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Preventing Medical Device-Borne Outbreaks

The Case of High-Level Disinfection Policy for Duodenoscopes

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14.1 INTRODUCTION

Multiple outbreaks of antibiotic-resistant bacteria in recent years have been traced to contaminated duodenoscopes in health care facilities in the United States and Europe.[1] These events prompted intensive postmarket surveillance of three large duodenoscope manufacturers, the creation of voluntary hospital-based culturing programs,[2] and US Food and Drug Administration (FDA) safety warnings emphasizing the importance of following manufacturers' instructions for use (IFUs) for performing high-level disinfection (HLD) or sterilization of equipment, also known as reprocessing.[3] However, as outbreaks continued, the US Joint Commission made high-level disinfection or sterilization of all reusable scopes and probes a central component of its 2018 hospital accreditation programming.[4] This chapter highlights the regulations governing medical devices, the etiology of the duodenoscope outbreaks, and the policy measures implemented and regulatory challenges persisting in the wake of the outbreaks. Given the proliferation of scopes and probes in medical care – including outbreak settings of highly infectious diseases such as the Ebola virus disease[5] and carbapenem-resistant Enterobacteriaceae (CRE)[6] – reprocessing cannot and should not remain an abstract part of device regulation. Amplifying the perspective of infection prevention and control in the medical device regulatory landscape is critical to achieve optimal and sustainable reforms.

[1] Zachary A. Rubin & Rekha K. Murthy, Outbreaks Associated with Dudoenoscopes: New Challenges and Controversies, 29 Curr. Opin. Infect. Dis. 407 (Aug. 2016).

[2] US Food & Drug Admin., Infections Associated with Reprocessed Duodenoscopes, www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/infections-associated-reprocessed-duodenoscopes.

[3] Id.

[4] The Joint Commission, High Level Disinfection BoosterPak, www.dilon.com/wp-content/uploads/2020/05/Joint-Commision-HLD-and-Sterilization-BoosterPak.pdf.

[5] Patricia Henwood, Imaging an Outbreak: Ultrasound in An Ebola Treatment Unit, 381 N. Engl. J. Med. 6 (Jul. 2019).

[6] Rubin & Murthy, supra note 1.

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14.2 REGULATORY HISTORY AND DUODENOSCOPE OUTBREAKS

Under FDA regulations, devices fall into three classes. Duodenoscopes are categorized as Class II devices, which confer moderate risk and require regulatory controls such as the establishment of performance standards, postmarket surveillance, patient registries, and/or labeling requirements.[7] Class II devices require only premarket notification through the FDA's 510(k) pathway.[8] By contrast, Class III devices such as implantable pacemakers, which "support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury,"[9] require premarket approval (PMA), the most stringent type of device market application required by the FDA.

Yet despite its classification as a Class II device, duodenoscopes were linked to at least twenty-five outbreaks of CRE between 2012 and 2015.[10] The actual toll was likely far higher, but unknown given gaps in reporting and surveillance.[11] By early 2013, the manufacturer Olympus knew of two independent lab reports, which found that one of their duodenoscope models featuring a difficult-to-access elevator channel could harbor bacteria even after cleaning according to the manufacturer's instructions.[12] Even though the FDA began investigating elevator channels in 2013 in collaboration with the Centers for Disease Control and Prevention (CDC), Olympus did not forward the laboratory reports to the FDA or alert US hospitals, physicians, or patients to the risk of infection until February 2015.[13] Further investigation revealed that two major duodenoscope manufacturers failed to pursue a new 510(k) premarket notification prior to bringing their devices with elevator channels to market. Custom Ultrasonics, the manufacturer of an automated reprocessor that was implicated in some outbreaks, also failed to report critical updates to their device to FDA as required by law.[14] Finally, the FDA was also unaware of manufacturer warnings to European regulators that had occurred as early as 2013.[15]

These events highlighted various inadequacies in manufacturer reporting, hospital investigation, and regulator action, which prompted the CDC and FDA to reexamine reprocessing IFUs. In March 2015, the CDC released an interim duodenoscope surveillance protocol for health care facilities in cooperation with the FDA

