American Journal of Infection Control 46 (2018) 973-9

Contents lists available at ScienceDirect

# American Journal of Infection Control

journal homepage: www.ajicjournal.org

State of the Science Review

# Identifying safe practices for use of the urinary leg bag drainage system in the postacute and long-term care setting: An integrative review

Sharon M. Bradley RN, CIC <sup>a,\*</sup>, Steven J. Schweon RN, MPH, CIC <sup>b</sup>, Lona Mody MD, MSc <sup>c,d</sup>, Dheeraj Mahajan MD, FACP, CMD, CIC, CHCQM <sup>e</sup>, Russell N. Olmsted MPH, CIC <sup>f</sup>

<sup>a</sup> Pennsylvania Patient Safety Authority, Harrisburg, PA

<sup>b</sup> Steven J. Schweon, LLC, Saylorsburg, PA

<sup>c</sup> Geriatric Research Education and Clinical Center, Ann Arbor Veterans Affairs Healthcare System, Division of Geriatric and Palliative Medicine, Department

of Internal Medicine, University of Michigan Medical School, Ann Arbor, MI

<sup>d</sup> Division of Geriatric and Palliative Medicine, Department of Internal Medicine, University of Michigan Medical School, Ann Arbor, MI

e Chicago Internal Medicine Practice and Research, University of Illinois at Chicago, Edward Hines, Jr. VA Hospital, Hines, IL

<sup>f</sup> Trinity Health, Livonia, MI

Key Words: Indwelling urinary catheter urinary leg bag long-term care urine drainage urine collection disinfection urinary drainage bags **Background:** In the postacute and long-term care setting, the practice of changing the indwelling urinary catheter large sterile drainage bag to a small-size leg drainage bag is intended to maintain a person's mobility, dignity, and comfort. There is scant evidence that assesses the impact of intermittent use of a leg bag on frequency of urinary tract infection since this breaks the closed urinary drainage system.

**Methods:** We reviewed research published between 1993 and 2014 for the answers to 20 practice questions developed by experts and long-term care clinicians on the risks and benefits, cleaning, connection, and storage of reusable leg bags.

**Results:** Seventeen of the 26 publications and studies provided varying advice on the risk of breaking the closed system and on practices for changing, disinfecting, and storing leg bags between uses. Thirteen of 20 practice questions were answered by  $\geq 1$  publications, few of which were evidence based.

**Conclusions:** We identified the existence of low-level evidence that leg bags pose no evident, disproportionate risk of infection compared with maintaining a closed system. The lack of uniformity in evidence in the literature suggests aseptic technique should guide practice. Available evidence suggests that aseptic technique should guide practice.

© 2018 Association for Professionals in Infection Control and Epidemiology, Inc. Published by Elsevier Inc. All rights reserved.

# BACKGROUND

Residents in postacute and long-term care facilities (LTCFs) with a clinical need for a long-term indwelling urinary catheter may prefer to change from using a large urinary drainage bag to a more discreet, smaller, reusable urinary leg bag collection device during the

E-mail address: sbradley@ecri.org (S.M. Bradley).

Conflicts of interest: None to report.

day. Use of a leg bag may assist with optimizing mobility and independence with activities of daily living, and when concealed under clothing the leg bag may promote dignity for the resident. This practice requires a break in the closed urinary drainage system when the collection bag is changed to a smaller leg bag. The Centers for Disease Control and Prevention (CDC) guideline<sup>1</sup> and the Society for Healthcare Epidemiology of America, Inc (SHEA) compendium<sup>2</sup> both recommend maintaining a closed drainage system after aseptic insertion to avoid the risk for catheter-associated urinary tract infections (CAUTIs). Although current evidence supporting these recommendations comes from investigations among patients in acute care facilities, innate risks exist regardless of care setting. Kunin and McCormack's landmark observational study found a significant reduction of CAUTI using a closed system compared with an open system in which the catheter drains into an open urine collection container.<sup>3</sup> Subsequently, 2 studies in critically ill patients by Leone et al<sup>4,5</sup> found no statistical difference in incidence of bacteriuria in





CrossMark

<sup>\*</sup> Address correspondence to Sharon M. Bradley, RN, CIC, 5200 Butler Pike, Plymouth Meeting, PA 19462.

Funding/support: Supported by contract number HHSA290201000025I from the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services.

Disclaimer: The opinions expressed in this document are those of the authors and do not reflect the official position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

patients using a catheter plus drainage bag attached at insertion versus a system with a presealed catheter junction. Additional studies found that breaks in the system did not result in immediate harm.<sup>6,7</sup> The Infectious Diseases Society of America has critically appraised this evidence and concluded that incidence of catheter-associated bacteriuria may be reduced by using a preconnected system.<sup>8</sup> Although numerous guidelines, position papers, and best practice reviews have been published on various aspects of the use and care of reusable urinary leg bags, no definitive set of evidence-based infection prevention recommendations is available that can be widely used. This lack of evidence may result in variances in maintaining asepsis during urinary leg bag changes that may exacerbate the potential for development of a CAUTI.

