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Sustainability of Single-Use Endoscopes

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Abstract

Interest in single-use, disposable endoscopes has been growing due to concerns about infection transmission with reusable endoscopes. Yet valid concerns remain about the sustainability of single-use endoscopes in the form of long-term economic, environmental, and social consequences, even with the assumption that single-use endoscopes eliminate infection risk completely, are technically equivalent, and are cost-neutral to patients and hospitals when compared with reusable endoscopes. Economic sustainability extends beyond the per unit cost of single-use endoscopes to the concept of economic growth without adverse effects on the environment and society. Environmental sustainability is responsibly interacting with the planet to protect and conserve natural resources to support health and well-being, now and in the future. Environmental sustainability is influenced by all stages in the life cycle of an endoscope including manufacturing, transport, use, and disposal, most of which remains obscured to hospitals and physicians. Social sustainability, the recognition of and a commitment to, ensure that new medical devices are available to all patients and that the manufacture, use, and disposal of medical devices does not harm others, particularly vulnerable populations. Physicians and hospitals deliberating the adoption of single-use endoscopes should carefully consider the full extent of sustainability and long-term consequences in their discussions.

Keywords: Single-use; Disposable; Sustainability; Environmental; Economic; Duodenoscope; Infection transmission; Equity; Pollution; Waste; Incineration; High-level disinfection; Endoscopy; ERCP.

Introduction

Single-use (disposable) duodenoscopes have recently been introduced in the market in response to concerns about infection transmission by reusable endoscopes. Introduction of any new technology, especially those which are complex and costly, mandates physicians to carefully weigh the consequences of adoption in the context of their core obligations to promote the well-being of individual patients, preserve public health, and act as prudent stewards of the shared societal resources with which they are entrusted.[1] These obligations are complementary, particularly when we take the long-term perspective and understand that resources are finite. Costs of healthcare continue to rise to unsustainable levels despite recognition of these obligations.[2]

Before widespread adoption of single-use endoscopes, it is essential to understand and determine its economic, social, and environmental impact on the society especially in years to come. Climate change is considered the biggest global health threat of the 21st century.[3] Physicians are uniquely poised to not only treat environment-related health problems but to raise awareness and mitigate the effects of climate change. The US healthcare system contributes 10% of the nation's carbon emissions, which increased by 30% between 2006 and 2016. This leads to an estimated indirect health burden equivalent to the 44,000-98,000 people who die in hospitals each year in the United States as a result of preventable medical errors.[4] Yet, unlike with medical errors, environmental costs of healthcare remain largely unreported, unrecognized, and disregarded in favor of short-term interests. The trend toward single-use surgical equipment may be an example of these unsustainable practices. While initially confined to small and inexpensive items such as single-use gloves, needles, syringes, and intravenous tubing, single-use has expanded to sophisticated and expensive equipment such as trocars, staplers, robotic surgical equipment, and endoscopes. Many of these complex single-use products were launched, accepted, and promoted based on utility, convenience, and profits with little consideration for sustainability and environmental impact. Although unsustainable, these practices are so entrenched in the healthcare system that they are exceedingly difficult to change. Single-use endoscopes are still relatively new to the market and we have an opportunity and a mandate to deliberately factor sustainability into our decisions about utilizing these devices.

What Is Sustainability?

Any discussion about sustainability must begin with a definition of the term sustainability. Over the years sustainability has grown from a concept, to a study, a trend,

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and a multibillion-dollar industry. To many, sustainability is a blanket term for all activities, products, and services that take some step to cause less harm to the environment. However, the concept of sustainability extends well beyond purely environmental concerns.

The word "sustainability" entered mainstream use after the release of the widely popular and controversial book "Limits to Growth" in 1972, wherein scientists used computer modeling to emphasize that continued exponential economic and population growth in the world would overwhelm the earth's natural resources and result in ultimate collapse.[5] The report directed global attention on the long-term consequences of uninhibited growth.

The most widely used definition of sustainability comes from a United Nations Commission formed to address growing social, health, and environmental inequities between countries following worldwide industrialization. It had become increasingly apparent that economic development at the cost of ecological health and social equity will not lead to long-lasting prosperity. The commission was chaired by former Norwegian prime minister Gro Harlem Brundtland. The Brundtland Commission in its final report in 1987, *Our Common Future*, defined sustainable development as "development which meets the needs of current generations without compromising the ability of future generations to meet their own needs."[6] In doing so, it firmly entrenched economic growth with social and environmental costs (Figure 1).

