

Other Possible Causes of a Well-Publicized Outbreak of *Pseudomonas aeruginosa* Following Arthroscopy in Texas*

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ABSTRACT

Background: Seven patients at a hospital in Houston, TX, were diagnosed during a two-week period in 2009 with joint space infection of pansusceptible *P. aeruginosa* following arthroscopic procedures of the knee or shoulder. Tosh *et al.* (2011), who investigated and published the principal report discussing this bacterial outbreak, conclude that its most likely cause was the improper reprocessing of certain reusable, physically-complex, heat-stable arthroscopic instruments used during these arthroscopic procedures. These reusable instruments reportedly remained contaminated with remnant tissue, despite diligent efforts by the hospital to clean their internal structures. This retained bioburden presumably shielded the outbreak's strain of embedded *P. aeruginosa* from contact with the pressurized steam, reportedly resulting in ineffective sterilization of these arthroscopic instruments and bacterial transmission. **Objectives:** First, to clarify which specific sterilization methods, in addition to steam sterilization, Methodist Hospital employed to process its reusable arthroscopic instrumentation at the time of its outbreak, in 2009; second, to evaluate Tosh *et al.*'s (2011) conclusion that ineffective steam sterilization due to inadequate cleaning was the most likely cause of this hospital's outbreak; third, to consider whether any other hitherto unrecognized factors could have plausibly contributed to this outbreak; and, fourth, to assess whether any additional recommendations might be warranted to prevent disease transmission following arthroscopic procedures. **Methods:** The medical literature was reviewed; some of the principles of quality assurance, engineering and a root-cause analysis were employed; and Tosh *et al.*'s (2011) findings and conclusions were reviewed and compared with those of other published reports that evaluated the risk of disease transmission associated with the steam sterilization of physically-complex, heat-stable, soiled surgical instruments. **Results and Conclusion:** Reports documenting outbreaks of *P. aeruginosa* or another vegetative bacterium associated with the steam sterilization of inadequately cleaned surgical or arthroscopic instruments are scant. This finding—coupled with a number of published studies demonstrating the effective steam sterilization of complex instruments contaminated with vegetative bacteria mixed with organic debris, or, in one published series of tests, with resistant bacterial endospores coated with hydraulic fluid—raises for discussion whether Methodist Hospital's outbreak might have been due to one or more factors other than, or in addition to, that which Tosh *et al.* (2011) conclude was its most likely cause. An example of such a factor not ruled out by Tosh *et al.* (2011) findings would be the re-contamination of the implicated arthroscopic instruments after sterilization. The specific methods that Methodist Hospital employed at the time of its outbreak to sterilize some of its arthroscopic instrumentation remain unclear. A number of additional recommendations are provided to prevent disease transmission following arthroscopic procedures.

Keywords: *Pseudomonas aeruginosa*; Arthroscopy; Disease Transmission; Healthcare-Associated Infection; Root Cause Analysis; Instrument Reprocessing; Bacterial Outbreak; Sterilization; Sterile Technique

1. Introduction

Seven patients at Methodist Hospital in Houston, Texas (USA), were infected during a two-week period, between

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April 22, 2009, and May 7, 2009, with pansusceptible *P. aeruginosa* following arthroscopic procedures of the knee (n = 6) or shoulder (n = 1) [1,2]. This outbreak was reported by Tosh *et al.* (2011), whose authors include representatives of Methodist Hospital, the Texas Department of State Health Services and the Centers for Disease Control and Prevention (CDC). Among other

risk factors, these researchers investigated the potential for these seven joint-space infections to be due to contaminated arthroscopic equipment [1]. During this outbreak, Methodist Hospital used certain reusable, physically-complex arthroscopic shaver handpieces and arthroscopic inflow/outflow cannulae, as well as rigid arthroscopes, to perform the procedures on these seven patients [1,2]. Tosh *et al.*'s (2011) report, which is a case-control study, concludes that the complex physical designs of these shaver handpieces and inflow/outflow cannulae were the primary factor responsible for this outbreak.

More specifically, these researchers conclude that the most likely cause of Methodist Hospital's *P. aeruginosa* outbreak was the inadequate reprocessing of these arthroscopic handpieces and inflow/outflow cannulae, which are heat-stable (*i.e.*, not damaged by a steam autoclave) and whose internal structures apparently do not facilitate thorough cleaning. These arthroscopic instruments reportedly remained contaminated with "remnant tissue" [1] (and, in the case of the shaver handpiece's suction channel, also with brush bristles) that was "not evident to the naked eye," [3] despite the shaver handpiece's suction channel reportedly having been cleaned in accordance with its manufacturer's instructions [1-3]. This retained tissue, which Tosh *et al.* (2011) suggest provided a "sanctuary for bacterial contamination," [1] presumably shielded and protected the outbreak's strain of *P. aeruginosa*, resulting in ineffective steam sterilization. As a direct consequence, these contaminated instruments apparently transmitted *P. aeruginosa* to these seven patients during these invasive procedures [1,2].

In addition to Tosh *et al.*'s (2011) investigation of this hospital's outbreak of *P. aeruginosa* [1], several other reports discuss the potential for disease transmission due to infectious remnant tissue remaining within the internal structures of these specific arthroscopic shaver handpieces [3,4] and inflow/outflow cannulae after their reprocessing [5]. These reports include a notice issued by the U.S. Food and Drug Administration (FDA), a report filed in the FDA's MAUDE¹ database, and a device recall [3-5]. Further underscoring its potential impact on public health, Methodist Hospital's bacterial outbreak was also the focus of the popular national news media (including *NBC's Nightly News* and *Fox News*) [2,6,7]. The completeness of a study like Tosh *et al.*'s (2011) important investigation of the possible causes of Methodist Hospital's *P. aeruginosa* outbreak may be better assured not only by performing a root cause analysis of this outbreak but also by providing, as warranted, additional recommendations to prevent infections of the same or of

¹MAUDE refers to the FDA's Manufacturer and User Facility Device Experience database whose data describe reports of adverse events involving medical devices.

a similar etiology. Indeed, the medical literature's inadvertent omission of every possible cause of, or factor contributing to, a healthcare facility's bacterial outbreak (or a similar type of adverse event) could hinder or prevent the development and implementation of crucial corrective actions, boding the possibility of the outbreak's recurrence.

2. Objectives

This article:

1) aims to clarify which specific sterilization methods, in addition to steam sterilization, Methodist Hospital employed to process its reusable arthroscopic instruments at the time of its bacterial outbreak, in 2009;

2) evaluates Tosh *et al.*'s (2011) conclusion that the most likely cause of this hospital's outbreak was the ineffective steam sterilization of reusable, heat-stable arthroscopic shaver handpieces and inflow/outflow cannulae, due to bioburden that was retained within the internal structures of these physically-complex instruments after their apparent thorough cleaning;

3) considers whether one or more hitherto unrecognized deviations, non-conformances, or factors—both unrelated to the ineffective sterilization of inadequately cleaned arthroscopic instruments and not ruled out by Tosh *et al.*'s (2011) data—might have contributed to or have been responsible for this hospital's outbreak; and

4) assesses whether any additional recommendations (not included in the Tosh *et al.* [2011] report) might be indicated to prevent bacterial infections following arthroscopic procedures of the knee and shoulder.