A subcommittee of the national project team coordinating the Agency for Healthcare Research and Quality (AHRQ) Safety Program for Long-Term Care: HAIs/CAUTI issued a call to action for researchers to conduct a search of the medical literature for evidencebased infection prevention practices in the use, cleaning, and storage of reusable urinary leg bags and the impact of leg bag use on development of CAUTI.

# **METHODS**

Initial examination of the available evidence pointed to the need to perform an integrative review because most studies were of low or very low quality in terms of strength and quality of methodology. The integrative review addressed this need by summarizing empirical experience and available evidence, allowing for expert or consensus opinion including theoretical strategies to inform both policy and practice.<sup>9</sup> In response to queries from LTCF clinicians and input from subject matter experts engaged in the AHRQ Safety Program for Long-Term Care: HAIs/CAUTI, the authors formed an expert panel to formulate questions in 4 research categories to better understand the current recommended practices. The expert panel consisted of 3 board-certified infection preventionists and 2 physicians with experience with infection prevention in aging populations. Twenty questions were formulated on the risks, benefits, cleaning, connections, emptying and storage of reusable urinary leg bags in residents of LTCFs who have long-term indwelling urinary catheters; the risk for CAUTI; and cleaning, connection, and storage of leg bags (Table 1). The U.S. Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services, and the National Association For Continence were contacted to reconcile conflicts or gaps in direction in national evidence-based guidelines, recommendations, and requirements. A sampling of 7 online manufacturer instructions was also searched for information on the use of reusable disposable urinary leg bags.

#### Search strategy

A comprehensive search strategy was developed with the assistance of a medical librarian to find English language studies and information on the main subject areas of the integrative review from 2008-2014 (Fig 1). The database search terms included the following: indwelling urinary catheter, urinary leg bag, long-term care, urine drainage, and urine collection. We identified original research, evidence-based guidelines, consensus papers, surveys, clinical practice and patient guides through MEDLINE, CINAHL, Embase, PubMed, ScienceDirect, Wiley, AccessMedicine, Journals@OVID, Google, and the Cochrane Library electronic database; and the Association for Professionals in Infection Control and Epidemiology, the Society for Healthcare Epidemiology of America, Inc, the Infectious Diseases Society of America, and the CDC Web sites. Most documents were published between 2008 and 2014. We opted to call out 3 older studies published from 1993-1998 that were cited in the more recent systematic reviews because of the value of the content.

We included studies or guidelines that provided recommendations on care and maintenance of indwelling urinary catheters or urinary drainage systems, and manufacturers' instructions for use available online in the public domain. We excluded studies of these devices in pediatric populations. We included only the literature that answered  $\geq 1$  of the 20 key questions (Table 1).

#### Table 1

Research questions: 4 ca	ategories related to risks and	benefits of reusable disp	osable urinary leg bags: use	, cleaning, connection, and storage

Research category	Practice question		
Risks and benefits of use of urinary catheter leg bags	1. Should we use leg bags? If so, then are we are breaking the closed system?		
	2. Should there be a protocol to change a large collection bag to a leg bag?		
Cleaning and changing	1. How should the bag exterior be cleaned? How often?		
Procedures	2. How should the leg straps be cleaned? How often?		
Chemical	3. How should the leg bag caps be cleaned?		
Frequency	4. What is the best chemical to use when rinsing the leg bag: vinegar, bleach, or soap and water?		
Dwell time	5. What is the optimal procedure: continual rinse or let the bag soak in the chemical? If so, how long?		
	6. Should the leg bag be rinsed after the chemical disinfectant is used?		
	7. How should the urine collection drainage container be rinsed? Is tap water sufficient?		
	8. Should the leg bag be changed weekly, every 2 weeks, monthly? Or as needed (eg, bag cleanliness is compromised)?		
Connection	1. When connecting the leg bag to the Foley catheter, should the leg bag nozzle be wiped with an alcohol		
Aseptic technique	preparation pad prior to connecting it to the catheter?		
Chemical	2. When connecting the leg bag to the Foley catheter, the leg bag cap is sometimes attached to the gravity		
• Timing	bag. Should the gravity bag nozzle be disinfected first? How often should the cap be changed? Should the cap itself be disinfected? How?		
Storage	1. How do you store the bags in between use?		
Procedure	2. Should the leg bag be stored upright, open to air, and allowed to dry?		
Location	3. Is storing the leg bag and gravity bag in the resident's bathroom ideal?		
	4. Where in the bathroom should they be stored—on top of the toilet, in the shower (if available), or on the floor (in a washbasin)?		
	5. If stored in a washbasin how often should this basin be cleaned?		
	6. Should the leg bag nozzle be kept sterile or clean while the leg bag is in use?		
	7. Should the urine collection container be stored upright or upside down? If stored upside down, should it sit on a paper towel first?		
	8. Should leg bag caps air dry? Should they be stored upright or upside down?		