Sustainability is now entrenched in the vocabulary of administrators, planners, and executives operating at a much more local level and with much shorter time horizons. As a result, many healthcare solutions claim to be sustainable, but on closer inspection, are merely "less unsustainable." On occasion, even well-intentioned sustainability initiatives create new problems. Take the example of the rise of electric vehicles driven by imperatives to decarbonize and reduce greenhouse gases. While electric vehicles are emission free, significant amounts of energy and environmental resources are used to mine and refine battery materials as well as manufacture and ship batteries. In Chile's Salar de Atacama region, a major center of lithium production, 65% of the region's water is consumed by mining activities. This affects farmers in the area who must then import water from other regions.[7] The high demand for cobalt used in making of lithium batteries has led to illegal mining and child labor, a scenario that the Brundtland Commission specifically hoped to avoid. Disposal and recycling of millions of lithium batteries at the end of their life cycle is another big environmental concern.[7] Finding a practical solution will take time, meanwhile the global electric vehicle market is expected to continue growing at almost 40% in next 7 years.[8]

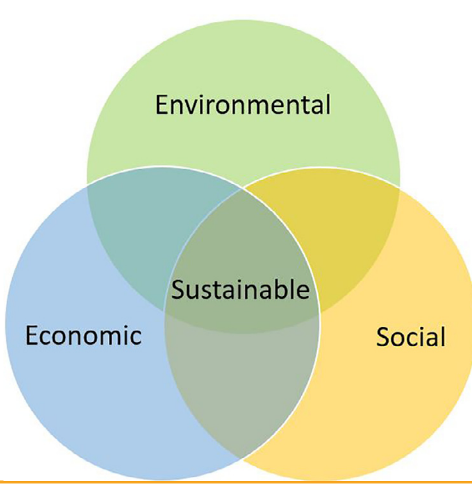

Figure 1. Components of Sustainability.

Sustainability is a complex global issue that affects people at all levels. The United Nations 2030 Agenda for Sustainable Development specifically addresses diverse and interrelated issues of poverty, hunger, reducing inequality within and among countries, responsible consumption and production, access to justice for all, and promotion of peaceful societies.[9] In the last few years, some private companies have shown remarkable ownership, ability, and agility to find sustainability solutions but the healthcare industry often lags behind. In this review, keeping in mind the scope of the paper and readers' interests, our focus is on the sustainability of single-use endoscopes as reflected by costs of care, environmental, and social impacts.

The Scope of the Problem

The main reason for adopting single-use endoscopes is to eliminate the risk of infection from reusable endoscopes. Following case reports of clusters of infection with multidrug resistance bacteria traced to contaminated duodenoscopes, studies were performed in which cultures were obtained from different parts of the endoscopes after high-level disinfection. These studies demonstrated that most of the residual contamination was at the distal end of the duodenoscopes, where a fixed plastic or rubber cap is permanently glued to the metal edges to prevent tissue injury. This design limits accessibility for cleaning the crevices at the distal end. The reported contamination incidence rates for duodenoscopes have a wide range, likely due to different study designs and culture methods. A postmarket surveillance study by the US Food and Drug Administration (FDA), reported a 9% contamination rate for duodenoscopes.[10] Ofstead et al assessed endoscope reprocessing, drying, and storage practices at 3 hospitals and detected microbial growth in 71% of endoscopes. They examined 45 endoscopes of which only 5 were duodenoscopes. In this study, the authors reported multiple breaches in recommended endoscope cleaning protocols.[11] Their findings were mirrored by an FDA study on human errors associated with manual reprocessing of duodenoscopes, which showed that 87% of the participants failed to complete the recommended elevator brushing task.[12] High contamination rates in gastroscopes and colonoscopes suggest reasons other than endoscope tip design such as persistence of biofilms in biopsy channels and inadequate drying of the endoscopes. Contamination is simply presence of microorganisms on or inside the endoscope and does not necessarily portend infection, which is the transmission of organisms to patients, generally accepted as bacteremia or presence of blood-borne infection. Estimated rates of infection have a wide range from 1 in 1.8 million to 1 in 276,000 due to inconsistencies in defining both the numerator (number of infections) and the denominator (number of procedures).[13] Irrespective of this variation in estimated incidence, the actual risk of a patient of becoming infected by a contaminated endoscope seems to be exceptionally low.