3. Methodology

The medical literature was reviewed; some of the principles of quality assurance, engineering and a root cause analysis were employed; and Tosh *et al.*'s (2011) data, findings and conclusions were compared with those of other published studies that evaluated the risk of disease transmission associated with the steam sterilization of physically-complex, heat-stable surgical instruments contaminated with bioburden and/or another type of soil or debris. To provide additional insight into risk factors associated with the transmission of *P. aeruginosa* in the healthcare setting, also reviewed were a number of other studies that discuss outbreaks not only of *P. aeruginosa* associated with improperly reprocessed flexible endoscopes, but also of *P. aeruginosa* and other bacteria linked to: poor hand hygiene or to the contaminated hands of healthcare workers; the re-contamination of instruments after sterilization (or disinfection) due to, for example, their improper handling; and contaminated environmental surfaces, including tap water and hand-washing sinks.

4. Results

Tosh *et al.* (2011) report that, during the time of its *P. aeruginosa* outbreak, in 2009, Methodist Hospital processed both its arthroscopic shaver handpieces and inflow/outflow cannulae (but not its rigid arthroscopes; *see below*) using either traditional steam sterilization or flash (steam) sterilization. In addition to using it as many as “6 times daily during the outbreak period” and to process arthroscopic instruments used on two of the seven infected patients [1], these authors also report that Methodist Hospital used flash sterilization “on rare occasions for routine sterilization,” [1]. Briefly, whereas traditional steam sterilization may be achieved using a gravity displacement sterilizer or a pre-vacuum sterilizer that is generally installed in a central (and often remote) reprocessing area, either type of which features an extended terminal drying phase, flash sterilization, which is a more rapid process without a terminal drying phase (*note*: this point-of-use process is indicated only in emergency situations, for example, to process instruments that were inadvertently dropped on the floor), may be installed in or near the operating-room suite. Further, Tosh *et al.* (2011) report that this hospital employed at the time of this *P. aeruginosa* outbreak a device that uses hydrogen peroxide gas plasma², but reportedly only to process the hospital’s rigid arthroscopes (including their light cords and camera/power cords) [1].

This article’s review of the medical literature presents a number of additional findings. First, it identified several reports that document outbreaks (and pseudo-outbreaks) of *P. aeruginosa* associated with a number of different types of reusable medical instruments, including bronchoscopes, gastrointestinal endoscopes and transrectal ultrasound-guided prostate biopsy equipment [9-17]. These instruments, however, unlike the arthroscopic shaver handpieces and inflow/outflow cannulae discussed by Tosh *et al.* (2011), are damaged by heat, and for each of these reported outbreaks disease transmission was linked, not to ineffective steam sterilization, but to inadequate high-level disinfection or liquid chemical sterilization. These latter two types of processes use a low-temperature liquid chemical disinfectant or sterilant to effect their outcome, and the cause of infection associated with either is often attributed to the terminal rinsing of heat-sensitive instruments with water that was contaminated with bacteria [10-15].

Second, this review found that published reports asso-

²This processor’s reported use notwithstanding, no reports were identified in the FDA’s MAUDE database discussing its use by Methodist Hospital at the time of this bacterial outbreak, in 2009. Describing a different outbreak, however, a MAUDE report, dated 2010, associates five *P. aeruginosa* infections with the use of this same processor (which uses a hydrogen peroxide gas plasma) to sterilize arthroscopes [8].

ciating infections of *P. aeruginosa* (or another vegetative bacterium) to the use of reusable, heat-stable, physically-complex surgical or arthroscopic instruments exposed to a (properly functioning) steam sterilization process (*i.e.*, a steam autoclave), no matter whether the instruments were inadequately cleaned, are scant and with few exceptions, such as Tosh *et al.*’s (2011) report. (Most types of vegetative bacteria are readily destroyed by even as limited a decontamination process as low-level disinfection [18]).

And, third, this review identified a number of studies that demonstrate pressurized steam’s successful sterilization of complex surgical instruments that not only were inoculated with high numbers of vegetative bacteria, or even with high numbers of resistant bacterial endospores, but that also were contaminated with a soil or organic debris and, in one instance, with hydraulic fluid, which reportedly poses a more formidable hindrance to effective sterilization than bioburden [19-22].

5. Discussion

Tosh *et al.* (2011) conclude that the most likely cause of Methodist Hospital’s bacterial outbreak was, in the following temporal sequence: the inadequate cleaning of certain arthroscopic shaver handpieces and inflow/outflow cannulae, resulting in remnant bioburden remaining within their suction channel and lumen, respectively; the ineffective sterilization of these instruments due to this bioburden shielding and protecting infectious bacteria; and the subsequent transmission of surviving *P. aeruginosa* to the seven case patients (during the arthroscopic procedures that used these implicated arthroscopic instruments). This conclusion is replete with important public-health implications, although it is also somewhat exceptional. Moreover, that the potential causes of Methodist Hospital’s bacterial outbreak have been studied by the FDA and CDC, as well as having been the focus of the national news [2,6,7], is testimony to the importance not only of Tosh *et al.*’s (2011) investigation, findings and conclusions, but also of developing and implementing validated corrective and preventive actions documented to prevent the recurrence of this type of bacterial outbreak (as well as of other types) [1-7].

5.1. Effectiveness of Steam Sterilization

Notwithstanding Tosh *et al.*’s (2011) conclusion of this bacterial outbreak’s most likely cause, this review identified a number of studies that demonstrate pressurized steam’s successful sterilization of physically-complex surgical instruments contaminated with bioburden. Voyles *et al.* (1995), for example, report that a 3-minute flash sterilization cycle destroyed high concentrations of vegeta-

tive bacteria (like *P. aeruginosa*) inside a 12-mm reusable metal laparoscopic cannula³ [20]. This outcome was reportedly achieved despite—as an additional challenge to the sterilization process’s effectiveness and for the purpose of creating a scenario that was “much worse than should ever occur in a clinical setting” [20]—the cannula both having had its openings sealed to interfere with the steam’s direct contact with the bacteria and having been packed with organic debris (*i.e.*, hamburger meat inoculated with the bacteria) [20].