[7] US Food & Drug Admin., Regulatory Controls, www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls.
[8] Id.
[9] US Food & Drug Admin., Premarket Approval, www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma.
[10] Health, Education, Labor Pensions Committee, U.S. Senate, Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients (2016).
[11] Id.
[12] Id.
[13] Id.; US Food & Drug Admin., supra note 2.
[14] Health, Education, Labor Pensions Committee, supra note 10.
[15] Id.

and the American Society for Microbiology (ASM).[16] In October of the same year, the FDA ordered three major duodenoscope manufacturers to conduct postmarket surveillance studies to better understand duodenoscope-transmitted infections.[17]

However, it was not until June 2017 that the FDA promulgated regulations to require manufacturers of certain high-risk reusable Class II medical devices to include validated IFUs regarding cleaning, disinfection, and sterilization in their premarket notification 510(k).[18] These regulations acknowledged that the design of some devices, such as those with lumens or crevices, were higher risk than others.[19] Additionally, the regulations emphasized the importance of the validated instructions not only for automated reprocessors and washing devices, but also for such high-risk devices.[20]

Over the next four years, the FDA released six general updates of reprocessing instructions, twelve general communications on duodenoscopes, and sixteen public correspondences to duodenoscope manufacturers.[21] In November 2015, there was a mandatory recall of Custom Ultrasonics reprocessors and in February 2018, the FDA, CDC, and ASM released voluntary standardized protocols for duodenoscope surveillance culturing.[22] Yet in an August 2019 safety communication, the FDA's postmarket surveillance report noted a continued "elevated rates of contamination, including the presence of high concern organisms" such as E. Coli and Pseudomonas aeruginosa, highlighting persisting concerns of HLD and complex endoscope design.[23]

These concerns have helped fuel a growing market for single-use equipment, with manufacturers of varying scopes and probes developing completely disposable designs. In November 2019, the FDA recommended transitioning to duodenoscopes with disposable components and one month later, gave market clearance for the first fully disposable duodenoscope.[24]

14.3 CHALLENGES

Amid this backdrop, several practical difficulties and regulatory challenges remain. First, although IFUs for reprocessing higher-risk medical devices must now be

16 US Food & Drug Admin., supra note 2.
17 Id.
18 Health, Education, Labor Pensions Committee, supra note 10; infra note 19.
19 Medical Devices: Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications, 82 Fed. Reg. 26,807 (June 2017).
20 Id.
21 US Food & Drug Admin., supra note 2.
22 Health, Education, Labor Pensions Committee, supra note 10; US Food & Drug Admin., FDA Webinar: Duodenoscope Sampling and Culturing, www.fda.gov/media/112402/download.
23 US Food & Drug Admin., supra note 2.
24 US Food & Drug Admin., FDA recommending transition to duodenoscopes with Innovative Designs to Enhance Safety, www.fda.gov/medical-devices/safety-communications/fda-recommending-transition-duodenoscopes-innovative-designs-enhance-safety-fda-safety-communication; US Food & Drug Admin., New Release: FDA Clears First Fully Disposable Duodenoscope, www.fda.gov/news-events/press-announcements/fda-clears-first-fully-disposable-duodenoscope-eliminating-potential-infections-caused-ineffective.

validated in accordance with FDA regulation, processes for validation are not standardized and are often unclear. Current FDA guidance refers manufacturers to technical information reports (TIRs) developed by the Association for the Advancement of Medical Instrumentation (AAMI), specifically AAMI TIR 2 ("labeling instructions for reusable medical device") and TIR 30 ("compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices").[25] However, most AAMI TIRs were last published in 2010 and are in critical need of updating.

In 2015, AAMI published the more rigorous "Standard 91: Flexible and semi-rigid endoscope processing in healthcare facilities," which outlines facility-level quality control practices, addresses human factors issues related to reprocessing, and comments on the design and flow of reprocessing departments.[26] Yet full implementation of this standard, including cleaning verification processes, schedules, and tracking and tracing of all related endoscope equipment, remains challenging.[27] Additionally, given rapid advances in disinfection and sterilization science and changes in regulation, this guidance also requires updating.[28] Work on this has been ongoing since early 2019, but a new draft document had not yet been released as of December 2020.[29]