Given unclear data on the prevalence of the problem, how assiduously should we act to prevent endoscope associated infections? The FDA recently recommended moving away from using duodenoscopes with fixed endcaps to those with single-use components that include single-use endcaps or to fully single-use duodenoscopes.[14] The American Society of Gastrointestinal Endoscopy also announced its commitment to achieving the goal of zero duodenoscope associated infections[15]—in other words, these infections were deemed a "never event" in the parlance of the National Quality Forum. Yet whether duodenoscope associated infections truly fit the definition of a "never event" and is a meaningful and realistic goal should be further considered. The National Quality Forum defines serious reportable events (SRE) as healthcare events that are adverse, indicative of a problem in a healthcare setting's safety systems, and important for public credibility or public accountability.[16] "Never events" are certain SREs that unambiguously fit the above definition, such as wrong patient or wrong site surgeries, and are universally preventable and should never occur. However, other SREs such as serious injury from patient falls in a hospital, may only be largely but not universally preventable due to complex causes that are difficult to alter or infeasible to eliminate. Guidelines recommend multifactorial interventions including medical devices, patient screening, and changes in the physical environment.[17,18] Fall prevention could have been treated as a "never event" and eliminated with resource intensive methods such as permanent staff supervision of patients, but such methods are neither feasible nor sustainable.

Indeed, healthcare providers and systems routinely accept certain low levels of risk for patients including other infection risks that are routinely overlooked and widely accepted. For example, surgical site infections are the second most common cause of Healthcare-Associated Infections with an overall incidence rate of about 2.6% in the United States.[19,20] An estimated 50%-70% of all Healthcare-Associated Infections are transmitted through the hands of healthcare workers. Studies have found contamination rates of >80% on mobile phones in the operating room while the surgeon is scrubbed in surgery. Although no direct causation has been established, cell phones likely are a contributory factor since the microbial contamination of the hands and cell phones is similar. It is recommended that mobile devices be properly cleaned and disinfected prior to being brought into the operating room, preoperative, and postoperative areas[21,22] yet very few healthcare workers clean their phones regularly. Should we mandate leaving communications devices outside of sterile environments and consider single-use communication technology in the operating rooms? It is important to consider endoscope associated infections in this framework. Treating duodenoscope associated infections as a "never event" may not be correct. While all practical and sustainable solutions should be considered to bring infection rate close to zero, facile solutions such as single-use endoscopes that theoretically eliminate infection risk must be carefully analyzed on the sustainability of such a practice.

Economic Sustainability

Economic sustainability is economic growth without reduction in natural or social capital. While economic growth is important, sustainability calls for aligning economic interests of the manufacturer and hospital with that of the society, ie, a company prospers only if its products and activities are in the long-term best interests of the environment and society at large. Alternatively, if a product is profitable for the manufacturer or decreases costs for a hospital but is harmful to the environment or creates social inequity, then it is not economically sustainable. Many companies have initiated efforts towards sustainability goals, but a large divide remains to be bridged.

Economic Sustainability From a Hospital and Facility Perspective

Economic sustainability from the standpoint of hospitals and facilities may be more accurately defined as financial viability. Indeed, economic arguments in favor of single-use endoscopes center around financial benefits to the hospital, including avoiding endoscope reprocessing costs and the high cost of postinfection hospitalization. Since hospitals are the core purchasers of single-use endoscopes, widespread adoption by hospitals would be the trigger for downstream economic impacts on society at large.

The claimed financial benefits of single-use endoscopes for the hospitals may benefit from further investigation. Costs related to reprocessing of endoscopes vary across studies. A study funded by Invendo Medical, a maker of single-use endoscopes, surveyed 14 healthcare institutions and 5 commercial vendors and concluded that the total cost of reprocessing one endoscope ranged from $114 to $281.[23] These costs included labor, material and endoscope repairs. In this study, the time required to manually prepare the scope for automated reprocessing was 76 minutes, which is much higher compared to other studies. For example, in a report from Johns Hopkins Hospital, manual reprocessing time for each colonoscope was only 19 minutes.[24] A significant percentage of the total reprocessing costs is attributed to labor. However, it is important to recognize that using single-use endoscopes will likely not eliminate all the labor costs since technicians who reprocess endoscopes remain essential for other tasks such as reprocessing other surgical equipment in the case of central services technicians and intraprocedural assistance in the case of surgical and endoscopic technicians.