Like Voyles *et al.* (1995), [20] Rutala *et al.* (2008) [21] performed a series of similar tests designed to evaluate the effectiveness of steam sterilization during “worst-case” (*i.e.*, most challenging) conditions. During one series of tests, these latter authors contaminated physically complex surgical instruments with high numbers of heat-resistant spores of *Geobacillus stearothermophilus*. (These spores are significantly more resistant to pressurized steam than vegetative bacteria, and, therefore, from a probability standpoint, a steam sterilization process’s complete eradication of high numbers of spores of *G. stearothermophilus* assures the destruction of high numbers of *P. aeruginosa*.) These contaminated instruments—which featured a hinged surface, a crevice or a thumb screw, and, therefore, are each seemingly as (if not more so) physically complex and challenging to sterilize as the arthroscopic shaver handpieces and inflow/outflow cannulae used by Methodist Hospital during the time of its bacterial outbreak, in 2009—were air dried and then coated with (20 mL of) an oil-based hydraulic fluid, to further challenge the sterilization process [21]. During a second series of tests similarly designed to challenge the sterilization process’s effectiveness, Rutala *et al.* (2008) placed contaminated scalpel blades, which had been inoculated with more than 10⁶ spores of *G. stearothermophilus*, air dried, and then coated with (20 mL of) hydraulic fluid, into the center of a relatively long and narrow lumen [21]. For both of these series of tests, these authors reported that the contaminated surgical instruments were successfully sterilized. Based on their findings, Rutala *et al.* (2008) conclude that their data demonstrate steam sterilization’s “robustness” and “huge margin of safety,” even of contaminated instruments that had also been coated with hydraulic fluid [21].

In their study Tosh *et al.* (2011) discuss a report by Belvins *et al.* (1999) that investigated three cases of organ/space surgical-site infections (SSIs) due to coagulase-negative *Staphylococcus* (“CoNS”) following ar-

³Voyles *et al.* (1997) also reported that exposure of the sealed cannula to steam sterilization for 7 minutes destroyed high numbers of *Geobacillus stearothermophilus* spores (contained within a biological indicator), although an exposure time of only 3 minutes was required to destroy these heat-resistant spores when the cannula was not sealed and one of its ports remained open [20].

throscopic procedures [22]. Implicating a single set of arthroscopic inflow/outflow cannulae that had been used during each of these three cases as a potential source of these SSIs, Belvins *et al.* (1999) identified “dried organic material” in the lumens of some of these cannulae after their reprocessing, with cultures from three of this set’s six cannulae (but not necessarily from the retained organic material itself) being “positive” for CoNS. Although these findings appear to be consistent with Tosh *et al.*’s (2011) conclusion (that Methodist Hospital’s outbreak was most likely due to ineffective sterilization resulting from inadequate cleaning), Belvins *et al.* (1999) also performed a number of experimental tests during their investigation that documented the *successful* steam (and flash) sterilization of arthroscopic cannulae inoculated with CoNS in the presence of blood [22]. In summary, the studies by Voyles *et al.* (1995) and Rutala *et al.* (2008), as well as Belvins *et al.*’s (1999) experimental tests, demonstrating the effectiveness of steam sterilization and its wide margin of safety, coupled with a dearth of reports associating the steam sterilization of physically-complex surgical instruments with bacterial outbreaks in the healthcare setting, save for Tosh *et al.*’s (2011) report, raise for discussion the possibility that one or more other, hitherto unrecognized causes—both unrelated to that which Tosh *et al.* (2011) conclude was its most likely cause and not excluded by their findings—might have contributed to or been responsible for Methodist Hospital’s *P. aeruginosa* outbreak.

5.2. Contaminated Surfaces, Hands

Outbreaks of *P. aeruginosa* have been associated with the improper reprocessing of flexible endoscopes, often due to their terminal rinsing with contaminated water following high-level disinfection or liquid chemical sterilization [9-18]. Yet, improper reprocessing of reusable medical equipment—whether of a flexible endoscope, an arthroscopic instrument, or another type of medical instrument—is but only one of many factors documented to be responsible for infections of *P. aeruginosa* in the healthcare setting. For example, reports also describe infections of *P. aeruginosa* and other bacteria associated with poor hand hygiene or the contaminated hands (and fingernails) of healthcare workers; with the re-contamination of (unwrapped) instruments during their improper handling; and with hand-washing sinks colonized with bacteria [18,23-30]. Like the studies by Voyles *et al.* (1995) and Rutala *et al.* (2008), these reports also lend credence to the possibility that, not necessarily the ineffective steam sterilization of the implicated arthroscopic instruments, but rather another factor—for example, the inadvertent failure to have sterilized the instruments

using *any* method [31]⁴—might have contributed more to Methodist Hospital’s outbreak than has been recognized. **Table 1** lists, along with Tosh *et al.*’s (2011) suggestion of its most likely cause, a number of other factors that would appear to be plausible contributors to this hospital’s bacterial outbreak in 2009.

5.3. Re-Contamination after Sterilization?

Unlike Belvins *et al.*’s (1999) report, which found cultures from three of the sampled cannulae to be “positive” for CoNS, Tosh *et al.* found (2011) that none of the cultured samples collected during their investigation from Methodist Hospital’s shaver handpieces and inflow/outflow cannulae grew *P. aeruginosa* or another bacterium [1]. While this null result, by itself, neither assuredly exculpates these complex arthroscopic instruments as a contributor to this outbreak nor, on the other hand, certainly refutes Tosh *et al.*’s (2011) claim of their culpability, cultured samples that grew the outbreak’s strain of pansusceptible *P. aeruginosa* would have been expected if steam sterilization of the implicated arthroscopic instruments, contaminated with remnant tissue, had been ineffective as Tosh *et al.* (2011) suggest [1]. Instead, these authors (2011) found, in addition to four samples of this hospital’s tap water being contaminated with *Pseudomonas* species isolates, twelve environmental isolates of *Pseudomonas* species collected from sink drains were pansusceptible *P. aeruginosa*. Like the studies by Hota *et al.* (2009) [29] and Lowe *et al.* (2012) [30]—both of which found one or more hand-washing sinks (or their drains) to be contaminated with, and the source [29] (or a contributing reservoir [29]) of, their respective outbreak’s strain of bacteria (presumed to have been transmitted to patients via “splashing” water [29,30])—Tosh *et al.* (2011) report that one of the twelve environmental isolates that was collected from the drain of the sink in the hospital’s decontamination room had pulsed-field gel electrophoresis (PFGE) patterns indistinguishable from the outbreak’s strain of *P. aeruginosa* [1]—a finding that suggests this sink’s drain may have been a source or reservoir of this hospital’s outbreak.