Literature search databases:

PubMed, Embase, Journals@OVID,

ScienceDirect, Wiley, AccessMedicine,

APIC, SHEA, IDSA, CDC, Google

Search results combined (n=26)

Results

.



One product review

- One consensus paper
- One observational study



Figure 1. Selection criteria. APIC, Association for Professionals in Infection Control and Epidemiology; CDC, Centers for Disease Control and Prevention; IDSA, Infectious Disease Society of America; SHEA, Society for Healthcare Epidemiology of America, Inc.

# RESULTS

Key recommendations and findings related to the risks and benefits, use, cleaning, connection, and storage of reusable disposable urinary leg bags are listed in Table 2. Seventeen (65%) of the 26 articles met initial eligibility criteria and addressed  $\geq 1$  of the 20 key questions about urinary leg bag care. The 17 publications included 5 systematic reviews, 3 guidelines, 2 clinical practice procedures, 2 randomized controlled trials, 2 patient care guides, 1 observational study, 1 product review, and 1 consensus paper. All 17 publications addressed questions from >1 of the 4 categories of research questions in Table 1. The literature search did not provide guidance on cleaning the outside of the leg bag or storage location of the leg bag and accessories.

# Risks and benefits

Eight articles supported the use of leg bags for resident comfort, dignity, mobility, and independence.<sup>10,11,15,16,18,19,22,25</sup> Seven articles address the risks identified with reusing leg bags, including potential increased risk of CAUTI from disrupting the closed system, potential operational difficulties and harm during the cleaning procedure, odor, and breach of drainage bag integrity.<sup>11-15,17,22</sup> Underhill suggests that the use of a link system in which a large drainage bag is attached at night to a leg bag with a reflux valve decreases the risk of ascending infection because of the distance from the indwelling urinary catheter when opening the closed system.<sup>11</sup> Gray et al<sup>18</sup> state that "maintenance of a closed drainage system is of no benefit in chronically catheterized patients, of whom approximately 95%-100% are colonized by 30 days with bacteria in their lower urinary tract." Wilde et al<sup>12</sup> found studies demonstrating that despite opening the closed drainage bag for decontamination, this procedure did not increase bacterial colony count or increase CAUTI.

# Cleaning and disinfection: Procedures, chemicals, frequency, contact time, and changing

Twelve articles addressed cleaning and disinfection procedures using various chemical disinfectants and antimicrobial products, each with varying duration of contact time.<sup>10,12-14,16,18-22,24-26</sup> Smith et al<sup>22</sup> and the Cleveland Clinic<sup>10</sup> supported a protocol using 5% acetic acid (vinegar) to clean and disinfect leg bags. Gray et al<sup>18</sup> noted that either dilute sodium hypochlorite (bleach) or vinegar may be used. Herter and Kazer,<sup>19</sup> Dille et al,<sup>26</sup> Hixon et al,<sup>24</sup> Jones et al,<sup>21</sup> and the National Association For Continence<sup>20</sup> supported the use of bleach. The Canterbury District Health Board<sup>13</sup> suggested washing the leg bag with warm water and mild detergent between uses. Hus et al<sup>16</sup> noted, "The current available evidence does not support the cleaning of urinary drainage bags." Wilde et al<sup>14</sup> discussed several studies in which bleach of varying concentrations was used to disinfect the bags and to control odor. Concerns raised with using bleach include determining the correct concentration to use and safe work practices in the home with handling this caustic chemical.

Nine articles addressed timing and rationale for changing a reusable leg bag. The Canterbury District Health Board,<sup>13</sup> Dailly,<sup>17</sup> Jones et al,<sup>21</sup> Yates,<sup>23</sup> and Rogers et al<sup>25</sup> concluded that the leg bag should be changed at 5- to 7-day intervals. Wilde et al<sup>12</sup> found that singleuse vinyl urinary leg bags are safe for use up to 8 days after daily decontamination with diluted bleach. The process was deemed "safe for use" if the contamination process did not increase the risk of CAUTI. Dille et al<sup>26</sup> and Herter and Kazer<sup>19</sup> concluded that leg bags were safe up to 4 weeks after daily bleach cleaning. The Canterbury District Health Board<sup>13</sup> noted the manufacturer instructions for use should be followed. Yates<sup>23</sup> recommended changing leg bags every 5-7 days in line with the manufacturer's recommendations.