Estimations of infection risk and costs also pose questions on clinical relevance and accuracy. Estimated cost of treatment of infection ensuing from a contaminated endoscope have an outsized influence on the total procedure cost and thus on the cost-effective analyses comparing single-use and reusable endoscopes. Interpretation of these studies requires careful consideration of core assumptions, especially risk of infection and costs of hospitalization. The model patient may have many comorbidities and inflated hospital charges are used for cost calculations. For example, a cost-effective analysis showed a saving of $118 per procedure with the single-use bronchoscope compared to reusable bronchoscope.[25] However, this study assumed an immunocompromised patient treated in an intensive care unit setting with an estimated risk of 21% for ventilator associated pneumonia, leading to an average marginal cost of pneumonia of $28,383 per case. While this study is often quoted to justify single-use bronchoscope, the average patient on who the bronchoscope is used for likely does not have the same risks. Much may also depend on if studies use mean or median cost estimates. For example, in another study, single-use bronchoscope for percutaneous dilatational tracheostomy was shown to be cheaper by $148 when mean costs were used but only by $26 when median was used.[26] In a cost-utility analysis comparing different scope disinfection techniques, single-use endoscopes and single-use endcaps, Barakat et al assumed treatment of cholangitis with a 2-night stay in the intensive care unit and 1 day stepdown, would cost $375,000.[27] Bang et al used activity-based costing to estimate the cost of ERCP to be $297, $797, and $1547 at 0%, 0.4%, and 1% infection rate, respectively.[28] The assumption in these calculations was that infection would lead to cholangitis, which would cost $125,000 including a 2-night stay in the intensive care unit. The hospital charges decreased to $50,000 if the care was provided in a noncritical setting. Since hospital charges are often inflated,[29] the actual cost to the hospital is many magnitudes lower. Further, even though cholangitis was used to estimated cost of treatment, cholangitis is due to inadequate bile duct drainage and not an infection attributable to use of a contaminated endoscope.

Hospitals and facilities may remain shielded from the cost of single-use endoscopes for some time, at least for Medicare outpatients. Effective July 1, 2020, Medicare approved a new transitional pass-through (TPT) code (C1748) for single-use duodenoscopes, which is generally effective for 2-3 years.[30,31] TPT payments are Medicare reimbursements paid on top of facility fees to an ambulatory surgical center (ASC) or hospital outpatient department when new technology is introduced in the market. Notably, FDA approval for TPT payments does not require any safety or efficacy studies. Medicare makes TPT payments budget neutral by a corresponding decrease to ASC payments for all services, which given the overall budget of Medicare may amount to only tenth of a percent.[32] The amount of TPT payments is decided based on that facility's charges and cost to charge ratio so the actual cost of the disposal duodenoscope is not a deterrent for the hospitals and may even be a source of revenue. Currently, the cost of the single-use duodenoscope is fully reimbursed only by one payor, Medicare, and only when performed at hospital outpatient department. At an ASC, patients may still be responsible for the statutory 20% copayment. Upon expiration of the TPT, Medicare will analyze the usage data and use it to adjust the facility payment for the procedure. Single-use duodenoscopes are not reimbursed for inpatient procedures, which account for the majority of ERCPs, although manufacturers have applied for inpatient New Technology Add-on Payment and the decision is expected within a year. Reimbursement by private payors for single-use duodenoscopes remains undecided. If final reimbursement by payors is less than the cost of the single-use endoscope, the difference would have to be assumed by the manufacturer (decreasing price), the facility or by the patient (direct billing for the device).

Other reasons for adoption of single-use endoscopes have been proposed such as single-use duodenoscopes are a convenient, low-cost alternative for facilities that perform very few ERCPs and do not want to invest in expensive reusable duodenoscopes, and facilitation of after-hours procedures due to convenience of not having to clean the endoscopes. These may be valid reasons for the benefit and convenience of the hospitals and, hence, if these are the primary reasons for adoption, the cost should be borne by the hospital only. It is also important to note that most cost analyses of single-use duodenoscopes assume 0% risk of infection transmission during endoscopy. While this seems logical, it is not proven. Other sources such as contaminated water bottles and irrigation systems have been implicated in post endoscopy infections.[33] A study evaluating the real-life infection risk is necessary but given the very low overall risk would be cost-prohibitive and unlikely to be funded and models must accept this assumption for now.

Understanding the assumptions and costs, discussed above, is important before physicians and hospitals generalize the findings to their population and decide if $2000-$3000 for a single-use duodenoscope is justified.