Based on this result, Tosh *et al.* (2011) conclude that the implicated arthroscopic instrumentation was most likely contaminated during the “gross decontamination

⁴The inadvertent omission of a reprocessing step is not unprecedented. A practice associated with a self-evident risk of infection, reports document the cleaning, but not high-level disinfection or sterilization, of medical instruments prior to their clinical use [31]. Also, Tosh *et al.* (2011) report that Methodist Hospital’s sterilizer logs, at least those associated with the hydrogen peroxide gas plasma processor, were deficient, namely, documentation of the use of biological and chemical indicators during the time of its outbreak was incomplete, which prevented investigators from confirming that the sterilization process was properly functioning and that each load, pack or set of arthroscopic equipment had indeed been exposed to the sterilization process [1].

Table 1. Factors that may have contributed to or have been a cause of Methodist Hospital’s bacterial outbreak^a.

- 1) As suggested by Tosh *et al.* (2011), ineffective steam sterilization of reusable arthroscopic shaver handpieces and inflow/outflow cannula, due to remnant bioburden (contaminated with *P. aeruginosa*) remaining within their internal structures after reprocessing [1];
- 2) Bacterial contamination of the implicated arthroscopic instruments *after* successful sterilization—for example, during: their inadvertent contact with contaminated water, a contaminated sink (e.g., during splashing) or another contaminated environmental surface [27,29,30]; or, their improper handling by contaminated hands [23-25];
- 3) The unwitting and unrecognized failure to have terminally sterilized the implicated arthroscopic instruments using *any* method [31];
- 4) Ineffective sterilization of the implicated arthroscopic instruments due to a deficiency or unrecognized fault in one or more of the hospital’s sterilization processes;
- 5) Immersion of the implicated arthroscopic equipment in a liquid chemical disinfectant or sterilant, followed by its rinsing with water contaminated with the outbreak’s strain of *P. aeruginosa* [9,10,12, 15-17]; and/or
- 6) A factor unrelated to the reprocessing of the hospital’s implicated arthroscopic instruments—for example, the possibility that the outbreak’s strain of *P. aeruginosa* might have originated from a source hitherto not identified, such as an intrinsically contaminated irrigant used during the procedures, or due to retrograde flow from a contaminated suction canister [1].

^aTosh *et al.* (2011) suggest that this table’s first listed factor was this outbreak’s most likely cause. None of the other scenarios presented in this table, however, are ruled out by Tosh *et al.*’s (2011) findings [1].

steps.” [1] These authors also note that this strain (which may have formed a biofilm of pansusceptible *P. aeruginosa* on this sink’s surfaces [1]) was “likely introduced into the case patients’ joint spaces by direct insertion of (these) contaminated instruments or by infusion of fluids through the contaminated lumen [1].” While Tosh *et al.*’s (2011) explanation of the likely cause of Methodist Hospital’s outbreak is certainly plausible, if not entirely accurate, their investigation, nonetheless, do not rule out the possibility (and, in some instances, their report’s data and findings appear consistent with the possibility⁵) that one or more other unrecognized factors might have contributed to, or have been primarily responsible for, this outbreak (and/or that an unrecognized source may have been the origin of this outbreak’s bacteria). An example of such a factor would be the inadvertent re-contamination of the implicated arthroscopic instrumentation with the sink drain’s isolate (which was indistinguishable from the outbreak’s strain) *after* its successful sterilization (possibly, due to the splashing of contaminated water from the sink onto this instrumentation) (*see: Table 1*).

⁵An example would be, Tosh *et al.*’s (2011) finding that none of the cultured samples collected from the implicated shaver handpieces and inflow/outflow cannulae grew the outbreak’s strain of *P. aeruginosa* [1].

5.4. An Anomalous Outbreak

Based on this review, the possibility that Methodist Hospital's cluster of seven *P. aeruginosa* infections in 2009 may have been due more to another, unrecognized deviation, cause, or factor unique to Methodist Hospital's practices (see: **Table 1**) than (if at all) to ineffective sterilization (resulting from bioburden that remained within the internal structures of inadequately cleaned arthroscopic instrumentation) warrants consideration. Indeed, in addition to rationalizing and providing a viable alternative to Tosh *et al.*'s (2011) conclusion that *P. aeruginosa* (which is ordinarily destroyed even by low-level disinfection [18]) likely survived exposure to steam sterilization (albeit in the presence of remnant tissue), this possibility might explain another issue that Tosh *et al.*'s (2011) report (and, too, a communication by the FDA [3]) does not resolve: why this outbreak (and other bacterial outbreaks of the identical or similar etiology) was reported only *once* at this one hospital, in 2009, and has not also been reported at other times, at other medical facilities, nationwide, that also use these same arthroscopic instruments [1,2]. This apparent anomaly is all the more puzzling, because Tosh *et al.* (2011) report that arthroscopic shaver handpieces used at *other* medical facilities were inspected by officials of Methodist Hospital and were found, too, to have retained bioburden (after cleaning)—a finding that prompted these authors to conclude that “this problem is not specific to (Methodist Hospital) or to a specific manufacturer [1].”

Raising more questions, this review did not identify any other instances of bacterial infections or outbreaks associated with the inadequate cleaning and unsuccessful steam sterilization of the implicated arthroscopic shaver handpieces and inflow/outflow cannulae. During its discussions with, and an inspection of its facility by, the FDA just a few months after Methodist Hospital's outbreak, in August, 2009, the manufacturer of this hospital's arthroscopic shaver handpieces reported that for the previous decade it had “frequently” identified remnant “tissue-like” materials remaining within the internal structures of these handpieces returned by healthcare facilities for service, inspection and/or repair [32]. In the FDA's report detailing its inspection of this manufacturer's facility, the manufacturer stated that it was unaware of any bacterial outbreaks, save for Methodist Hospital's, linked to this specific non-conformance [32]. According to this manufacturer, data indicating that bioburden retained within the internal structures of these heat-stable arthroscopic handpieces, which are routinely steam sterilized after each use in accordance with their labeling instructions, posed a substantive risk of patient harm are lacking, an assessment of risk that appears consistent with other published reports [18,20-22].

5.5. High-Level Disinfection or Sterilization?

Crucial to understanding all of the possible causes of its bacterial outbreak is the determination of each of the specific methods and processors Methodist Hospital used between April 22, 2009, and May 7, 2009, to sterilize at least some of its arthroscopic instrumentation. Tosh *et al.* (2011) use a number of different terms to describe the intended function of the hydrogen peroxide gas plasma processor that Methodist Hospital used at the time of its outbreak to sterilize its rigid arthroscopes. For example, the text of Tosh *et al.*'s (2011) report (which is distinguished from its tables) aptly describes this device (whose trade or brand name, however, their report does not mention) as achieving that for which the FDA cleared it⁶: *low-temperature sterilization* [1]. Tosh *et al.*'s (2011) Table 2, however, describes this same gas plasma processor as achieving *high-level decontamination* [1]—an unusual descriptor that is distinct from low-temperature sterilization (and high-level disinfection). Further, Tosh *et al.* (2011) do not define this descriptor in their report; nor does the FDA associate high-level decontamination with any legally marketed sterilizer or other type of terminal processor. Tosh *et al.*'s (2011) report also describes this processor as achieving a third outcome: *high-level disinfection*⁷, the FDA having not cleared this (or any other) terminal sterilization processor for this intended use notwithstanding.

