CONCISE COMMUNICATION

Response to Alert on Possible Infections with *Mycobacterium chimaera* From Contaminated Heater-Cooler Devices in Hospitals Participating in the Canadian Nosocomial Infection Surveillance Program (CNISP)

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Canadian hospitals were made aware of the risk of *Mycobacterium chimaera* infection associated with heater-cooler units (HCUs) through alerts issued by the US food and Drug Administration (FDA) and the US Centers for Disease Control and Prevention (CDC). In response, most hospitals conducted retrospective reviews for infections, informed exposed patients, and initiated a requirement for informed consent with HCU use.

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Heater-cooler units (HCUs) used during cardiothoracic surgery have been identified as the source of a global outbreak of *Mycobacterium chimaera* infections.[1,2] To date, all reported cases have been associated with HCUs manufactured by a single company, LivaNova (formerly Sorin, London, UK), with likely point-source contamination during manufacturing.[2]

The risk of acquiring *M. chimaera* from a contaminated HCU is estimated at 0.1–1%[3] or 0.39 cases per 10,000 patient years.[4] A number of risk-mitigation strategies have been proposed, including (1) changes in HCU disinfection protocols, (2) removal of HCUs from operating rooms, (3) microbiologic testing of HCU water, (4) retrospective review for case identification, (5) notification of exposed patients, (6) education of healthcare providers, and (7) obtaining modified consent from patients undergoing cardiac surgery going forward. A recall of all LivaNova HCUs manufactured prior to September 2014 was recommended by regulatory bodies (US Food and Drug Administration [FDA] and Centers for Disease Control [CDC] in October 2016 and Health Canada in February 2017),[5] which is not feasible, given the extensive use of these devices globally.[6]

Various approaches have been taken by hospitals based on local infrastructures and available resources. In this study, we provide a summary of the responses of Canadian hospitals participating in the Canadian Nosocomial Infection Surveillance Program (CNISP) to a survey regarding HCU risk mitigation.

METHODS

The CNISP conducts surveillance of hospital-associated infections and of antimicrobial resistant organisms across Canada and is a collaborative effort of the Public Health Agency of Canada (PHAC) and the Association of Medical Microbiology and Infectious Diseases (AMMI) Canada. Currently, 65 urban, secondary, and tertiary acute-care hospitals across 10 provinces are participating.

Data were collected through a survey sent to all participating CNISP hospitals. Support for the survey on *M. chimaera* and HCUs was obtained at the annual CNISP meeting in November 2016. The survey was developed, reviewed, pilot tested by a working group, and subsequently distributed to the 65 CNISP hospitals in February 2017 through an online web survey (www.Fluidsurveys.com). One electronic reminder was sent in March 2017.

RESULTS

Of the 65 CNISP hospitals, 25 (38%) perform cardiac surgeries and 21 of these (84%) responded to the survey; 1 survey provided information from 2 linked CNISP sites for a total of 20 responses. The number of cardiac surgeries conducted at participating hospitals ranged from 250 to 2000 per year. Not all respondent provided answers to all questions.

Of 17 respondents, 7 (41%) first learned of the risk through FDA and CDC alerts. Only 1 site (6%) became aware through provincial notification, and none became aware through notification from Health Canada. LivaNova HCUs were used at 18 sites (90%), with 13 sites (65%) using them exclusively. Maquet (Wayne, NJ) was the only other brand of HCU used for cardiac surgery by respondents.

Prior to the alert, 12 hospitals (67%) with LivaNova HCUs were cleaning the devices according to the manufacturer's protocol, 2 hospitals (11%) had their own internal disinfection protocols, and 2 hospitals (11%) reported no specific cleaning. All 18 hospitals with LivaNova HCUs followed updated protocols once available.

In total, 12 sites (67%) sent water samples from LivaNova HCUs for testing for Mycobacteria and 2 sites (11%) were in the process of sampling (Table 1). Of those 12 sites, both cultures and polymerase chain reaction assays (PCR) were performed at 8 sites (67%); 2 sites performed only PCR (17%); and 2 sites did only cultures (17%). For non-LivaNova HCUs, 3 of 7 hospitals (42%) performed microbiologic testing. Of the 70 LivaNova HCUs tested, 46 (66%) tested positive for nontuberculous mycobacteria (NTM), and 33 (47%) tested positive for *M. chimaera*. All 12 sites that tested their LivaNova

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TABLE 1. Risk Mitigation Strategies of the 18 Hospitals With LivaNova Hearter-Cooler Units (HCUs)