Economic Sustainability From a Society Perspective

Can society absorb the financial burden of complete adoption of single-use endoscopes? Assuming 400,000 ERCPs per year in the United States, a 0.4% infection rate,[28] and average reimbursement of $2500 per duodenoscope, adoption of single-use duodenoscopes for all ERCPs results in an annual outlay of a billion dollars to avoid 1600 duodenoscope contamination associated infections or $500,000 per infection. This is almost 5-10 times above the accepted cost-effective threshold for healthcare and safety.

If the goal of zero contamination associated infection is extended to every endoscopy and single-use endoscopes are used for all estimated 50 million endoscopies in the United States,[34] an incremental conservative mean cost of $500 for all endoscopes translates into an annual healthcare expense of 25 billion dollars.

Market trends suggest that this scenario may not be completely far-fetched. Global single-use endoscopes market size was valued at one billion dollars in 2019 and expected to grow at a compound annual growth rate of 20% over next 7 years.[35] These rosy expectations are based on market performance of similar devices. Sales for single-use bronchoscope are growing at a Compound Annual Growth Rate of 124%, a 126-fold increase since 2014. In contrast, the global market for reusable bronchoscopes is expected to grow at only 2.7% over the next 10 years. Additionally, since the launch of single-use rhinoscope in 2019, sales have grown by 441%.[36]

Presently, lack of reimbursement and limited manufacturing of single-use duodenoscopes have limited their use to high-risk patient populations. But the natural trend of a new healthcare service or technology, especially ones marketed as convenient, safe, or a significant technological advancement, is rapid adoption to low-risk populations. These changes soon become the new standard of care and an expectation for patients and providers, forcing slow adopters to follow for fear of losing market share or reputation. Notably "standard of care" is dictated by practices of other reasonably competent healthcare professional in the similar community and not on evidence or value. Examples of such trends include use of anesthesia directed sedation for low-risk endoscopies and increasing use of robotic surgery. Use of anesthesia administered deep sedation for propofol for low-risk colonoscopies has continued to increase, despite many studies demonstrating no improvement in quality indicators and some concern about increase in overall complication rates. In a retrospective analysis, Liu et al reported an increase in anesthesia assistance for endoscopies from 14% in 2003 to 30% in 2009, at an additional cost of one-billion dollars in 2009.[37] Widespread adoption of anesthesia has only hastened in the ensuing years; in an analysis of more than 4 million outpatient colonoscopies by Kriger et al, anesthesia assistance more than tripled from 16.7% in 2006 to 58% in 2015.[38]

Robotic surgery is another cautionary example of how a sophisticated technology with limited proven use can rapidly expand at significant cost to hospitals and society. Robotic surgery estimated annual procedure volume increased from 136,000 in 2008 to 877,000 in 2017, with 73% procedures performed in the United States. In 2017, hospitals paid the primary supplier more than $3 billion, equating to $3568 per procedure. Before robotic surgery, total operating room costs for common general surgery procedures ranged from $3000 for cholecystectomy) to $7000 for pancreatectomy. Instruments account for less than 20% of this cost. The increase in robotic surgeries is most in the area of general surgery and gynecologic surgery where robotic surgery has failed to demonstrate superior outcomes compared to laparoscopic surgery.[39] The discrepancy between the rapid adoption of technology despite unclear clinical benefit is not uncommon and unfortunately often a one-way trend, since hospitals invest in the technology, advertise and build up patients' expectations.

Single-use endoscopes must demonstrate economic sustainability not only from the perspective of cost savings to the hospital but by its value and its effects on society at large. The cost of these devices is borne by the healthcare system even if it is not obvious at first. If a hospital absorbs the cost of disposal endoscopes it may cut back on other services; if the insurance company covers the cost, premiums may increase; if Medicare reimburses the cost, then it may decrease payments for other services for the sake of budget neutrality; and if patients must pay out of pocket, a further financial burden is created. In each case, manufacturers will get paid and society at large will foot the bill. As with prior examples in healthcare, once high cost and low value practices are adopted, they are seldom abandoned.

Environmental Sustainability

Physicians have long recognized and studied the environment and its effect on the population health. According to the report, "Health Care's Climate Footprint," from Arup (a global consultancy firm) and Health Care Without Harm, the global healthcare industry is responsible for 4.4% of worldwide net emissions.[40] United States is the world's highest emitter of healthcare greenhouse gases, accounting for 27% of the global healthcare footprint.[41] The causes and consequences of rapid climate change have made environmental stewardship an obligation for physicians, hospitals, and professional medical societies.