Thus, over the past decade, manufacturers have largely been left to author IFUs without clear guidance as to what is an acceptable or standard cleaning protocol,[30] resulting in widespread variation in how IFUs are structured and written, the methods used to demonstrate that effective disinfection has occurred, and storage and handling practices.[31] For example, there are no agreed-upon standards to assess if proper cleaning (e.g., detection of protein versus blood versus microbial DNA) has occurred,[32] when older equipment should be sent for maintenance, repair, or replacement, or whether borescopes – an optical device – should be used to detect microscopic rips or tears, particularly in otherwise inaccessible cavities.[33]

[25] US Food & Drug Admin., Reprocessing Medical Devices in HealthCare Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff Document, www.fda.gov/media/80265/download.

[26] Am. Ass'n Med. Instrumentation, ANSI/AAMI ST91:2015 Flexible and semi-rigid endoscope processing in healthcare facilities, www.aami.org/standards/aami-st91.

[27] Beyond Clean Podcast, infra note 29; Judie Bringhurst, Special Problems Associated with Reprocessing Instruments in Outpatient Care Facilities: Physical Spaces, Education, Infection Preventionists, Industry Reflections, 47 Am. J. Infect. Control A58 (June 2019).

[28] Am. Ass'n Med. Instrumentation, supra note 26; Beyond Clean Podcast, infra note 29.

[29] Beyond Clean Podcast, Mary Ann Drosnock: AAMI Overview, ST91 Update, Flexible Scope Reprocessing, https://beyondclean.libsyn.com/mary-ann-drosnock.

[30] Ralph Basile, AAMI TIR 12 and the Future of Device Processing Instructions, 53 Biomedical Instrumentation & Tech. 67 (Jan. 2019).

[31] Id.; US Food & Drug Admin., Factors Affecting Quality of Reprocessing, www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/factors-affecting-quality-reprocessing.

[32] US Food & Drug Admin., FDA Webinar: Duodenoscope Sampling and Culturing, www.fda.gov/media/112402/download; US Food & Drug Admin., supra note 25.

[33] Id.; Am. Ass'n Med. Instrumentation, supra note 26; Bringhurst, supra note 27.

Particularly critical to the disinfection process are manual precleaning steps. Although the FDA requires that reprocessing instructions "should be understandable,"[34] many IFUs are dense and difficult to follow (some IFUs exceed 100 pages). In mandated human factors postmarketing surveillance studies conducted by Fujifilm and Olympus, "most participants expressed some difficulty adhering to the reprocessing manual," with one study concluding that the materials "are not sufficient to consistently ensure user adherence in these core reprocessing areas: precleaning, manual cleaning, manual high-level disinfection, rinsing, and storage and disposal."[35]

IFUs can also contradict guidance from professional societies, which can be in conflict with each other. For example, the Society of Gastroenterology Nurses, the Association for Professionals in Infection Control and Epidemiology, and the Association of Perioperative Registered Nurses all have different recommendations on storage and "hang time" – the maximum duration of storage time before the endoscope is processed for next use.[36] Recognizing such variability, the Joint Commission recently released its own clarification for hospitals, outlining that the IFU remains paramount to professional society guidance and consensus documents. Yet, gaps remain when IFUs are nonspecific or do not address key concerns, leaving hospitals in the position of having to reach out to manufacturers directly.[37]

The interplay between IFUs can also be a challenge. While device manufacturers create their own IFUs, they typically do so separately from the manufacturers of automated reprocessors and high-level disinfectants.[38] This creates another layer of complexity for end users in health care facilities, particularly those that use manual methods of disinfection. In reconciling IFUs, a hospital's ability to swiftly recognize concerns and call attention to appropriate leadership can be hampered.[39] Some device manufacturers of scopes create their own reprocessing equipment exclusively for their own devices,[40] which can mitigate the burden of IFU coordination but can

[34] Supra note 19; Basile, supra note 30.

[35] US Food & Drug Admin., supra note 24; US Food & Drug Admin., Factors Affecting Quality of Reprocessing, www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/factors-affecting-quality-reprocessing; US Food & Drug Admin., 522 Postmarket Surveillance Studies, www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm.

[36] Am. Ass'n Med. Instrumentation, supra note 26.