Variable	LivaNova HCUs (n = 18), No. (%)[a]			Non–LivaNova HCUs (n = 7), No. (%)[a]		
	Completed or in Progress	Under Consideration	Not Planning	Completed or in Progress	Under Consideration	Not Planning
Water sampling	14 (78)	0 (0)	4 (22)	3 (75)	0 (0)	1 (25)
Cleaning/Disinfection/Physical barriers						
By manufacturer of all HCUs[a]	4 (22)	3 (17)	11 (61)	0 (0)	0 (0)	4 (100)
By manufacturer of all *Mycobacterium chimaera*–positive HCUs	5 (29)	2 (12)	10 (59)	0 (0)	0 (0)	4 (100)
On site of all HCUs	9 (50)	1 (6)	8 (44)	1 (25)	0 (0)	3 (75)
On site of all *M. chimaera*–positive HCUs	7 (47)	1 (6)	7 (47)	4 (80)	0	1 (20)
Replacing parts	10 (56)	1 (6)	7 (39)	1 (25)	0 (0)	3 (75)
Redirect HCU exhaust	15 (83)	1 (6)	2 (11)	4 (80)	0 (0)	1 (20)
Move HCUs out of the operating room	2 (11)	3 (17)	13 (72)	0 (0)	0 (0)	4 (100)
Purchasing new HCUs[a]	5 (29)	9 (53)	3 (18)	1 (25)	1 (25)	2 (50)
Management of at-risk patients						
Raise awareness in healthcare providers	18 (100)	0 (0)	0 (0)	4 (80)	0 (0)	1 (20)
Patient retrospective review	18 (100)	0 (0)	0 (0)	3 (60)	0 (0)	2 (40)
Retrospective patient notification	18 (100)	0 (0)	0 (0)	3 (60)	0 (0)	2 (40)
Consent for new patients	17 (94)	0 (0)	1 (6)	3 (60)	0 (0)	2 (40)

[a]Missing data for some responses from 1 or more hospitals

HCUs had at least 1 HCU positive for NTM, and 10 sites had at least 1 HCU with *M. chimaera* detected.

Only 4 of 18 sites (22%) sent their LivaNova HCUs back to the manufacturer for deep disinfection. In addition, 9 sites (50%) completed or were in the process of disinfecting their LivaNova HCUs locally. Other risk-mitigation strategies included replacement of device tubing at 10 sites (56%) and redirection of the exhaust in the operating room at 15 sites (83%). Only 1 site (6%) had moved the HCU outside of the operating room; this measure was in progress in another site, and 3 sites (17%) were considering this approach. Moreover, 9 sites were considering purchasing new HCUs (53%), but only 5 (29%) had proceeded to do so at the time of the survey.

All responding sites initiated an awareness campaign for healthcare providers, conducted a retrospective review to identify infections, and retrospectively informed potentially exposed patients. The scope retrospective reviews of patient records ranged from all patients who had ever had cardiac surgery (17%) to limiting the review to certain time periods (83%), often starting between October 2011 and January 2012 (66%). Of 11 sites, 5 (45%) reviewed all patients with positive NTM cultures; 4 (36%) reviewed all patients with *M. intracellulare* complex; and only 2 (18%) were able to limit reviews to detection of *M. chimaera*. In addition, 18 hospitals (90%) sent letters to at-risk patients; 12 hospitals (60%) provided a hotline; 9 hospitals (45%) provided information on the hospital website; and 8 hospitals (40%) issued a press release. All 17 hospitals that responded to this question adopted new requirement of informed consent for incoming patients regarding the *M. chimaera* risk, and 11 of them (65%) created informed consent documents for all patients with exposure to any HCU, while 6 (35%) created them for exposure to LivaNova HCUs only. Only 1 case of *M. chimaera* infection linked to a LivaNova HCU has been identified among the 21 sites at the time of survey completion.

DISCUSSION

In this national survey of CNISP sites, a significant number of sites learned about the risk of *M. chimaera* in HCUs through international alerts, namely those issued by the FDA and CDC. The HCU testing and risk-mitigation strategies were diverse among respondents, while approaches to identifying and managing at-risk patients were similar. LivaNova HCUs were used in most surveyed sites, and at least 1 HCU tested positive for NTM in sites that conducted water testing. Although only 1 case of *M. chimaera* infection was reported, 3 other cases have been identified in Canada since this survey, 2 of which occurred in non-CNISP hospitals.[7]

Most surveyed hospitals tested water samples for *M. chimaera*, even though negative cultures can be falsely reassuring.[5,8] Furthermore, implications of positive cultures are unclear, and long-term results after deep disinfection of HCUs are disappointing.[8] Few sites purchased new HCUs, only 1 site was successful in removing the HCUs from the operating room, and another developed an HCU housing unit.[8] Presumably, the most effective risk-mitigation strategy at this time would be a separation of the HCU air exhaust from the operating room.

All hospitals contacted exposed patients. Patient notification through letters may have been recommended from a legal perspective,[9] and it enables patients to self-identify symptoms of infection. However, such broad strategies may have had

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unintended consequences of triggering fear from a remote risk. Indeed, we are unaware of any cases directly identified through enquiries from notified patients.

In conclusion, CNISP cardiac surgery sites learned of the *M. chimera* risk mainly from US agencies, and most of the sites conducted a retrospective review to identify potential infections, informed exposed patients, and changed surgical consent for future patients.

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