Procedure−intense specialties, such as surgery or endoscopy, are major contributors to the environmental impact of the heath care sector. Pohl et al estimated that waste per year generated from endoscopic procedures would fill 980 single-family houses. If all colonoscopies and ERCPs were performed with single-use endoscopes, it would fill up additional 185 single-family houses per year, an increase of 19%.[42] In order to truly determine the environmental impact of single-use endoscopes a detailed life cycle analysis of these devices is necessary.

Life cycle analysis is the determination of how products impact the environment during production, use, and end of life stages. The production step of the life cycle may have a far larger environmental impact than other stages of the cycle. Raw materials for making a sophisticated gadget such as endoscopes are procured from all over the world, shipped to factories (often on a different continent) for manufacturing, and transported to distribution centers as finished products to further supply hospitals or other facilities when ordered. Emissions from transportation depend on the location of production sites and the destination of the endoscopes as well as mode of transportation and type of energy used for transportation. Both major manufacturers of single-use duodenoscopes, Boston Scientific and Ambu source and assemble from disparate locations. Boston Scientific assembles endoscopes in Indiana, USA which are then transported to a distribution center in Massachusetts, USA from where they are shipped to endoscopy units. Ambu single-use endoscopes are assembled in Malaysia and transported to a distribution center in Kentucky, USA. Very few have attempted to calculate the carbon footprint of devices used in healthcare. Horwood et al in the United Kingdom calculated the approximate carbon footprint for the transportation of 1 ton of sutures, from raw material to operating theatre, to be 26 tons of CO_2, which could be offset by planting 435 tree seedlings and growing them for 10 years. Apathy to this issue and its resultant waste was further highlighted by the observation that their hospital submitted an average of 4.5 individual orders for different sutures every week, equating to ten thousand miles from the warehouse to a single hospital every week, due to poor communication between different operating rooms.[43] A similar scenario is likely with single-use endoscopes where a single hospital may order ureteroscopes, bronchoscopes or duodenoscopes separately the same week due to lack of communication between specialties and recognition of environmental impact.

Location of manufacturing can also highly impact emissions since a product produced in Europe would likely have a smaller CO_2 footprint given the average energy mix in Europe is less carbon intensive due to higher share of hydro and nuclear power. Energy sources in other areas such as Malaysia are predominantly nonrenewable fossil fuels—coal and natural gas, while the United States similarly relies on oil followed by natural gas and coal.[44,45] Manufacturers have begun to address these environmental concerns. Ambu reports that approximately 10% of the electricity is generated by solar panels installed on the roof of their manufacturing plant[46] and Boston Scientific pledges to be carbon neutral by 2030.[47]

Though production is the largest component of environmental impact in the device life cycle, the focus for marketing of these devices is often around disposal likely because of its visibility and more apparent direct control by hospitals and healthcare providers. Both Ambu and Boston Scientific have taken initiatives to promote recycling of single-use endoscopes by collaborating with Sharps Compliance, Inc (Houston, TX, USA) a medical waste disposal management company. Endoscopy units are provided with collection containers and prepaid large cardboard boxes which are used to ship used single-use endoscope to Sharps Compliance. At the recycling facility, metals and plastics from the endoscope are separated. Metals are sorted into ferrous and nonferrous, shredded, and finally molted in a furnace for recycling into secondary products. Plastics are autoclaved and then burnt to generate electricity. Single-use duodenoscopes are thus promoted as "recyclable." However, only the small metal portion of the duodenoscope is, in fact, truly recycled. The rest of the endoscope (plastic) is incinerated similar to other medical waste.

Energy recovery from plastics, at face value, seems like a win-win solution to the medical waste problem, but it is not without controversy. Burning plastics generates many pollutants such as sulfur dioxide, nitrogen oxides, dioxins, and mineral particulates, although stricter environmental regulations have resulted in substantial reductions in these emissions. Further, treatment of waste uses more energy than can be recovered and, in the process, generate substantial amounts of CO_2. Burning waste is one of the most expensive forms of energy generation in the United States, costing 2 times that of solar and 3 times that of wind. These facilities require a constant flow of waste to remain operational and profitable. This necessitates shipping of waste from all over the country, increasing the carbon footprint of disposal to the point that burying waste plastic in landfill is a preferred to burning as a method of carbon capture and storage.[48]

