance above or below the 75th percentile nationally can affect payments from the Centers for Medicaid and Medicare Services (CMS). In quarter Q3 of calendar year 2015, CUH performed at the 72nd percentile for *C. difficile* SIR. The SIR is calculated by the NHSN and is a comparison between the observed number of infections that occur in a facility to the number expected (or predicted) to have occurred, based on the national baseline. A positive *C. difficile* test that results on day 4 or later of the patient's admission factors into the standardized infection ratio (SIR) calculation. Being a LabID event, consideration for clinical symptoms is not taken into account and, thus, CMS does not differentiate between colonized and infected patients [8]. Inappropriate testing leading

[2] Not monitored in an XmR due to limited data points.

[3] The project team could not continue comparing beyond 2015 into 2016 using 2014 data due to the change in NHSN risk modeling, switching to their new 2015 re-baseline version.

FIGURE 3: CUH Facwideln *C. diff* SIR

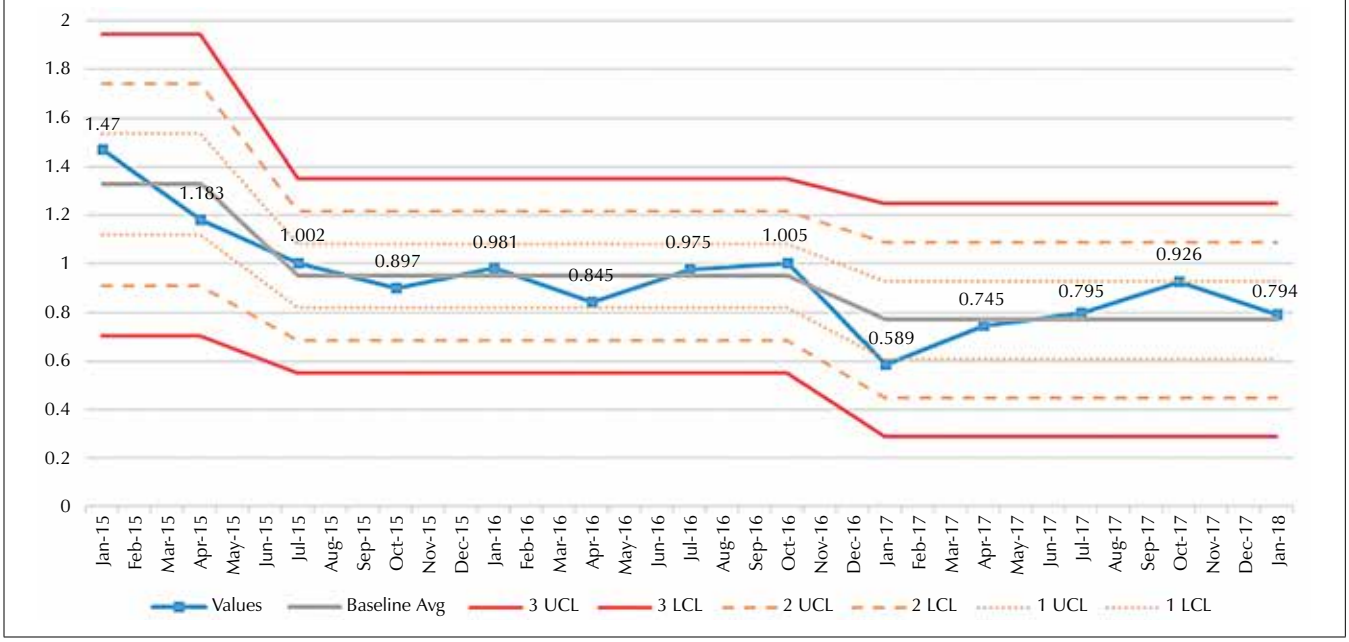
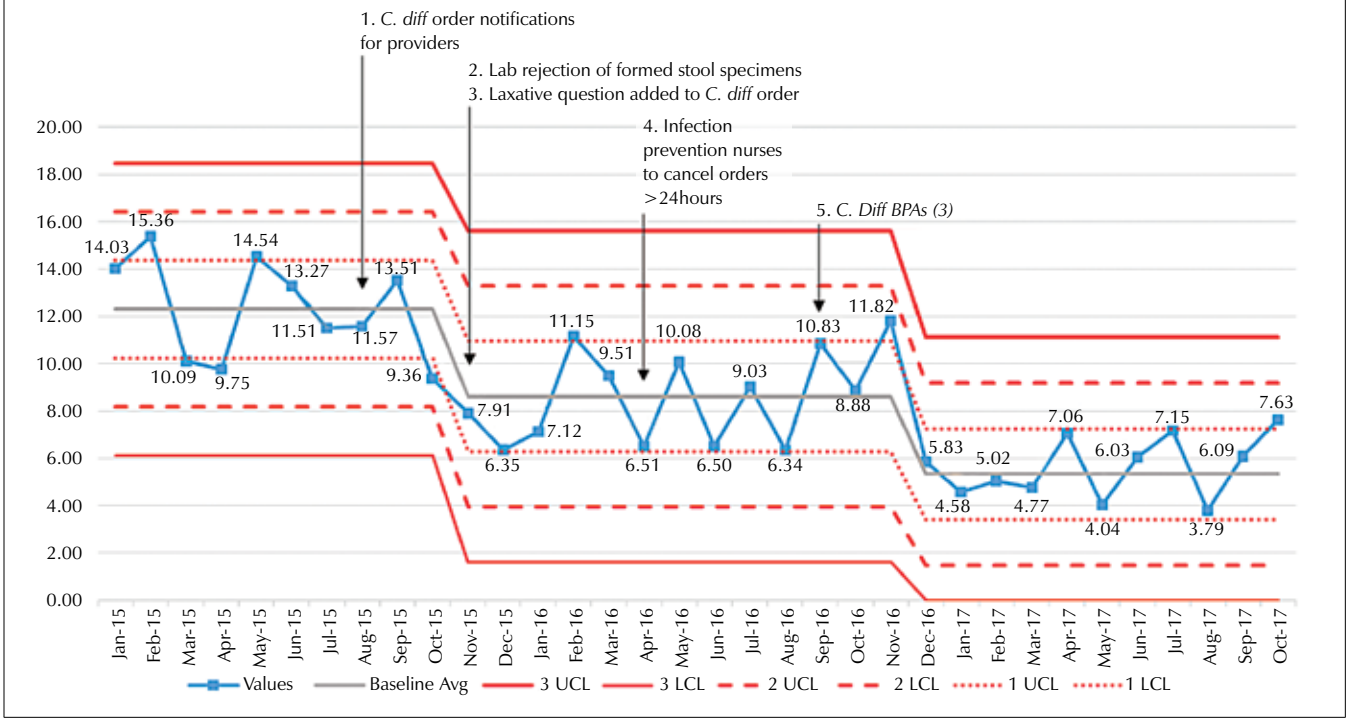