# Connection: Aseptic technique, chemicals, and timing

Hus et al<sup>16</sup> recommended using soap and water at the end of the catheter tubing when connecting and reconnecting the bags. Smith et al,<sup>22</sup> Jones et al,<sup>21</sup> and Rogers et al<sup>25</sup> suggested using alcohol to clean taps when disconnecting and reconnecting bags. Wilde et al,<sup>14</sup> Hixon et al,<sup>24</sup> Dille et al,<sup>26</sup> and the Cleveland Clinic<sup>10</sup> recommended using alcohol or a chemical disinfectant approved by the manufacturer to clean the connectors and caps.

Only the Cleveland Clinic<sup>10</sup> noted that because leg bags are smaller than regular drainage bags, they require more frequent emptying. One literature review found a range of recommendations from emptying the leg bag when it is half or three-quarters full, to emptying the bag at least twice a day, to emptying it every 4-6 hours.<sup>21</sup> The rationale for the frequency of drainage bag emptying ranged from comfort and dignity issues associated with full bags, to minimizing

#### Table 2

Synthesis of safe practices for use of urinary leg bag articles

Study	Guidance	Benefits and risks of use $(n = 12)$	Cleaning (n = 15)	Connection and emptying (n = 13)	Storage (n = 7)
Cleveland Clinic <sup>10</sup>	Patient care guide	Allows mobility, dignity	Daily rinse with 1:1 vinegar and water. Soak 20 min, warm water rinse, clean straps with soap and water.	Wash hands, empty when half full or twice a day, clean connector tips with alcohol; cap end of drainage bag	Hang to dry
Underhill <sup>11</sup>	Product review	Maximize patient comfort and dignity; link system* decreases risk of infection		Wash hands, nonsterile gloves Connect leg bag (attached to catheter) to overnight bag	
Wilde et al <sup>12</sup>	Systematic review	Changing drainage bag compromises integrity of closed system	Bleach and manufacturer-approved disinfectant more effective in reducing colony counts compared with 0.25% acetic acid or 3% hydrogen peroxide. Single-use vinyl leg bags safe for use 8 d after bleach decontamination. No increase in CAUTI.	Soak connectors in manufacturer-approved disinfectant then clean with small brush and reattach to bag	Hang on hook to dry; air dry with connections open; for outpatients cap, close bottom o bag and save in clean towel for next day
Canterbury District Health Board <sup>13</sup>	Best practice review	Closed link system <sup>*</sup> to reduce CAUTI risk	Wash with warm water and mild detergent between uses; change disposable drainage bags weekly or if damaged or odorous sediment. Follow mfg. IFU.		-
Wilde et al <sup>14</sup>	Cross-sectional study	Frequency of CAUTI not significant based on leg bag cleaning or changing practices	<ul> <li>Variation: soap and water, vinegar, bleach, commercial product.</li> <li>Most cleaned bags if in use 15-21 d. Change frequency variation: 1 to &gt; 30 d; most 7 d.</li> </ul>		
Geng et al <sup>15</sup>	Guideline	Mobility, discrete Maintain closed system—prevents CAUTI	Unresolved.	Connect leg bag to large capacity overnight bag to maintain closed system (link system <sup>*</sup> )	
Hus et al <sup>16</sup>	Evidence review	Promote ambulation and activity	Current evidence does not support cleaning with half- strength vinegar or reuse.	Aseptic technique; soap and water to clean distal end of tubing during connection	
Dailly <sup>17</sup>	Best practice guide	Maintain closed system except for bag changes decreases CAUTI	Catheter drainage bags should be changed every 5-7 d	Aseptic technique—handwash and gloves before changing or emptying	
Gray et al <sup>18</sup>	Consensus paper	Comfort and convenience	Instill bleach and water 1:10, or vinegar and water 1:3 at least every other day.		
Herter and Kazer <sup>19</sup>	Literature review	Useful for ambulatory patients	Daily use of diluted bleach extends life of leg bags to 1 mo without increase in bag colonization or rate of CAUTI.		
National Association For Continence <sup>20</sup>	Patient care guide		1 part bleach and 10 parts water solution.	Wash hands, wear clean gloves	Place bag and tubing over hook of towel rack
Jones et al <sup>21</sup>	Evidence review		Use up to 1 mo if decontaminated daily with bleach solution. Rinse bag with diluted bleach or distilled vinegar; follow mfg. IFU. Change every 5-7 d.	Wash hands, wear clean gloves, clean tap with alcohol	Drain and dry with upper connection recapped—lower taj open
Smith et al <sup>22</sup>	Guideline	Improved ambulation Use increases risk for CAUTI because of reflux of urine from the bag to the bladder and opening the closed system	Rinse with a 1:3 dilution vinegar between uses.	Aseptic technique; alcohol to clean distal end of tubing during connection	Dry after rinsing; develop policie for aseptic connection, cleaning storage
Yates <sup>23</sup>	Clinical procedure		Change leg bag every 5-7 d or manufacturer instructions.	Aseptic technique; caregivers wash hands, wear clean gloves	
Hixon et al <sup>24</sup>	Guideline		Rinse bag with cold tap water, fill with 30 mL; bleach and water 1:10 dilution, agitate, empty and rinse with tap water (vinegar does not kill bacteria).	Squirt 30 mL of bleach solution onto drainage spigot, bell, sleeve, cap, connector	Allow bag to air dry—keep top of bag uncapped and drainage spigot open
Rogers et al <sup>25</sup>	Observational study	Allows for mobility	Change leg bag at least once a week.	Disinfect external surfaces with alcohol	-
Dille et al <sup>26</sup>	Randomized controlled study		Tap water rinse and 1:10 5.25% bleach: water decreased colony counts. No clinical symptoms noted after using vinyl urinary drainage bags for up to 4 wk.	Pour beach 1:10 on drainage spigot bell, sleeve, cap, connector	Drain and air dry