Tosh *et al.*'s (2011) use of the unusual term *high-level decontamination* in their Table 2 to describe the outcome achieved by this hydrogen peroxide gas plasma processor (which the FDA cleared to achieve *low-temperature sterilization*) is seemingly inadvertent. But, their report's use, additionally, of the term *high-level disinfection* to describe this gas plasma processor's outcome introduces for consideration whether some of Methodist Hospital's arthroscopic (or surgical) instrumentation at the time of its outbreak was just that: exposed to a process that terminally achieves high-level disinfection (or liquid chemical sterilization⁸) (see: **Table 1**). As previously noted, these authors report that an isolate collected from the drain of the sink in this hospital's decontamination room had PFGE patterns indistinguishable

⁶Tosh *et al.*'s (2011) report states: “The manufacturer-recommended procedure for arthroscope reprocessing included gross decontamination with submersion in enzymatic solution for 10 - 15 minutes before *low-temperature sterilization* [1].”

⁷Tosh *et al.*'s (2011) report states: “The arthroscope-cleaning procedure at (Methodist Hospital) involved wiping down the instrument following a brief submersion of the instrument in enzymatic solution before *high-level disinfection* [1].”

⁸No reports were identified during this review that would suggest that an automated device labeled to achieve “liquid chemical sterilization [9],” but considered by some healthcare facilities to achieve high-level disinfection, was used by Methodist Hospital to process any of its arthroscopic instrumentation at the time of its outbreak (although it seems plausible that this hospital might have used this specific device, in 2009 to process at least some surgical instruments).

from the outbreak's strain of *P. aeruginosa* [1]. If any of the implicated arthroscopic instruments were indeed high-level disinfected (accidentally, inadvertently, or unwittingly), then the microbial quality of the hospital's water would have been necessary to determine in order to evaluate whether this water—which would have been used to rinse the instruments terminally after their chemical immersion and, if contaminated with the outbreak's strain of *P. aeruginosa*, would most likely have been a source of this bacterial outbreak [10,13,15,17]—might have played more of a role in causing this outbreak than has been recognized⁹. No matter, Tosh *et al.*'s (2011) use of these three different terms to describe this gas plasma processor and its outcome leaves unclear and unresolved which specific methods Methodist Hospital used to process at least some of its arthroscopic instrumentation during the time of its bacterial outbreak, in 2009.

5.6. Additional Implications

Listed in **Table 2**, two additional issues, among others, arise from this review of Tosh *et al.*'s (2011) report, both with important implications to public health. First, that *P. aeruginosa* might remain viable within the internal structures of physically-complex surgical instruments, or at least of the implicated arthroscopic instruments, after their cleaning and steam sterilization—which Tosh *et al.* (2011) conclude is both the most likely cause of Methodist Hospital's outbreak and a "problem" not specific to this one hospital or to any one manufacturer—is a potentially portending suggestion with concerning implications not just to instrument cleaning, sterilization, instrument design, and public health, but also to the FDA's regulation of reusable medical equipment. As a consequence of these authors' investigation of Methodist Hospital's outbreak, reasonable questions may be asked of the FDA about which specific reusable, physically-complex heat-stable surgical instruments used today in US healthcare facilities, including reusable arthroscopic shaver handpieces and inflow/outflow cannulae [1], may preclude thorough cleaning and, therefore, be prone to disease transmission during surgery. Such suspect instruments would seemingly warrant redesign or another corrective action to improve the effectiveness of its reprocessing and prevent patient harm.

Second, due to the acknowledged limitations of low-temperature sterilization [18,33,34], not only is the exclusive use of steam sterilization to process surgical instruments not damaged by pressurized steam recommended, but also the use of low-temperature sterilization to process heat-sensitive surgical instruments (for which

⁹Tosh *et al.* (2011) state that due to "suboptimal water-sampling techniques," contamination of Methodist Hospital's tap water with *Pseudomonas* was "likely underestimated [1]."

Table 2. Several salient findings that arise from this review of the Tosh *et al.* (2011) report.

1) According to Tosh *et al.* (2011) [1], infectious *P. aeruginosa* may remain viable within the complex internal structures of surgical instruments, or at least of the implicated arthroscopic instruments, after their cleaning and exposure to one or more steam sterilization cycles, and be transmitted to patients [1].

2) This review raises for discussion the possibility that a factor or practice: a) unrelated to the ineffective sterilization of the implicated arthroscopic instruments; b) unique to Methodist Hospital's practices at the time of its outbreak; and c) not ruled out by Tosh *et al.*'s (2011) findings might have contributed to or have been primarily responsible for this hospital's *P. aeruginosa* outbreak.

3) Due to its inherent limitations compared to steam sterilization [18,33,34], the use of low-temperature sterilization (the active agent of which may be a gas, plasma, or vapor) to process surgical instruments whose labeling indicates that steam sterilization is an acceptable method or that are heat-sensitive (and for which this method might otherwise be suitable), but that feature physically-complex, difficult-to-clean internal surfaces and structures, the "cleanliness" of which cannot be verified (whether by visual examination or another method), is not recommended.

4) Efforts to prevent additional instances of infection, like that of any adverse event, may be advanced and optimized by the application of a root cause analysis to identify every possible cause and contributory factor that might have been responsible for disease transmission and to develop and implement corresponding corrective actions whose effectiveness has been validated.

5) Improvements in the federal oversight and regulation of reusable medical instruments, particularly those that are complex in physical design and may not facilitate cleaning and sterilization, may be necessary to reduce the risk of healthcare-associated infections.

these processes might have been originally intended to process) featuring complex internal surfaces and structures that, like the designs of Methodist Hospital's implicated arthroscopic instruments, hinder reprocessing and whose cleanliness (after cleaning) cannot be verified (whether by visual examination or another method) would be questioned (*see: Table 2*). (The ineffectiveness of a steam sterilization process would assure the failure of a low-temperature sterilization process [33,34]¹⁰).

