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REUSE OF SINGLE-USE MEDICAL DEVICES IN CANADIAN ACUTE-CARE HEALTHCARE FACILITIES, 2001

Introduction

Thousands of different medical devices exist worldwide that are used to detect, diagnose, and treat medical conditions of every type. Many such devices are available in both reusable and single-use versions. Reusable devices are designed to be able to be thoroughly cleaned and to withstand appropriate disinfection or sterilization between use in different patients; although, the adequacy of these processes - even under normal circumstances - has been questioned[1,2]. Single-use medical devices (SUMeD's) are designated by the manufacturer to be used once only. Some SUMeD's are extremely complex (containing lumens, hinges, and/or miniature moving parts), while others are simple and appear to be no different than their reusable counterparts. In fact, some experts have argued that many SUMeD's are identical to the reusable version and the single-use designation is a marketing choice[3]. Based on the expense of SUMeD's, the environmental impact of their disposal, and the perception that some of them may be safely reused on different patients, internationally many healthcare institutions have decided to reuse SUMeD's. To assess the extent of SUMeD reuse in acute-care facilities in Canada, and the existence of reuse committees and written guidelines, we conducted a mail survey of SUMeD reuse among all Canadian acute-care hospitals.

Methods

An anonymous reuse survey was designed to assess the reuse of selected critical and semi-critical SUMeD's. Devices were chosen by infection control experts, based on instrument complexity, expected peak frequency of use, or categorization as critical/semi-critical. Sixty-seven critical or semi-critical SUMeD's and 17 other SUMeD's used in respiratory procedures were included in the survey. General questions about the healthcare facility included the number of beds, geographic location, and the existence of a reuse committee. Device-specific questions addressed the number of reuses per item, the number of procedures per year (in which a particular SUMeD is used), the type of reprocessing used, and the presence of a written reuse protocol. Surveys were mailed to the infection control practitioner in every Canadian healthcare facility, with a 3-month deadline. Responses were entered into a database and analyzed using SAS. Differences between proportions were analyzed by means of the chi-square statistic and considered significant if a p value of $<= 0.05$ was reached.

Results

Surveys were sent out to 741 acute-care hospitals. Four hundred and twenty-one (57%) surveys were returned, and 403 (53%) of them were from acute-care facilities. Eighteen (4%) long-term care facilities were disqualified from analysis because they did not have any acute-care beds. Response rates, seen in Table 1, were highest in New Brunswick (77%) and lowest in British Columbia (36%). Hospital demographics can also be seen in Table 1. The mean bed size of responding hospitals was 178 (median 75; range 3 to 2,247 beds) with 79 (20%) having > 250 beds. Only 41 (10%) had reuse committees, this being most common in the largest hospitals of > 250 beds (38%) and

significantly less common as hospital bed size decreased ($p < 0.001$) (Table 1). Hospital reuse committees were most common in New Brunswick (29%) and Nova Scotia (22%), and not in any of the responding facilities situated in Saskatchewan, Prince Edward Island, or the territories. Only 11 of 99 (11%) hospitals in Ontario and six of 62 (10%) facilities in Quebec had reuse committees. Information concerning individual SUMeD reuse (for selected items) can be seen in Table 2.

Table 1: Survey response rates (by province) and hospital demographics of respondents - Canada, 2001

Province	**Number of questionnaires returned /number mailed (%)**
Newfoundland	8/18 (44%)
Nova Scotia	19/32 (59%)
Prince Edward Island	5/7 (71%)
New Brunswick	17/22 (77%)
Quebec	67/133 (50%)
Ontario	102/189 (54%)
Manitoba	51/69 (74%)
Saskatchewan	53/84 (63%)
Alberta	54/95 (57%)
British Columbia	30/84 (36%)
Northwest Territories	3/5 (60%)
Yukon	2/3 (67%)
Unknown	10/- (-)
Total	**421/741 (57%)**
Type of institution	**Number (% of respondents)**
Mixed adult/pediatric - acute-care	246 (59%)
Adult only - acute-care	69 (16%)
Pediatric only - acute-care	6 (1%)
Long-term care only*	18 (4%)
Not stated	82 (20%)
Total	**421 (100%)**
Number of beds	**Result**
Mean (+/- standard deviation)	178 +/- 259
Median (range)	75 (3 - 2,247)
Proportion of hospitals with a reuse committee†	
> 250 beds	30/79 (38%)
75 to 250 beds	7/85 (8%)
36 to 74 beds	4/69 (6%)
< 36 beds	0/170
British Columbia	6/30 (20%)
Alberta	2/49 (4%)
Saskatchewan	0/53
Manitoba	6/51 (12%)
Ontario	11/99 (11%)
Quebec	6/62 (10%)
New Brunswick	5/17 (29%)
Nova Scotia	4/18 (22%)
Prince Edward Island	0/5
Newfoundland	1/8 (13%)