CAUTI, catheter-associated urinary tract infection; IFU, instructions for use; mfg., manufacturer. \*Link system: urinary drainage system product in which the leg bag is attached to the indwelling urinary catheter at the time of insertion and is attached to a larger drainage bag at night.

the possibility that a heavy bag will result in urethral trauma and inflammation, to preventing backflow into the indwelling urinary catheter.<sup>21</sup> Dailly<sup>17</sup> stated that changing a drainage bag is a clear clinical reason to break the closed system. The author suggests the use of a system that connects a larger night bag to the leg bag, citing that the system break is a greater distance from the indwelling catheter, reducing the risk of ascending biofilm. Eight articles addressed the importance of using aseptic technique, handwashing, and clean gloves when the system is disrupted during connecting or emptying the leg bag.<sup>10,11,16,17,20-23</sup>

# Storage: Procedure and location

Seven articles addressed procedures involved in the use of leg bags and their proper storage and storage location.<sup>10,12,20-22,24,26</sup> The Cleveland Clinic<sup>10</sup> noted the bag should be hung up to dry but did not specify a location. Smith et al<sup>22</sup> recommended that a facility develop a policy identifying a leg bag storage location. Hixon et al<sup>24</sup> noted the importance of allowing the urine collection bag to air dry by keeping the top of the bag uncapped and allowing the drainage spigot to remain open. In the Dille et al study,<sup>26</sup> the leg bag was connected to the bed bag at night. The Wilde and McDonald systematic review<sup>12</sup> discussed one study whose authors recommended changing a leg bag every 5-7 days, rinsing it, and storing it dry.

# Randomized controlled trials

Of the available evidence, Dille et al<sup>26</sup> was one of the few randomized controlled trials. This study involved 54 patients and the goal was to determine safety of a 4-week reuse of urinary leg drainage bags and overnight drainage bags (bed bags). Both the large drainage bag and the leg bag types of urinary collection bags were rinsed daily with 1:10 diluted bleach. The drainage bag was changed weekly in the control group and every 4 weeks in the experimental group. The trial found that strict daily bleach rinse reduced organism growth and did not affect function or integrity of mediumor large-capacity leg bags assessed at 1- and 4-week intervals.

The Wilde et al<sup>12</sup> cross-sectional analysis described the catheter care practices of 202 persons with long-term indwelling urinary catheters. The study was a single-blind randomized trial revealing that most drainage bag changes occurred between 1 and 7 days; variations in cleaning practices included water alone (35%), vinegar and water (33%), and soap and water (29%). Cleaning with bleach was found to be more effective than vinegar and peroxide in decreasing colony counts and on increase in the rate of CAUTI.

#### Regulatory and manufacturer guidance

The FDA requires device manufacturers to label devices according to whether they are intended for single or multiple patient uses and according to whether they are disposable or reusable. The FDA requires that reusable leg bag products display instructions for cleaning and disinfecting the urine collection leg bag.<sup>27</sup> The phrasing single-use only generally refers to a single use on a single patient. In case of uncertainty for the product, labeling should be checked. A sampling of 7 online manufacturers' instructions for use of urinary leg bags yielded a variety of conflicting directions for cleaning and changing leg bags, including "change every 7 days," "use up to 14 days as recommended by your clinician," "clean with a manufacturer recommended orthophosphoric acid," "rinse with water or vinegar," and "store in a clean dry place." Those labeled single use direct the user to dispose of the item after use. All 7 referred patients to a health care professional for specific instructions. One manufacturer refers questions on care of urinary leg bags to the National Association For Continence. The CDC, FDA, and Centers for Medicare and Medicaid Services have published a variety of guidance documents for urinary drainage bags and single-use devices (Table 3). Our sampling of manufacturers' instructions for use did not reveal any information regarding recommended frequency for emptying the small-capacity leg bag.