[37] The Joint Commission, Clarifying Infection Control Policy Requirements, 39 Perspectives (Apr. 2019); The Joint Commission, Manufacturer's Instructions for Use- Addressing Conflicts Amongst IFUs for Different Equipment and Products: Frequently Asked Questions, (Apr. 2020), www.jointcommission.org/standards/standard-faqs/hospital-and-hospital-clinics/infection-prevention-and-control-ic/000002252/.

[38] Bringhurst, supra note 27; US Food & Drug Admin., Information about Automated Endoscope Reprocessors and FDA's Evaluation, www.fda.gov/medical-devices/reprocessing-reusable-medical-devices/information-about-automated-endoscope-reprocessors-aers-and-fdas-evaluation.

[39] Supra note 19; Bringhurst, supra note 27.

[40] Olympus, Olympus Investor Day 2017: Medical Business Strategy, www.olympus-global.com/ir/data/pdf/id_2017e_03.pdf.

also result in undue contractual leverage, limiting the ability of hospitals to diversify their inventories.

More broadly, concern exists that HLD may be insufficient for scopes.[41] The decades-old Spaulding criteria outlines the use of HLD for semi-critical devices such as scopes and sterilization for critical devices such as surgical instruments.[42] Performing HLD typically results in a 6-$\log_{10}$ reduction of micro-organisms, whereas sterilization results in at least a 12-$\log_{10}$ reduction.[43] However, flexible endoscopes acquire high levels of microbial contamination or bioburden during each use, and may contain ten[44] enteric micro-organisms after use, with buildup around closed channels.[45] Accordingly, some infection prevention experts refer to HLD as creating a "nonexistent margin of safety" that is unable to achieve disinfection consistently.[46]

Challenges also exist with sterilization. Typical scope materials cannot handle the high temperatures required for the most commonly available and robust methods of sterilization (i.e., steam).[47] Additionally, existing sterilants have notable drawbacks. For example, ethylene oxide, a sterilant for rigid scopes, requires lengthy processing and aeration time.[48] In high quantities, it also poses health hazards, including carcinogen risk.[49] Because of this risk, ethylene oxide is unavailable in many US hospitals. In 2019, two large device facilities were closed by state environmental protection agencies in response to higher than acceptable levels of ethylene oxide in the air, creating abrupt shortages of sterilized devices.[50]

Finally, while the market for single-use equipment may be viewed as a clear path forward, inadequate attention has been given to associated waste streams. Use of disposable duodenoscopes[51] would contribute to the market growth of disposable

[41] William A. Rutala & David J. Weber, Disinfection, Sterilization, and Antisepsis: An Overview, 47 Am. J. Infect. Control A3 (June 2019); Rutala & Kanamori, infra note 43; Spaulding, infra note 42.

[42] E.H. Spaulding, Chemical Disinfection of Medical and Surgical Materials, in Disinfection, Sterilization and Preservation (C. Lawrence & S.S. Block eds., 1968).

[43] William A. Rutala et al., What's New in Reprocessing Endoscopes? Are We Going to Ensure "The Needs of the Patient Come First" by Shifting from Disinfection Sterilization?, 47 Am. J. Infect. Control A62 (June 2019).

[44] Health, Education, Labor Pensions Committee, supra note 10; supra note 19; US Food & Drug Admin., supra note 24; US Food & Drug Admin., supra note 32.

[45] Rutala et al., supra note 43.

[46] Id.; Rutala & Weber, infra note 48.

[47] Rutala & Weber, infra note 48; US Envtl. Protection Agency, Ethylene Oxide, https://cfpub.epa.gov/ncea/iris2/chemicalLanding.cfm?substance_nmbr=1025.

[48] Willian A. Rutala & David J. Weber, CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf.

[49] Id.; US Envtl. Protection Agency, supra note 47; Caryn Roni Rabin, To Prevent Deadly Infections, FDA Approves the First Disposable 'Scope', N.Y. Times (Dec. 13, 2019).

[50] US Food & Drug Admin., Statement on concerns with medical device availability due to certain sterilization facility closures, www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-2-reduce-ethylene-oxide-emissions (last visited July 6, 2020).