5.7. A Root Cause Analysis

The possibility that any one of the several plausible factors, considerations, or causes listed in **Table 1** might have contributed to Methodist Hospital's outbreak underscores another of this review's findings: that efforts to prevent of disease transmission and an outbreak's recurrence may be advanced and optimized by the completion of a root cause analysis. During this analysis, every deviation that might have caused or contributed to a medical facility's outbreak (or other type of adverse event) is

¹⁰Whereas steam sterilization is associated with a SAL of 10^{-6} , processes that achieve low-temperature sterilization are less reliable, especially for processing complex instruments soiled with organic debris, and may be associated with a greater likelihood of failure (e.g., a SAL of 10^{-3}) [33,34].

identified and associated with one or more corresponding corrective actions whose effectiveness has been validated. **Table 3** lists a number of additional recommendations (which supplement those included in Tosh *et al.*'s [2011] report) that are, in part, a consequence of the root cause analysis of Methodist Hospital's outbreak that was performed during this review and are provided to prevent bacterial outbreaks (such as Methodist Hospital's). This review's root cause analysis is provided in **Table 4** (although this analysis is not inclusive of every one of Methodist Hospital's deviations).

6. Conclusions

Tosh *et al.*'s (2011) impressive report is as distinguished as its advice is prophylactic. Its conclusion that the most likely cause of Methodist Hospital's bacterial outbreak in 2009 was due to a vegetative bacterium (e.g., *P. aeruginosa*), albeit in the presence of remnant tissue, that likely survived on and was transmitted by surgical instruments exposed to at least one complete and robust steam ster-

Table 3. Additional recommendations provided to prevent bacterial outbreaks like Methodist Hospital's in 2009^a.

- 1) Ensure that the medical facility's sterilizers are not only maintained and serviced, but also that their logs are complete.
- 2) Confirm that each pack, container, set or load of instruments has been successfully sterilized via the results of chemical indicators (CIs) and, as required, of biological indicator (BIs).
- 3) Confirm that staffers responsible for the cleaning and sterilization of surgical instruments are trained (and certified, as required) to ensure the proper reprocessing of every instrument in inventory.
- 4) Confirm that staffers adhere to proper hand hygiene and the aseptic handling of processed surgical instruments.
- 5) Verify that critical, invasive instruments are not being high-level disinfected (unless recommended by the instrument's manufacturer). Sterilization of these items is recommended whenever feasible.
- 6) Ensure that hand-washing sinks and other environmental surfaces in or near the area where surgical procedures are performed are properly designed and both cleaned and disinfected in accordance with published guidelines or maintenance instructions.
- 7) Verify that wet, processed instruments are dried prior to reuse [35]. (*Caution* is advised whenever surgical instruments that are moist or wet with water are introduced into a sterile field.)
- 8) Consider periodically monitoring the medical facility's water supply, as required, to ensure it does not contain unsafe levels of opportunistic microorganisms, such as *P. aeruginosa*. Instruments that have been reprocessed, but that come in contact with contaminated water prior to their clinical use, could pose an increased risk of disease transmission, with associated patient morbidity and mortality [36].
- 9) The use of low-temperature sterilization processes, such as those that use a gas, plasma, or vapor, to process any type of surgical instrument whose labeling indicates that steam sterilization is an acceptable method (*i.e.*, that pressurized steam will not damage the instrument) is not recommended (see: **Table 2**, item # 3).

^aThese recommendations supplement those in the Tosh *et al.* (2011) report.

ilization cycle (that is, one completed sterilization cycle after each of the arthroscopic instrumentation's clinical uses, which may have been several uses and cycles during this outbreak's two-week period¹¹) is arguably as significant as "the discovery of retained bioburden in the suction channel of arthroscopic shaver handpieces despite reprocessing according to the manufacturer's instructions," [1] which Tosh *et al.* (2011) report is "the most consequential aspect of this outbreak [1]."

Resolution of the apparent disparity between, on the one hand, Tosh *et al.*'s (2011) conclusion of the most likely cause of Methodist Hospital's outbreak and, on the other, the conflation of, first, the medical literature's lack of more reports like Tosh *et al.*'s (2011) documenting *P. aeruginosa* outbreaks associated with the traditional steam sterilization, or even the flash sterilization, of complex surgical and arthroscopic instruments, including those that may retain remnant tissue within their internal structures; and, second, a number of studies validating steam sterilization's robustness and effectiveness for the prevention of disease transmission under the most challenging testing conditions [19-21,33,34] on its face is difficult. Indeed, the solution could rest, however, with another of this review's findings, which warrant reemphasis (*see*: **Table 2**): the possibility that, not ineffective steam sterilization of the implicated arthroscopic instruments due to their inadequate cleaning, but rather one or more other (unrecognized) factors, considerations, or causes, unique to Methodist Hospital's practices at the time of its outbreak in 2009, might have contributed to, or have been primarily responsible for, this hospital's seven cases of *P. aeruginosa* infection. That the outbreak's strain of bacteria could have been transmitted, not by a contaminated arthroscopic instrument, but rather via another, undetermined mode is a possibility that Tosh *et al.*'s (2011) findings do not exclude (*see*: **Table 1**).

Finally, Tosh *et al.*'s (2011) conclusions also suggest that improvements in the federal oversight and regulation of medical devices are necessary—particularly of some reusable arthroscopic and surgical instruments that are complex in physical design and may not facilitate cleaning and sterilization—to improve the quality of health care and to prevent outbreaks of *P. aeruginosa* and other types of patient harms following surgery. One example of such an improvement (in addition to the re-design of reusable surgical instruments that cannot be adequately cleaned) would be the requirement by the FDA that manufacturers demonstrate with more scientific rigor the validated effectiveness of the reprocessing protocol(s) they provide in their reusable instrument's labeling and instructions for use ("IFU").

¹¹The individual arthroscopic instruments were not tracked at the time of this hospital's outbreak [1], and, therefore, the number of times each might have been used and reprocessed during this time would not likely have been known.

Table 4. A root cause analysis of the *P. aeruginosa* outbreak investigated at Methodist Hospital in 2009.**1) Instrument Design Considerations**

a) Deviation: Despite being cleaned in accordance with its manufacturer's reprocessing instructions, the suction channel of a reusable arthroscopic shaver handpiece remained contaminated with remnant tissue (and retained brush bristles).

b) Concern: The inadequate cleaning of the internal structures of any reusable surgical instrument poses an increased risk of ineffective sterilization and, therefore, of disease transmission. Tosh *et al.* (2011) report that this deviation was most likely the cause of this cluster of seven infections at Methodist Hospital in 2009. According to these authors, reusable arthroscopic shaver handpieces, as well as reusable arthroscopic inflow-outflow cannulae (*see:* below), remained contaminated with bioburden after cleaning, resulting in the introduction of *P. aeruginosa* into each patient's surgical site.

c) Some of this deviation's root causes and/or contributing factors: i) The hospital used reusable shaver handpieces, the physical designs of which are complex and do not necessarily facilitate the adequate cleaning (and sterilization) of their suction channel [1]. ii) Nor does the shaver handpiece's design reportedly facilitate the hospital's visual examination of its internal suction channel (or the use of another simple, non-invasive, standardized, and validated procedure, tool or kit) to verify that it was adequately cleaned prior to terminal sterilization. iii) Disposable brushes with bristles that could become dislodged were used to clean the suction channel of these arthroscopic shaver handpiece. iv) This review did not identify any marketed disposable counterpart that this hospital could have used instead of the reusable implicated shaver handpiece.