Northwest Territories	0/5
Unknown	0/6
Total	**41/403 (10%)**

* Excluded from the analysis

† $p < 0.001$ for the difference in the proportion among hospitals of different sizes

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Table 2: Instrument-specific details of single-use medical device reuse among 408 acute-care hospitals - Canada, 2001

Device	No. hospitals reusing	No. hospitals reusing > 20 times each (%)	No. hospitals performing > 1,000 procedures /year with such device	No. hospitals with written reuse protocol	Additional notes
Ventilator circuits	105	36 (34%)	47 (45%)	49 (47%)	five facilities use low-level disinfection
Cardiac angiocatheters	2	0	not answered	1 (50%)	
Electrophysiology catheters	9	1 (11%)	1 (11%)	6 (67%)	five of nine facilities use device six to 10 times
Electromyogram concentric needles	10	2 (20%)	1 (10%)	3 (30%)	
Electro-encephalogram bonnet with needles	3	1 (33%)	0	0	one facility uses alcohol disinfection
Gastro-intestinal (GI) sclerotherapy needles	9	1 (11%)	0	2 (22%)	one facility uses alcohol disinfection
GI snares	42	11 (26%)	5 (12%)	11 (26%)	one facility uses "quat" disinfection*
GI hot biopsy forceps	37	22 (59%)	1 (3%)	16 (43%)	one facility uses alcohol disinfection
GI microvasive biopsy forceps	30	15 (50%)	9 (30%)	15 (50%)	one facility uses alcohol disinfection
GI guidewires	44	11 (25%)	2 (5%)	11 (25%)	two facilities use "quat" disinfection*
GI esophageal dilators	37	19 (51%)	1 (3%)	11 (30%)	two facilities use "quat" disinfection*
GI polyp forceps	49	17 (35%)	4 (8%)	19 (39%)	
GI sphincterotome	38	0	0	12 (32%)	
Breast pump kit	65	28 (43%)	4 (6%)	22 (34%)	three

					facilities use "quat" disinfection*; one facility uses alcohol disinfection
Liver biopsy needle	3	1 (33%)	0	1 (33%)	
Bile duct stone extractor	16	4 (25%)	0	5 (31%)	
Stereotactic brain biopsy needle	5	3 (60%)	0	2 (40%)	one hospital uses iodophor disinfection
Oxygen nasal prongs	44	21 (48%)	10 (23%)	16 (36%)	
Laparoscopic instruments					
scissors	49	12 (24%)	3 (6%)	12 (24%)	one facility
trocar	23	9 (39%)	2 (9%)	5 22%)	uses "quat"
dissecting hook	18	6 (33%)	1 (6%)	3 (17%)	disinfection*
endo scissors	22	3 (14%)	1 (5%)	6 (27%)	for trocar &
endo shears	27	5 (19%)	2 (7%)	7 (26%)	hook
endo grasp	24	4 (17%)	3 (13%)	4 (17%)	
Urodynamic catheters	11	3 (27%)	1 (9%)	3 (27%)	

* "quat" = disinfectant containing quaternary ammonia compounds.

Discussion

In the United States (U.S.), the Federal Drug Administration (FDA) has recently issued regulations governing third-party and hospital reprocessors engaged in reprocessing single-use devices for reuse[4]. In Canada, the Canadian Healthcare Association stated in 1996 that "reuse should not be an ad hoc practice or treated casually" and that "a reuse program should demonstrate that single-use devices which are reprocessed are as safe as reusable medical devices that have been processed"[5]. Since each SUMeD is unique in its design, construction, materials, cost, and intended use, reuse must be considered on a case-by-case basis for each device. Such complex reuse decisions should be made by knowledgeable individuals - usually part of a reuse committee. In fact, the American Society for Healthcare Central Service Professionals states that hospitals should "appoint a multi-disciplinary committee to develop policies and practices relating to reuse"[6]. In addition, a SUMeD reuse program should include written policies pertaining to all aspects of the reprocessing, including the mechanical aspects, education, training, and quality assurance.