[51] V. Raman Muthusamy et al., Clinical Evaluation of a Single-Use Duodenoscope for Endoscopic Retrograde Cholangiopancreatography, 18 Clin. Gastroenterol. Hepatol. 2108 (Nov. 2019).

designs for other scopes and probes, but the environmental footprint of single-use equipment has yet to be modeled nationally and internationally.[52] In one study, single-use laryngoscope handles generated an estimated sixteen to eighteen times more lifecycle carbon dioxide equivalents (CO_2-eq) than traditional low-level disinfection of the reusable steel handle, and single-use plastic tongue blades generated an estimated five to six times more CO_2-eq than the reusable steel blade treated with high-level disinfection.[53] However, some studies suggest higher emissions of Co_2-eq may be offset by the cost of personal protective equipment (PPE), and that the energy consumption of reprocessing equipment also needs to be considered.[54] These comments underscore the need for further data points to build comprehensive models.

14.4 SOLUTIONS AND FUTURE DISCUSSION

Addressing the above challenges requires engagement between manufacturers, clinicians, regulators, central processing departments, infection prevention and control leadership, and health care administrators. Inconsistencies between IFUs and the lack of transparency and standardization around validation in all domains – precleaning, disinfection, storage, maintenance, and repair – should be key priorities for the FDA and AAMI. Encouragingly, updates to key TIRs are in progress.[55] While working groups developing these documents include diverse stakeholders, including key manufacturers, regulators, and infection prevention experts, TIRs are not made available for public comment.[56] The AAMI standards are made available for public comment, but are solicited by notice in "appropriate AAMI publications or on the AAMI website."[57] Making drafts of TIRs under review publicly available for comment, and making AAMI standards more widely available for review may present opportunities for improvement and promote swifter uptake by manufacturers and health care facilities.[58] Additionally, ensuring timely and concordant adoption of TIRs by the CMS could help ensure that health care facilities and manufacturers keep up to date.

[52] Sherman, infra note 53; Niall F. Davis et al., Carbon Footprint in Flexible Ureteroscopy: A Comparative Study on the Environmental Impact of Reusable and Single Use Ureteroscopes, 32 J. Endourology 214 (Mar. 2018); Sorenson & Gruttner, infra note 54.

[53] Jodi D. Sherman et al., Life Cycle Assessment and Costing Methods for Device Procurement: Comparing Reusable and Single Use Disposable Laryngoscopes, 127 Crit. Care & Resuscitation 434 (Aug. 2018).

[54] Birgitte L. Sorenson & Henrik Gruttner, Comparative Study on Environmental Impacts of Reusable and Single Use Bronchoscopes, 7 Am. J. Envtl. Protection 55 (2018).

[55] Beyond Clean Podcast, supra note 29; Basile, supra note 30.

[56] Am. Ass'n Med. Instrumentation, Development of Consensus Standards and TIRs, www.aami.org/standards/how-are-standards-developed/standards-policies-and-procedures-intro/development-of-standards-and-tirs.

[57] Id.

[58] Bringhurst, supra note 27; Basile, supra note 30.

Even with updated AAMI standards, however, implementation will remain a challenge. To facilitate optimal execution, health care administrators should seek to invest in competency and training programs for reprocessing staff and consider including them in contracted services with manufacturers and vendors.[59] Coordination of IFUs across vendors requires close coordination of health care facility infection prevention and control, biomedical/clinical engineering, supply chain, and contracting departments. While committees comprised of representatives from these groups may be found at many large acute care inpatient centers, they may not exist in ambulatory settings or surgical centers, where procedures are common.[60] The absence of such committees should be considered in a facility's gap analysis and should be examined as part of regulatory and reaccreditation requirements.[61]

Since the outbreaks began in 2012, the FDA has expanded its ability to examine the regulatory controls for medical device regulation. The Medical Device Innovation Consortium (MDIC) is a 501(c)(3) public-private partnership with the objective of advancing approaches that "promote patient access to innovative medical technologies and the use of real world evidence in guiding the needs for all stakeholders."[36] As part of the MDIC, the National Evaluation System for Health Technology coordinating center (NESTcc) aims to conduct "efficient and real-world evidence studies throughout the total product life cycle," to "develop, verify, and operationalize methods of evidence generation" and data use in both the pre and postmarket space, and to bring together stakeholders, including the voice and preferences of the patient.[62] The MDIC patient-centered benefit-risk framework creates decision analysis models that evaluate tradeoffs such as risk of infection or associated length of stay associated with a device that a patient may consider.[63] However, the MDIC and NESTcc should ensure the completeness of data to inform such metrics. For example, the risks of device-associated infection cannot be properly quantified without understanding real-world gaps in IFUs related to disinfection and sterilization.