FIGURE 4: CUH Inpatient Facility *C. diff* Healthcare Facility-Onset Incidence Rate per 10,000 Patient Days



to the identification of colonized patients increases the number of LabID events which negatively affects the SIR, can result in a monetary penalty and reflects poorly on the institution.

Limitations

With the in-depth analysis and categorization of positive tests as HO or HAI, it became more evident that improvements could be made to more appropriately use the *C. difficile* PCR assay. These areas included: 1) re-education of laboratory personnel to reject formed stools; 2) reminding staff to send stool within the first 3 days of admission if CDI suspected; 3) providing nursing staff with the authority to cancel an outstanding order for *C. difficile* PCR when a stool sample was not collected within 24 hours of the order; and 4) not testing within 48 hours of administering stool softeners, laxatives and enemas. Positive tests for *C. difficile* in the setting of

diarrhea associated with laxative usage was a significant problem and accounted for the majority of patients thought to be colonized and not truly infected. The creation of Best Practice Advisories and having specific questions in the order set resulted in a reduction in the overall amount of testing. This, in conjunction with other measures to reduce the burden of *C.difficile* in the hospital, resulted in a decrease in true infections from 40%
pre-intervention to 31% post intervention.

Due to the financial incentive for hospitals with lower rates of CDI, under-reporting has become a potential issue in that testing is not performed, even when appropriate. In these situations, patients are often treated empirically for CDI without any documentation of a positive test. To address this issue, some states, including Texas, perform random audits of hospital infection rates. The issue of diagnostic testing is further thrust into the spotlight with discussions revolving around the utility of two-step testing to differentiate between colonization and true infection.

The process and outcome measure control charts indicate that our intervention-driven approach to improving *C. difficile* SIR has resulted in new baselines and control limits. Continued performance within these boundaries is expected. However, even within our stable processes,[4] variation remains, and, while some degree of variation is inevitable, our current control limits are such that expected variation could cause our SIR rate to fail to meet performance targets during given reporting periods. To prevent common cause variation from exceeding specification limits, additional interventions or process changes may be necessary to reduce the spread of the distribution.

CONCLUSIONS

With the aid of CDS and clinical education, the project team was able to successfully hardwire *C. difficile* testing and diagnosis best practice guidelines into the diagnostic pathway. Infection Prevention's *C. difficile* notifications for providers and the launch of the *C. difficile* BPAs preceded two of the largest shifts in *C. difficile* healthcare facility-onset incidence rate, per the process behaviour chart. The BPA provider bypass rate varied by service and BPA type, but the overall effectiveness of the BPAs in influencing behaviour change was modest. However, even a modest (25-50%) improvement in adherence to *C. difficile* best practice guidelines correlated with the attainment of project targets.

As a teaching institution, we benefitted from trainee engagement to disseminate knowledge identified as part of this project. Specifically, a Urology resident reviewed all of the HAI CDI cases in his department and presented data on over-testing at a teaching conference. Also, a resident in Internal Medicine used one of our cases to write a clinical vignette in *JAMA Internal Medicine* [10].

There were unintentional byproducts of the project's success that resulted in benefits to areas not directly involved. In 2016, following enforcement of the lab's rejection of formed stool policy, 1,250 orders were cancelled, which resulted in an approximate yearly savings of $60,000. Other important but less quantifiable benefits of the project include the empowerment of nursing through the addition of the *C. difficile* order question, "Order may be discontinued if sample not collected within 24 hours," as well a renewed interest in antimicrobial stewardship as part of the multifaceted approach to reducing infections due to *C. difficile*.

Ultimately, the multidisciplinary approach to integrate quality analytics with performance improvement and informatics proved to be effective as we were able to incorporate *C. difficile* testing and diagnosis best practices into clinical workflows.

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[4] Processes remain stable as of October 2017.