# DISCUSSION

This integrative review examined evidence pertaining to use and care of urinary leg bags used in LTCFs and the potential for CAUTI risk for long-term care residents who are independent, mobile, and engaged with their care. Results indicate a general paucity of wellconducted, randomized controlled studies that address benefits and risks of using leg bags or discuss optimal changing, cleaning, and storing practices for the bags. A major concern in the use of leg bags is the risk of organisms entering the bladder through a breach in a closed drainage system. Papers reviewed (Table 2) suggest that although maintenance of closed drainage systems in short-term users may be of benefit in reducing CAUTI, there is likely no such benefit in patients with long-term catheters, who universally have microbial colonization within a month of catheter placement. Therefore, the enhanced quality of life offered by the independence and mobility gains associated with use of leg bags may outweigh the risk of infection that can result from breaking a closed drainage system.

Although our narrative review identified several optimal cleaning protocols and recommended cleaning solutions, well-conducted randomized controlled trials are lacking. Dilute bleach solutions of

#### Table 3

National association or agency recommendations, guidelines, and requirements for use and care of urinary leg bags

Agency	Recommendations, guidelines, and requirements
National Association For Continence <sup>20</sup>	Urine collection devices, such as a condom catheter, external pouch, or leg bag, should be leak-proof and airtight. All reusable parts should be disinfected regularly with a commercial cleaner or with a solution of 1 part white vinegar to 2 parts water. Bleach is harsh, and although it kills bacteria, it does not dissolve urine crystals the way vinegar and commercial cleansers do. It is best to clean appliances the way the manufacturer recommends.
U.S. Food and Drug Administration <sup>27,28</sup>	All urine drainage leg bags on the market are registered as class II medical devices subject to FDA regulations and special controls. All leg bag manufacturers are required to comply with specific labeling requirements, including whether the item is single use or reusable, and directions for cleaning and disinfection if it is reusable.
Centers for Medicare and Medicaid Services <sup>29,30</sup>	Published guidance for long-term care facilities on reprocessing of single-use medical devices states, in part, that they must be discarded after use. However, this guidance is not applicable to reusable disposable leg bags, which are single-patient use but not necessarily one-time use; these devices are not critical or semi-critical medical devices appropriate for resterilization and do not appear on the FDA's list of items approved for reprocessing. <sup>37</sup> The guidance refers to FDA guidelines for single-use medical devices.
Centers for Disease Control and Prevention <sup>1</sup>	Guideline does not address cleaning and reuse of urine leg bags.

varying concentrations (0.06%-1%) were most often tested, and results were similar in controlling microbial contamination in the drainage bags. Clinical practice guidelines differed in advice on bag decontamination; some did not address the question. Further research is recommended to evaluate the efficacy of decontamination procedures in patients with long-term indwelling catheters and drainage bags.

Furthermore, studies recommended using standard precautions and basic aseptic technique (hand hygiene and cleaning of surfaces) when caring for residents with urinary catheters and using gowns and gloves when splashing is expected. Eye protection is also appropriate if splash is expected. Additionally, facilities should consider monitoring care practices with any device, including leg bags. Users of urinary leg bags should check the manufacturer's instructions for use to determine whether the product is indeed reusable for a single resident and follow the instructions for use, cleaning and disinfecting, changing, and storage.

Expert panel consensus was used to develop appropriate recommendations when the research question was not addressed in the literature review or the findings were underpowered. Noticeably absent from the literature review was guidance specifically addressing cleaning of the leg bag exterior, disinfection of caps and nozzles when changing from leg bag to gravity bag, or storage of leg bags and attachments. The expert panel concluded that aseptic technique and manufacturer instructions for use should guide clinical staff in these practices.

#### Limitations

The most significant limitation of our review is the absence of well-designed, randomized controlled trials comparing the use of leg bags with use of a continuously closed, indwelling urinary catheter system, measuring clinically significant outcomes about CAUTI. Therefore, the evidence we identified drew heavily from opinions of clinical experts and from practical experience. Some sources were from home care settings rather than long-term care settings. Only 2 trials involved periodic disinfection plus replacement of the leg bag device; however, the limited sample size of these trials precludes generalizations that could definitively inform practice.<sup>14,26</sup> In addition, we limited our search to studies of adult populations. Few research studies or guidelines have been published that provide comprehensive evidence-based practices to prevent contamination and urinary tract infection when using, cleaning, or storing reusable urinary drainage bags.