d) Corresponding corrective actions or risk-reducing strategies: In response to this outbreak, several of the following measures were performed: [1] i) The hospital promptly removed from service and replaced the implicated arthroscopic shaver handpieces. ii) The hospital promptly retrained its staff and revised its instrument reprocessing protocols to include, among other improvements, the immersion of the shaver handpiece in a detergent (enzymatic) solution for 10 - 15 minutes during its "gross decontamination," to dislodge tissue and other contaminants from its suction channel prior to terminal sterilization^a. iii) The hospital promptly retrained its staff and revised its quality assurance protocols to include enhanced measures that better assure the adequate cleaning of the shaver handpiece's suction channel prior to its terminal sterilization. Recommended by the FDA, these measures included staff's use of a borescope (which is a 3-mm clinical video endoscope) to examine and inspect the reprocessed shaver handpiece's suction channel for remnant tissue (or fluids) after its cleaning and prior to terminal sterilization [3]. iv) The hospital may have begun using non-bristled brushes to clean the shaver handpiece's suction channel. v) The hospital promptly redesigned the gross decontamination room, where its instruments are cleaned prior to terminal sterilization, to improve workflow [1].

e) Corresponding outcome measures: In response to this outbreak, each of the following was presumably performed (although not each of these measures is discussed by Tosh *et al.* [2011]): i) Staff promptly inspected the inventory of instruments to confirm that the implicated arthroscopic instrumentation was removed from service. ii) The reprocessing practices of staff responsible for instrument reprocessing were periodically audited (and certified) to confirm compliance with the hospital's revised instrument reprocessing protocols (*i.e.*, the shaver handpiece's immersion in the detergent solution for 10 - 15 minutes during the gross decontamination steps and, presumably, its cleaning using non-bristled brushes). iii) Staff used a borescope (which is a 3-mm clinical video endoscope) to verify the effectiveness of the revised cleaning procedure and to ensure via visual examination that the reprocessed shaver handpiece's suction channel did not contain remnant tissue (or fluids) prior to terminal sterilization [3]. iv) Staff may have evaluated the efficiency of the workflow (*e.g.*, instrument reprocessing) in the redesigned gross decontamination room and made additional changes, as warranted.

2) More Instrument Design Considerations

a) Deviation: The lumen of the reusable arthroscopic inflow/outflow cannulae was inadequately cleaned, resulting in its remaining contaminated with remnant tissue.

b) Concern: The inadequate cleaning of the internal structures of any reusable surgical instrument poses an increased risk of ineffective sterilization and, therefore, of disease transmission. Tosh *et al.* (2011) report that this deviation was most likely the cause of this cluster of seven infections at Methodist Hospital in 2009. According to these authors, reusable arthroscopic inflow-outflow cannulae, as well as reusable arthroscopic shaver handpieces (*see:* above), remained contaminated with bioburden after cleaning, resulting in the introduction of *P. aeruginosa* into each patient's surgical site.

c) Some of this deviation's causes and/or contributing factors: i) The hospital used reusable inflow/outflow cannulae, the physical designs of which are complex and do not necessarily facilitate the adequate cleaning (and sterilization) of their internal lumens [1]. ii) Nor did the design of these cannulae reportedly facilitate the hospital's visual examination of its internal lumen (or the use of another simple, non-invasive, standardized, and validated procedure, tool or kit) to verify that it was adequately cleaned prior to terminal sterilization. iii) Despite the manufacturer's instructions recommending cleaning the cannulae's lumen using a brush, the hospital during the time of (and before) the outbreak instead "cleaned" the lumen by running tap water through it, which, according to Tosh *et al.* (2011), "likely contributed to the residual bioburden" identified within this lumen [1]. iv) The implicated inflow/outflow cannulae are reusable, although this review identified some marketed disposable counterparts.

d) Corresponding corrective actions or risk-reducing strategies: In response to this outbreak, several of the following measures were performed [1]: i) The hospital promptly retrained its staff and revised its instrument reprocessing protocol to require that the lumen of the inflow/outflow cannula be cleaned using a (non-bristled) brush, not merely rinsed with running tap water. ii) The hospital might also have promptly retrained its staff and revised its quality assurance protocols to include enhanced measures to better assure the adequate cleaning of the inflow/outflow cannula's lumen for retained tissue. iii) The manufacturer of the inflow/outflow cannula revised its cleaning instructions to be more detailed, complete, and to include its immersion in an enzymatic (and subsequently, a non-enzymatic) detergent solution for a minimum of 15 minutes [5]. iv) Because this review did identify some, the hospital could consider (if warranted and feasible) employing as a corrective action the use of a disposable (single-use) counterpart as a replacement for the implicated reusable inflow/outflow cannulae.

e) Corresponding outcome measures: In response to this outbreak, each of the following was presumably performed (although not each is discussed by Tosh *et al.* [2011]): i) The reprocessing practices of staff responsible for instrument reprocessing were periodically audited (and certified) to confirm compliance with the hospital's revised cleaning instructions (*i.e.*, using a non-bristled brush to clean the inflow/outflow cannula's lumen); and, too, with the manufacturer's updated reprocessing instructions, which were revised in March, 2011. ii) Although not specifically recommended by the FDA, staff might consider using a borescope (if warranted) to verify the effectiveness of the revised cleaning procedure and to ensure that the reprocessed inflow/outflow cannulae's lumen did not contain remnant tissue prior to terminal sterilization.

^aThe manufacturer's original instructions recommend that the shaver handpiece's suction channel be cleaned using a disposable bristled brush, followed by the handpiece's immersion in an enzymatic detergent, per the detergent's labeling, for "over 1 minute," followed by steam sterilization.