In addition to questions surrounding endoscope recycling programs, it is also unknown if hospitals will participate in single-use endoscope recycling programs. Single-use bronchoscopes have now been in the market for years and, to our knowledge, most hospitals are discarding their single-use bronchoscopes as regular trash. The makers of single-use bronchoscopes and Sharps Compliance were unable to provide information on participation. Personal communication with many hospitals using single-use bronchoscopes showed that none were using the recycling service. Further, even if there is broad adoption, current recycling facilities may not have the capacity to process large volumes of single-use endoscopes. The United States Environmental and Protection Agency estimates that a new combustion plant typically requires at least 100 million dollars to finance construction and larger plants may require double to triple that amount.[49] Economic benefits may take several years to be realized, which dissuades short-term investments.

Priorities of waste management from most to least favorable are refuse, reduce, reuse, recycle, recover (energy) and finally disposal. Thus far, the priority in healthcare has been solely on disposal with small inroads on recover. Use of single-use medical devices became popular in the 1960s with intravenous tubing and plastic syringes. Over time, the trend of single-use equipment has greatly accelerated, fueled in part by desire to minimize infection, convenience, and decreasing costs of single-use products. The providers, meanwhile, have remained oblivious to the concerns and consequences of increasing plastic use and growing piles of healthcare trash.

Most of the disposal medical products use polyvinyl chloride (PVC) which is made softer and pliable by addition of phthalates. Concerns about the hazards of PVC and additives are associated with its entire life cycle—from production to disposal. Varying amounts of toxic chemicals are released to the environment during production of PVC. Phthalate can leach to varying degrees from medical devices, directly exposing the patient and predominantly affecting the male reproductive tract. In 2002, the FDA advised healthcare professionals to switch to devices without PVC or other phthalates when treating vulnerable patients including male neonates, pregnant women, and peripubertal males.[50] A recent randomized, prospective study also linked prenatal exposure to phthalates with adverse impacts on neurodevelopment, including lower IQ, and problems with attention and hyperactivity, and poorer social communication.[51] Notably, phthalates were banned by the Consumer Product Safety Commission in 2008 for children's toys,[52] but it continues to be used in medical devices for children. Disposing products containing PVC are a particular problem—incineration releases harmful gases such as dioxins and they cannot be effectively recycled.[50] In their sustainability report, Ambu announced that as of October 2020, phthalates will not be used in their products.[53] This is certainly a step in the right direction, but phthalate-free PVC still uses other harmful chemicals during production. The available evidence strongly favors nonvinyl products from an overall environmental and health perspective.

The complexity of environmental impact of medical devices underscores the importance of a unified system to calculate and report emissions data for entire life cycle of the product, however, none exists. Single-use endoscopes are another example of the paucity of detailed and accurate information that is available to providers to help them make independent informed decisions. Most of the available literature on environmental sustainability comes from studies funded by single-use device manufacturers or by authors with ties to the industry. The choice, providers are made to believe, is between large amounts of waste generated during reprocessing of endoscopes and a clean recyclable endoscope. The facts, somewhere in the middle, are seldom revealed—only small metal components of endoscopes are recyclable, the rest is burned just like any other infectious waste and no different than waste generated during reprocessing. Attaching the phrase "recyclable" to these devices superficially assuages the associated environmental guilt attached with adopting these single-use endoscopes. It is also estimated that amount of waste generated by single-use endoscopes would actually be more compared to waste generated during reprocessing of endoscopes.[42]

The biggest challenge lies not in educating stakeholders about the environmental pitfalls but in navigating the trade-offs between short-term and long-term benefits.[54] Temporal discounting research has shown that present rewards are weighted more heavily than future ones and once rewards are very distant in time they cease to be valuable. This would be true for mitigating climate change, which many consider more relevant to distant places, future times, and other people than to the here and now and oneself. For instance, the stakeholders of single-use endoscopes—physicians, hospital administrators, regulators and company executives—are far removed from the present environmental pollution realities. By and large, they do not live near emissions from factories and incinerators or near the mines where underground water is polluted. Given the significant environmental impact of medical waste, it is imperative to shift the discussion away from accepting medical waste as a necessary downside of high-quality healthcare to advocating for the avoidance of healthcare waste as a component of high-quality healthcare.