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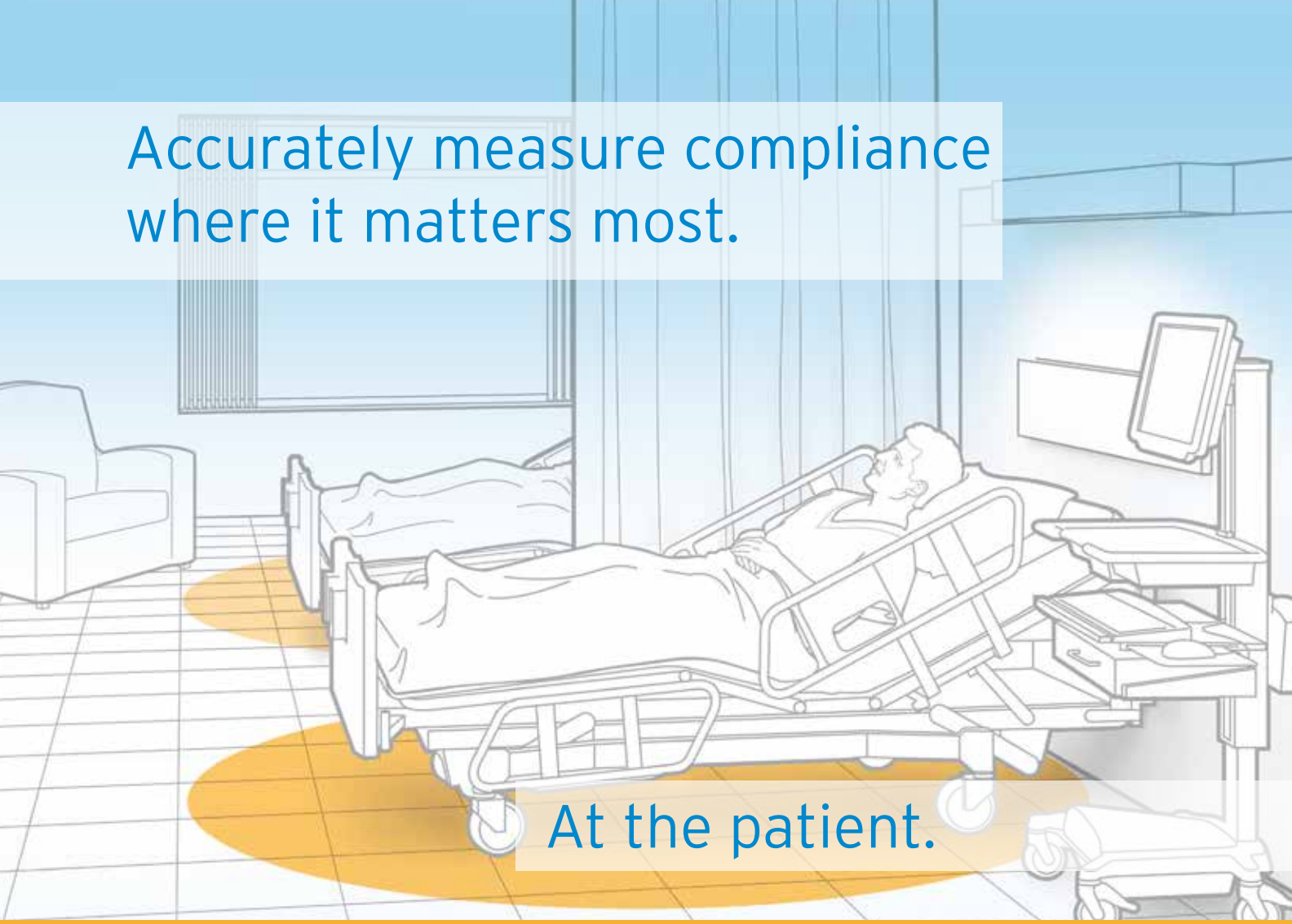

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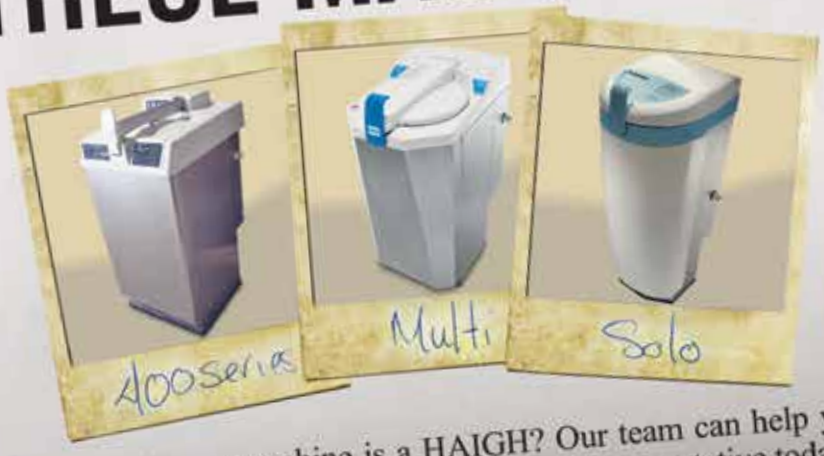

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