# CONCLUSIONS

Reusable urinary drainage leg bags are often used in postacute care settings and in LTCFs for residents who are mobile and have chronic indwelling urinary catheters. This integrative review of the available literature surrounding use and care of urinary leg bags found multiple guidelines to direct practice. Although 2 small, randomized controlled trials provided evidence for the use of bleach to clean drainage bags and for weekly bag replacement, the literature is not uniform regarding best practices for cleaning, connection, and storage of urinary leg bags. Limitations in study design and conflicting advice make it impossible to come to a clear evidencebased recommendation about the risk for CAUTI with reusable urinary leg bags. This integrative review provides suggested practices based on a summary of available evidence and expert opinion. Practices not supported by evidence-based guidelines should conform to the individual device manufacturers' instructions for use and be monitored for strict aseptic technique and urinary tract infection. Therefore, clinicians will need to continue to rely on their experience, basic aseptic principles, and the limited evidence on which to base their strategies to care for residents with indwelling catheters. Identifying approaches to safe use of these urinary collection devices should be a research priority in the care of catheter-dependent individuals. The expert team developed a frequently asked questions practice recommendation based on the literature and expert consensus. This practice guide is available on the AHRQ Safety Program for Long-Term Care: HAIs/CAUTI Web site.<sup>31</sup>

# Acknowledgments

We thank all nursing home participants, coaches, organizational leads, quality improvement networks, quality improvement organizations, and members of the national project team of the AHRQ Safety Program for Long-Term Care: HAIs/CAUTI.

#### References

- Gould CV, Umscheid CA, Agarwal RK, Kuntz G, Pegues DA; Healthcare Infection Control Practices Advisory Committee, Centers for Disease Control, Guideline for prevention of catheter-associated urinary tract infections 2009. 2017. Available from: http://www.cdc.gov/hicpac/pdf/CAUTI/CAUTIguideline2009final.pdf. Accessed February 28, 2017.
- Lo E, Nicolle LE, Coffin SE, Gould C, Maragakis LL, Meddings J, et al. Strategies to prevent catheter-associated urinary tract infections in acute care hospitals: 2014 update. The Society for Healthcare Epidemiology of America/Infectious Diseases Society of America practice recommendation. Available from: http:// www.icpsne.org/SHEA%202014%20Updated%20CAUTl%20Prevention %20Guidelines%20(1).pdf. Accessed November 29, 2015.
- Kunin CM, McCormack RC. Prevention of catheter-induced urinary-tract infections by sterile closed drainage. N Engl J Med 1966;274:1155-61.
- Leone M, Garnier F, Antonini F, Bimar MC, Albanèse J, Martin C. Comparison of effectiveness of two urinary drainage systems in intensive care unit: a prospective, randomized clinical trial. Intensive Care Med 2003;29:551-4.
- Leone M, Albanèse J, Garnier F, Sapin C, Barrau K, Bimar MC, et al. Risk factors of nosocomial catheter-associated urinary tract infection in a polyvalent intensive care unit. Intensive Care Med 2003;29:1077-80.
- 6. Huth TS, Burke JP, Larsen RA, Classen DC, Stevens LE. Clinical trial of junction seals for the prevention of urinary catheter-associated bacteriuria. Arch Intern Med 1992;152:807-12.
- Hartstein Al, Garber SB, Ward TT, Jones SR, Morthland VH. Nosocomial urinary tract infection: a prospective evaluation of 108 catheterized patients. Infect Control 1981;2:380-6.
- Hooton TM, Bradley SF, Cardenas DD, Colgan R, Geerlings SE, Rice JC, et al. Diagnosis, prevention, and treatment of catheter-associated urinary tract infection in adults: 2009 International Clinical Practice Guidelines from the Infectious Diseases Society of America. Clin Infect Dis 2010;50:625-63.
- Whittemore R, Knafl K. The integrative review: updated methodology. J Adv Nurs 2005;52:546-53.
- Cleveland Clinic. Care of the urine drainage bag and leg bag. Health, drugs, devices. 2015. Available from: https://my.clevelandclinic.org/health/drugs \_devices\_supplements/hic-care-of-the-urine-drainage-bag-and-leg-bag. Accessed February 15, 2016.
- 11. Underhill L. A versatile range of leg bags for use in community patients. J Commun Nurs 2014;28:64-8.
- Wilde MH, McDonald MV, Brasch J, McMahon JM, Fairbanks E, Shah S, et al. Long term urinary catheter users self-care practices and problems. J Clin Nurs 2013;22:356-67.
- Canterbury District Health Board. Catheter care guidelines. Canterbury Continence Forum. 2013. Available from: https://www.cdhb.health.nz/ Hospitals-Services/Health-Professionals/CDHB-Policies/Nursing-Policies -Procedures/Documents/Catheter-Care-Guidelines.pdf. Accessed February 15, 2016.
- Wilde MH, Fader M, Ostaszkiewicz J, Prieto J, Moore K. Urinary bag decontamination for long-term use: a systematic review. J Wound Ostomy Continence Nurs 2013;40:299-308.
- 15. Geng V, Cobussen-Boekhorst H, Farrell J, Gea-Sánchez M, Pearce I, Schwennesen T, et al. Evidence based guidelines for best practice in urological health care. European Association of Urology Nurses. 2012. Available from: https://www.scribd.com/document/121373485/Evidence-based-Guidelines-for-Best -Practice-in-Urological-Health-Care-Catherisation-Indwelling-catheters-in -adults-Urethral-and-Suprapubic. Accessed February 15, 2016.
- Hus J, Witts K, Jacobson T. Cleaning urinary drainage bags with vinegar following radical prostatectomy surgery: is it necessary? Urol Nurs 2012;32:297-304.
- Dailly S. Prevention of indwelling catheter-associated urinary tract infections. Nurs Older People 2011;23:14-9.
- Gray M, Joseph AC, Mercer DM, Newman DK, Rovner E. Symposium: consensus and controversy in urinary drainage systems: implications for improving patient safety. Safe Practices. 2010. Available from: https://www.vitalitymedical.com/ pdf/urinary-drainage-bags-safety.pdf. Accessed February 28, 2016.