The NESTcc could also elevate its voice in the postmarket space. In partnership with the FDA, the MDIC should continue to support and use evidence from medical device safety reporting by hospitals and device manufacturers through portals like the MedWatch and MedSun.[64] The MDIC and the NESTcc could also offer support in the design and development of postmarket surveillance studies.

[59] Basile, supra note 30.
[60] Bringhurst, supra note 27.
[61] Id.; Rose Seavey, Using a Systematic Approach for Adopting New Technologies in Sterile Processing Departments and Operating Rooms, 47 Am. J. Infect. Control A67 (June 2019).
[62] Med. Device Innovation Ctr., National Evaluation System for health Technology Coordinating Center, Overview, https://nestcc.org/about/about-us/.
[63] Med. Device Innovation Ctr., Medical Device Innovation Consortium (MDIC) Patient Centered Benefit-Risk Project Report, www.fda.gov/media/95591/download.
[64] Med. Device Innovation Ctr., supra note 62.

Though small, the human factors studies mandated by the FDA for Fujifilm and Olympus manufacturers in postmarket surveillance were revealing.[65] In particular, they plainly demonstrated the difficulty in adhering to complex IFUs.[66] If these studies were part of active surveillance in the postmarket period, they could offer critical and earlier insight for manufacturers, health care personnel, and the FDA.

In appreciating the pitfalls of complex IFUs, many infection prevention and control experts have called for the reclassification of scopes as critical devices that require sterilization.[67] There is regulatory precedent for such action. In 1992, the FDA mandated a shift from disinfection to sterilization for dental handpieces, even though there were no documented cases of disease transmission associated with dental hand pieces.[68] Professional societies should support this transition, and accreditation agencies should start developing standards to facilitate institutional accountability.[69]

Incentives will likely be needed to encourage further development of sterilization options, including low temperature sterilization technologies (LTSTs). The FDA recently started this process, announcing in November 2019 four participants in an "innovation challenge" to identify disinfection and sterilization alternatives that can be implemented at a large scale and maintain high throughput.[70] Two of these participants will focus on the use of vaporized hydrogen peroxide technology that is currently being used on a large scale to disinfect respirators during the COVID-19 pandemic.[71] While participation does not constitute "regulatory acceptance," manufacturers should expect that the FDA remains committed to expeditiously clearing LTSTs as they are developed if safety and effectiveness standards are met.[38] In turn, manufacturers should commit to the FDA's endorsement of creating scopes with innovative designs, including manufacturing scopes with materials that are compatible with LTSTs.[72]

More recently, the FDA announced a second innovation challenge to decrease ethylene oxide emissions.[73] In parallel and in light of closures of sterilization facilities due to high ethylene oxide emissions, the US Environmental Protection

[65] US Food & Drug Admin., supra note 35.
[66] US Food & Drug Admin., supra note 24; US Food & Drug Admin., supra note 35.
[67] Rutala & Weber, supra note 41; Rutala et al., supra note 43; Rutala & Weber, supra note 48.
[68] Rutala et al., supra note 43.
[69] Id.
[70] US Food & Drug Admin., FDA Innovation Challenge 1: Identify New Sterilization Methods and Technologies, www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-1-identify-new-sterilization-methods-and-technologies.
[71] US Food & Drug Admin., Investigating Decontamination and Reuse of Respirators in Public Health Emergencies, www.fda.gov/emergency-preparedness-and-response/mcm-regulatory-science/investigating-decontamination-and-reuse-respirators-public-health-emergencies.
[72] US Food & Drug Admin., New Release: FDA Clears First Fully Disposable Duodenoscope, www.fda.gov/news-events/press-announcements/fda-clears-first-fully-disposable-duodenoscope-eliminating-potential-infections-caused-ineffective; Rutala et al., supra note 43.
[73] US Food & Drug Admin., FDA Innovation Challenge 2: Reduce Ethylene Oxide Emissions, www.fda.gov/medical-devices/general-hospital-devices-and-supplies/fda-innovation-challenge-2-reduce-ethylene-oxide-emissions.