Social Equity

The third dimension of sustainability is social equity—how burdens and benefits of policy actions are distributed in the community. Social equity is relevant in all stages of single-use endoscopes—manufacturing, use and disposal. It entails social and ethical procurement of materials for manufacturing from suppliers, especially when sourcing globally with unfamiliar work cultures. For example, Democratic Republic of Congo produces more than 60% of the world's supply of cobalt, which is used to produce lithium-ion batteries for smartphones, laptops and electric cars but the extraction process in Congo has been beset with concerns of illegal mining, child labor and human rights abuse.[55] Corporations using these raw materials are increasingly held accountable to expected ethical standards. Apple, Google, Tesla, and Microsoft were among firms named in a lawsuit for failing to regulate their supply chains away from profiting from child exploitation.[56] These companies are now taking their role seriously. For example, Tesla is trying to use more nickel, sourced from other countries and phasing out cobalt and Apple is performing third-party audits of its suppliers.[57] Recognizing the importance of social equity, single-use endoscope manufacturers Ambu[58] and Boston Scientific[47] have committed to responsible practices and support the United Nations Sustainable Development Goals, which has responsible consumption and production as one of its 17 goals.[9]

Another aspect of social equity is affordability of services by different hospitals. Hospitals, especially those with low volume of ERCPs, may find single-use duodenoscopes cost prohibitive since they lack sufficient bargaining power or economies of scale. Yet these same facilities may find themselves compelled towards using single-use endoscopes due to market forces and optics (often a result of marketing and media coverage). The market trend of the da Vinci surgical system is illustrative. According to one report, 131 hospitals that had installed the robotic surgery system had 200 or fewer beds, where the number of surgeries performed would be less than the accepted proficiency threshold.[59] Further, many were safety-net hospitals and thus raising the question about priorities and best use of scarce resources for a surgical system that costs upward of $2 million.

Environmental justice is yet another aspect of social equity. The final stage in the life cycle of single-use endoscope is landfill or an incinerator. In the United States, 80% of the incinerators are located in low income communities of color.[60] The unfair burden that incinerators have long placed on these communities result in negative health impacts. Although the waste disposal companies have taken steps to

Table 1. Key Points in Evaluating the Sustainability of Reusable Endoscopes

Eliminating all possibility of endoscope associated infections may not be feasible or necessary.
Cost estimates of endoscope reprocessing and associated infections bear close scrutiny to underlying assumptions.
Medicare transitional pass through payments for reimburses the cost of single-use duodenoscopes for Medicare outpatients. Reimbursement for inpatient ERCPs is still pending. The reimbursements aid in adoption but may leave certain patients responsible for out-of-pocket costs.
Economic sustainability must be evaluated not only from the standpoint of individual hospitals but also from the standpoint of society at large.
The ‘recycling” programs offered for disposable endoscopes, actually recycle only a very small metal portion of the endoscope and the rest is burnt, similar to other trash.
Overseas manufacturing, assembly, and transportation of reusable endoscopes may result in a higher environmental burden than any recycling program can hope to recover.
Poor and disadvantaged communities and patients are more likely to suffer the environmental and economic burdens of reusable endoscopes without enjoying the benefits of their use.
Care should be taken to avoid discounting long term environmental, economic, and societal burdens of reusable endoscopes in favor of facile short-term solutions.
Other sustainable methods of minimizing infection risk should be carefully studied and encouraged.

control emission of air pollutants, it remains a significant problem. Most of the 73 incinerators are reaching the end of their lifespans and estimated 21 incinerators have been cited for multiple violations under the Clean Air Act.[61] Given the scale of waste that can be generated by single-use endoscopes and potential to exacerbate the health of vulnerable population, it is important for physicians to remain cognizant of disparate social impacts.

Conclusions

In this review, we have discussed how adoption of single-use endoscopes can affect the three pillars of sustainability—economic, environmental, and social equity. Driven by the small risk of transmission of infection from reusable endoscopes after high-level disinfection, single-use endoscopes provide a useful technological advancement that can eliminate this risk but comes at too high a cost for the current society and future generations. Alternative technologies warrant further investigation and current cleaning protocols should be evaluated, enhanced and rigorously implemented before the hastened use of an unsustainable option. Healthcare providers may be ignoring long term problems, and in trying their utmost to help one patient now, may be harming many others for years to come. Collectively, healthcare providers and hospitals can influence manufacturers by creating a demand for more sustainable products. We need a realistic long-term sustainability goal and human will to achieve that goal, without which short-term concerns and interests will start an unsustainable process that cannot be undone. We hope that intensive study and debate will proceed simultaneously. Until then, any push to replace reusable with single-use endoscopes would be a pyrrhic victory for healthcare (Table 1).

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