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3) Instrument Reprocessing Considerations

a) Deviation: i) Tosh *et al.* (2011) report that two “flash” autoclaves were used up to 6 times daily by Methodist Hospital during the outbreak period to flash sterilize some of the surgical instruments used on two of the case patients (and on 4 of the control patients). On rare occasions, these flash autoclaves reportedly were used for “routine sterilization [1].” ii) The logs of these flash autoclaves at the time of the outbreak were incomplete, lacking the patient’s name, operating room number, and instrument name. iii) At least in the context of the hospital’s use of the hydrogen peroxide gas plasma processor, “the sterilizer logs (at the time of the outbreak) revealed deficiencies in the documentation of biologic and chemical indicators that were performed on each load.” (iv) Individual instruments were not tracked at the time of the outbreak.

b) Concern: Guidelines contraindicate the use of flash sterilization for the routine sterilization of surgical instruments [18]. Moreover, the failure to maintain documentation verifying: (a) that each load, pack or container was processed and exposed to a sterilization process using a chemical indicator (or CI); and (b) that the sterilization process was routinely monitored as required (e.g., at least once a week) using a biological indicator (or BI) would preclude assurances that Methodist Hospital’s implicated arthroscopic instruments were exposed to a sterilization process and that, respectively, the process was functioning properly and achieving the conditions required for sterilization. Ineffective sterilization can result in the surgical instruments remaining contaminated and transmitting diseases¹. And, the hospital’s (inadvertent) failure, first, to maintain the completeness of a flash sterilizer’s log and, second, to track individual instruments precludes associating an increased risk of infection with a flash autoclave’s use or, respectively, with a specific instrument.

c) Some of this deviation’s causes and/or contributing factors: i) Flash sterilization may have been used more frequently than prudent or than guidelines recommend because: of its convenience and the brevity of its cycle; the location of the two flash autoclaves in the surgical pod where the majority of the case procedures were performed [1]; and limited resources likely resulting in a less than ideal number of arthroscopic instrument sets in inventory. ii) Maintaining the completeness of a flash autoclave’s log—like the documentation of the results of the BIs and CIs, whether using a hydrogen peroxide gas plasma processor or other type of sterilization process—can be inconvenient, time-consuming, and requires training and audits. iii) The hospital was not equipped with a system to track individual instruments at the time of Methodist Hospital’s outbreak.

d) Corresponding corrective actions or risk-reducing strategies: i) The hospital retrained staff and revised its reprocessing guidelines restricting the use of the flash autoclaves only to “emergency instances”—for example, when a surgical instrument falls onto the floor and the operating room and becomes potentially contaminated, requiring its prompt reprocessing for immediate use during the arthroscopic procedure [1]. ii) The hospital may have purchased additional arthroscopic instrument sets to significantly reduce its reliance, if not dependence, on flash sterilization. iii) The hospital likely retrained staff and revised its quality assurance protocols to ensure, first, the completeness of the flash autoclave’s log; second, that every load or instrument set was documented to be associated with a CI; and, third, that every sterilizer, including the hospital’s hydrogen peroxide gas plasma processor, was monitored, as frequently as required, using a BI. (iv) The hospital began tracking the individual instruments used during each surgical procedure [1].

e) Corresponding outcome measures: The following was presumably performed: i) The use of flash autoclaves by staff responsible for instrument cleaning and sterilization was periodically audited to confirm that the flash autoclave is used only in “emergency instances.” If flash sterilization was employed too casually, then the hospital might have been compelled to purchase additional arthroscopic instrument sets. ii) The sterilization practices of staff responsible for instrument cleaning and sterilization were periodically audited to confirm, first, the completeness of the flash autoclave’s log; second, that every load or instrument set was documented to be associated with a CI; and, third, that every sterilizer, including the hospital’s hydrogen peroxide gas plasma processor, was monitored, as frequently as required, using a BI. iii) “Mock” outbreak investigations may have been performed by the hospital to verify the effectiveness of the system employed to track the individual instruments used during each surgical procedure.

4) Environmental Considerations

a) Deviation: The drain of the sink in the hospital’s decontamination room was found to be contaminated with a biofilm of *P. aeruginosa* that was indistinguishable from the outbreak’s strain.

b) Concern: Sinks that are contaminated with biofilms of bacteria can become sources or reservoirs of infections and outbreaks [29,30]. These bacteria can be transmitted to patients during the cleaning of the surgical instruments in the sink; via water splashing; or, for example, by the hands of healthcare staff workers [1,23-25].

c) Some of this deviation’s causes and/or contributing factors: i) The decontamination room’s sink (including its drain) may not have been maintained or routinely cleaned and disinfected, to prevent the formation of a biofilm on its surfaces. ii) The sinks may not have been properly designed to prevent water splashing. iii) Proper hand hygiene measures, including drying, may not have been practiced.

d) Corresponding corrective actions or risk-reducing strategies: The following was presumably performed: i) The hospital retrained staff and reinforced the importance of proper maintenance and of both cleaning and disinfection of environmental (non-critical) surfaces, including the sink(s) in the decontamination area, as required to prevent the formation of bacterial biofilms. ii) The hospital assessed whether the sinks would require replacement and/or a new design (e.g., guards to prevent water splashing) during the acknowledged re-designing of the hospital’s gross decontamination room [1]. iii) Staffers were retrained in proper hand hygiene measures, including hand washing and drying.

e) Corresponding outcome measures: The following was also presumably performed: i) Staff were audited (and, as indicated, environmental samples collected and cultured) to confirm the effectiveness of the hospital’s measures to clean and disinfect the decontamination room’s sink and its surrounding environmental surfaces. ii) If splash guards (or another comparing engineering device) were employed, their effectiveness likely would have been assessed and verified. iii) The hand-washing practices of staff were periodically audited to confirm compliance with proper hand hygiene.

5) Miscellaneous Considerations

a) Deviation: Staff of Methodist Hospital observed and recorded the reflux of the intra-articular irrigant solution through the shaver handpiece at times when the suction tube was kinked or compressed during the arthroscopic procedure [1].

b) Concern: The reflux of an initially sterile irrigant through the contaminated suction channel of the shaver handpiece could result in contamination of the irrigant and surgical site [1].

c) Some of this deviation’s causes and/or contributing factors: Tosh *et al.* report that arthroscopy was performed during the time of the outbreak using kits that were equipped with easily compressible suction tubing. A medical supply company had reportedly replaced the original, more rigid

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suction tubing in these kits with this compressible suction tubing prior to Methodist Hospital's bacterial outbreak, without the hospital's knowledge [1].

d) Corresponding corrective actions or risk-reducing strategies: These arthroscopy kits were re-equipped with their original, more rigid suction tubing, which is less prone to kinking, compression, and to the reflux of irrigant from the shaver handpiece into the sterile surgical site during arthroscopy.

e) Corresponding outcome measures: The following was presumably performed: i) Periodic inspections were performed to ensure that these arthroscopy kits remained equipped at all times with the original, more rigid suction tubing. (Therefore, staffers were presumably trained on how to differentiate the original, more rigid suction tubing from the faulty, more easily compressible suction tubing.) ii) Surgeons may have been periodically interviewed to evaluate how effectively the original, more rigid suction tubing prevented the reflux of the intra-articular irrigant solution through the shaver handpiece.

This table lists: i) a number of deviations or non-conformances, most of which Tosh *et al.*'s (2011) investigation associated with Methodist Hospital's bacterial outbreak in 2009; ii) the concerns associated with these deviations; iii) some of these deviations' root causes and/or contributing factors; iv) the corrective actions or risk-reducing strategies that correspond to each of these causes or contributing factors; and v) corresponding outcome measures used to validate the effectiveness of these actions or strategies.

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