Agency (EPA) issued a notice of proposed rulemaking to solicit information from industry and the public on strategies for further reducing ethylene oxide emissions from commercial sterilization and fumigation operations. This includes reviewing and updating regulations for sources that emit ethylene oxide and to better understand and address ethylene oxide emissions at facilities.[74] Such interagency coordination will be needed to more identify the optimal role of ethylene oxide in medical device sterilization, the effects of endoscope sterilization, and the impact on the supply chain and transportation operations.[75]

Finally, hospitals and clinics will need to consider the far-reaching impacts of incorporating disposable equipment, especially as pathogens of high consequence such as CRE, take hold.[76] Hospitals and clinics will need to partner and engage early with major biomedical waste companies and recycling vendors both in the United States and globally to create a regulated, functional waste stream.[77] These groups will need to understand large throughput hospital- and clinic-based workflows, calculate new labor costs, and consider implications for their supply chains. Corporate social responsibility platforms should expand to account for the impact of such activities and integrate this work into ongoing sustainability efforts, including tracking fleet and incinerator emissions.[78] To more fully weigh complete environmental impact, cradle-to-grave lifecycle assessment and lifecycle costing methods should be used.[79] For example, the EPA's Tool for the Reduction and Assessment of Chemical and other Environmental Impacts can be used to model environmental impacts of greenhouse gases and other pollutant emissions.[80] As is required to examine ethylene oxide impacts, a sustained FDA and EPA partnership can help, facilitating detailed data gathering to inform national and international economic and environmental analyses. This effort should discuss how to weigh energy consumption of reprocessing departments and facilities, human labor costs, and PPE usage.

While the NESTcc represent the FDA's efforts to modernize the 510(k) process, the FDA will need to embed both the perspectives of infection control and environmental sustainability to transform its approach.[81] In particular, understanding the

[74] US Envtl. Protection Agency, EPA Seeks Input on Strategies to Reduce Ethylene Oxide Emissions from Commercial Sterilizer Operations, www.epa.gov/newsreleases/epa-seeks-input-strategies-reduce-ethylene-oxide-emissions-commercial-sterilizer.

[75] Id.; US Food & Drug Admin., supra note 73.

[76] Muthusamy et al., supra note 51; J.Y. Bang et al., Concept of Disposable Duodenoscope: At What Cost?, 68 Gut 1915 (2019).

[77] Rabin, supra note 49; Sharps Compliance, infra note 78.

[78] Sharps Compliance, Inc., Incineration and Treatment, www.sharpsinc.com/high-temperature-incineration; Stericycle 2019 Corporate Social Responsibility Overview, www.stericycle.com/white-papers/corporate-social-responsibility-2019.

[79] Sherman et al., supra note 53; Davis et al., supra note 52; Sorenson & Gruttner, supra note 54.

[80] Sherman et al., supra note 53.

[81] US Food & Drug Admin., Statement from FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health, on transformative new steps to modernize the FDA's 510(k) program to advance the review of the safety and effectiveness of medical

tradeoffs associated with sustainable production and consumptions practices can shift the FDA approach from reactive to proactive.[82]

14.5 CONCLUSIONS

High-level disinfection and sterilization of medical equipment has slowly evolved over the past three decades. The outbreaks of drug-resistant bacteria traced to contaminated duodenoscopes offer a case study in understanding the gaps in medical device regulation. Although the FDA has made strides in closing these gaps, important and critical problems persist; the concerns exposed in the duodenoscope outbreaks expand beyond scopes and spans larger concerns around device design, cleaning, disinfection, management, uptake and care. Together, these experiences call for a greater voice for infection prevention and control in the medical device ecosystem. The NESTcc and the FDA's ongoing private-public partnership consolidate national efforts for medical device safety: minimizing disease transmission and considering environmental harms should be part of that mission.

devices, www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-jeff-shuren-md-director-center-devices-and.

[82] Andrea J. MacNeill et al., Transforming the Medical Device Industry: Road Map to a Circular Economy, 39 Health Aff. 2088 (2020).

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