Concerns about the reuse of SUMeD's have surfaced all over the world. The Ministre d'État à la Santé et aux Services sociaux (Minister of Health and Social Services) in Quebec has banned the reuse of cardiac catheters, and the reuse of critical SUMeD's has been prohibited in Manitoba. Reuse of tonsillectomy equipment has been banned in the United Kingdom due to fears of transmitting prions. The U.S. has made reuse allowable only after reprocessing by certified centres. Most of the concerns revolve around: i) the ability to adequately clean and reprocess SUMeD's, so as not to transmit infectious diseases, and ii) the maintenance of a device's biomechanical integrity. While many outbreaks have been well-described secondary to reusable devices[7-9], reports of nosocomial infections related to the reuse of SUMeD's have just started to surface[10]. Some reusable instruments have been shown to contain residual patient debris after "usual" reprocessing[1]. In-

depth analyses of both single-use and reusable devices have shown in animal studies that viral hepatitis can be transmitted even after recommended reprocessing, with lumen-containing devices being the most difficult to sterilize [11,12]. Logic implies that complex SUMeD's, which are impossible to thoroughly disassemble or clean, are likely to be even more prone to transmit infections than reusable instruments.

Our survey found that widespread SUMeD reuse is occurring across Canada, despite the absence of a reuse committee in most hospitals and without written reuse protocols for most items. The number of reused SUMeD's per institution seems to have increased substantially since the last Canadian survey in 1986 [13], while the existence of written protocols has diminished since that study.

Reuse committees are necessary to bring together the necessary expertise in biomechanics, infection control, materials management, and sterilization, in order to assess the safety of individual SUMeD reuse. Written protocols and guidelines are crucial, since infections related to reusable devices have often been tracked to lapses in cleaning and/or disinfection/sterilization procedures. Yet most facilities responding in the current Canadian study lack both a reuse committee and written reuse guidelines.

The current survey data provide us with a measure of the extent of reuse of SUMeD's in Canada. Because many hospitals lack the multidisciplinary input of a reuse committee, and most don't have written reuse guidelines for SUMeD's, improper reuse of these disposable devices in Canada is probably occurring frequently. This, in turn, places patients at risk for device-associated infectious diseases and instrument malfunctions. The data from this study should be used as a starting point for standardizing national and provincial policies and procedures related to SUMeD reuse.

References

1. Rizzo J, Bernstein D, Gress F. *A performance, safety, and cost comparison of reusable and disposable endoscopic biopsy forceps: a prospective, randomized trial.* Gastrointest Endosc 2000;51:257-61.

2. Alfa MJ. *Methodology of reprocessing reusable accessories.* Gastrointest Endosc Clin N Am 2000;10:361-78.

3. American Society for Healthcare Central Service Professionals. *Comments to FDA's two guidance documents.* URL: <http://www.ashcsp.org/public/articles/details.cfm?id=9#603> Date of access: March, 2000.

4. *Enforcement priorities for single-use devices reprocessed by third parties and hospitals.* United States Department of Health and Human Services. August, 2000.

5. Canadian Healthcare Association. *The reuse of single-use medical devices: guidelines for healthcare facilities.* CHA Press, Ottawa, Ontario, Canada. 1996.

6. American Society for Healthcare Central Service Professionals. *Position on Reuse.* URL: < http://www.ashcsp.org/public/articles/details.cfm?id=8 >. Date of access: June, 1999.

7. Blanc DS, Parret T, Janin B et al. *Nosocomial infections and pseudo-infections from contaminated bronchoscopes: two-year follow-up using molecular markers.* Infect Control Hosp Epidemiol 1997;18:134-36.

8. Bronowicki JP, Venard V, Botte C et al. *Patient-to-patient transmission*

of hepatitis C virus during colonoscopy. New Eng J Med 1997;337:237-40.

9. Centers for Disease Control and Prevention. *Bronchoscope-related infections and pseudoinfections - New York, 1996 and 1998.* MMWR 1999;48;557-60.

10. Yardy GW, Cox RA. *An outbreak of* ***Pseudomonas aeruginosa*** *infection associated with contaminated urodynamic equipment*. J Hosp Infect 2001;47:60-3.

11. Ulualp KM, Hamzaoglu I, Ulgen SK et al. *Is it possible to sterilize disposable laparoscopy trocars in a hospital setting?* Surg Laparosc Endosc Percutan Tech 2000;10:59-62.

12. Chaufour X, Deva AK, Vickery K et al. *Evaluation of disinfection and sterilization of reusable angioscopes with the duck hepatitis B model*. J Vasc Surg 1999;30:277-82.

13. Campbell BA, Wells GA, Palmer WN et al. *Reuse of disposable medical devices in Canadian hospitals*. Am J Infect Control 1987;15:196-200.

Source: *MA Miller, MD, Infection Prevention and Control Unit, SMBD-Jewish General Hospital, McGill University, Montreal, Quebec; D Gravel BScN, MSc, CIC; S Paton MN, RN, Division of Nosocomial and Occupational Infections, Centre for Disease Prevention and Control, Health Canada, Ottawa, Ontario; Canadian Hospital Epidemiology Committee (CHEC); Canadian Nosocomial Infections Surveillance Program (CNISP).*

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