- Herter R, Kazer MW. Best practices in urinary catheter care. Home Healthc Nurse 2010;28:342-9.
- 20. National Association For Continence. Care of leg bag and night drainage systems. Bladder and Bowel Health. 2010. Available from: www.nafc.org/home. Accessed February 15, 2016.
- Jones S, Brooks A, Foxley S, Dunkin J. Care of urinary catheters and drainage systems. Nurs Times 2007;103:48-50.
- Smith PW, Bennett G, Bradley S, Drinka P, Lautenbach E, Marx J, et al. SHEA/APIC guideline: infection prevention and control in the long-term care facility. Am J Infect Control 2008;36:504-35.
- Yates A. Urinary catheters. Part 5: catheter drainage and support systems. Nurs Times 2008;104:22-3.
- Hixon AK, Joseph AC, Giroux J; American Association of Spinal Cord Injury Nurses, Bladder Management Content Development Group. Nursing clinical practice guideline: neurogenic bladder management. SCI Nurs 1998;15:21-56.
- 25. Rogers J, Norkett DI, Bracegirdle P, Dowsett AB, Walker JT, Brooks T, et al. Examination of biofilm formation and risk of infection associated with the use of urinary catheters with leg bags. J Hosp Infect 1996;32:105-15.
- Dille CA, Kirchhoff KT, Sullivan JJ, Larson E. Increasing the wearing time of vinyl urinary drainage bags by decontamination with bleach. Arch Phys Med Rehabil 1993;74:431-7.
- 27. U.S. Food and Drug Administration. Code of federal regulation, title 21, Vol. 8, part 876, subpart F therapeutic devices, section 876.5250. Urine collector and

accessories. Available from: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/ cfcfr/cfrsearch.cfm?fr=876.5250. Accessed February 15, 2016.

- 28. U.S. Food and Drug Administration. Guidance for the content of premarket notifications for urine drainage bags. 1994. Available from: http://www.fda.gov/ downloads/MedicalDevices/DeviceRegulationandGuidance/ GuidanceDocuments/UCM080999.pdf. Accessed February 16, 2015.
- 29. Centers for Medicare and Medicaid Services. Single use device reprocessing under tag F441. Revisions to interpretive guidance in Appendix PP. State Operations Manual (SOM) on Infection Control. 2014. Available from: https:// www.cms.gov/Medicare/Provider-Enrollment-and-Certification/ SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-25.pdf. Accessed February 15, 2016.
- 30. U.S. Food and Drug Administration. Devices for which a 510(k) should contain validation data (reprocessing final guidance appendix E). Available from: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ ReprocessingofReusableMedicalDevices/ucm436512.htm. Accessed February 14, 2018.
- 31. Agency for Healthcare Research and Quality (AHRQ). Safety Program for Long-Term Care: HAls/CAUTI. Frequently asked questions about the use of and care for leg bags in the long-term care setting. Available from: https:// www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/ cauti-ltc/modules/resources/tools/prevent/leg-bags-faqs.html. Accessed March 12, 2018.