

Reusing, Recycling, and Reprocessing in Healthcare

By: Lars Thording

In the United States, the healthcare sector is responsible for 8.5 percent of total greenhouse gas emissions, and emissions increased 6 percent¹ from 2010 to 2018. Today, U.S. hospitals generate more than 4.7 million pounds of waste annually (which equates to roughly 27 pounds of waste per staffed hospital bed in America per day), and they dispose of 2 million pounds of unused supplies each year, at a cost of \$15 million annually. Further, more than 70 percent² of a health system's greenhouse gas emissions are embedded in the products and services they buy (i.e., scope 3 emissions), such as pharmaceuticals and other chemicals, food and agricultural products, medical devices, hospital equipment, and instruments – the problem is not what the hospital *does*, the problem is what the hospital *buys*.

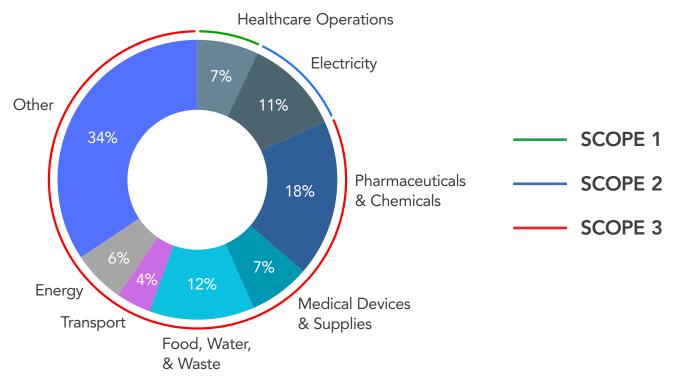


Figure 1: U.S. National Healthcare Greenhouse Gas Emissions by GHGP Scopes (2018)³

Medical devices are a substantial contributor to these scope 3 emissions (see figure 1). Every time a hospital purchases a medical device, a choice is made about the carbon emissions impact of the hospital. Some medical devices are reusable. Others are marked "single-use". Some medical devices can be reprocessed by third-party reprocessors. Others are sent to recycling. How does a healthcare buyer decide what products and services are better from a carbon emissions perspective?

Single-use medical devices

Single-use devices are extremely common in healthcare. The "single use" designation is made by the manufacturer, and it means that appropriate use implies throwing the device away after one use. The designation is intended for devices that for safety or functionality reasons should only be used once. Some are impossible to clean in the Sterile Processing Department (SPD), while others may have intricate functionality, materials, or parts that compromise the device in multiple uses. With a "single use" designation, the manufacturer does not provide the hospital with instructions about how to make a device ready for re-use through sterilization, and as a consequence, risk is minimized and profitability maximized for the manufacturer.

However, single-use devices are extremely burdensome financially as well as from a carbon emissions standpoint. The single-use label is a luring concept to the manufacturer that shifts the economic burden downstream. In the 1990s and 2000s, U.S. medical device manufacturers routinely shifted labeling from reusable to single-use, as they saw profits drop due to hospital device re-use. This often happened to the label without substantial changes to the IFU and it continues today. A single-use device is valuable to the manufacturer, because the more the hospital throws away, the more they have to buy more devices. Meanwhile, the more the hospital throws away, the bigger the environmental impact, the higher the spending, and the more vulnerable the provider is to supply chain shortages. These are three consequences US hospitals cannot ignore today, and therefore, the single-use label, as important as it is to patient safety, has also become a contentious issue.

And hence, the prevalence of single-use device usage in healthcare has come under much criticism of late, as the current political climate focuses on the environmental footprint of healthcare as well as the economic consequences of the "single-use" label and the supply chain vulnerability associated with the reliance of a single supplier.

But instead of limiting the number of single-use devices launched to reduce environmental impact, manufacturers have doubled down on this design strategy – and more and more devices are launched as single-use. More specifically, devices that once were reusable have been made "single-use", and as a consequence, more plastics are thrown away and more money is spent buying new devices. Today, we even see cables (insulated wires used for transmitting electricity) that never even touch the patient labeled as "single-use". Instead of designing devices from more durable materials and device mechanics that lend themselves to extended use, manufacturers seem focused on minimizing the lifetime of the device.

In a 2022 report⁴, the Agency for Healthcare Research & Quality (AHRQ) specifically called out the preference for designing products for single use: "Reliance on single-use disposable medical supplies and devices not only leaves health systems vulnerable to supply chain disruptions, as seen with the COVID-19 pandemic, but they are frequently cited as containing higher life cycle emissions per use compared with equivalent application of reusable alternatives. Healthcare organizations should strongly encourage and facilitate resource stewardship." Massive amounts of single-use

devices are produced and consumed in healthcare. Producing single-use devices increases profits for manufacturers, but when so many devices are thrown away after a single use, hospitals rely on a steady stream of new devices, and with backorders and recalls, this can threaten the continuity of the hospital's service provision⁵ in addition to the environment.

Single-use devices, like cables, also present safety and functionality problems. Not because they are unsafe or badly constructed, but because in reality many of them end up in the SPD. This happens in spite of the label, simply because it is difficult in a busy operating room to identify devices that are single-use versus devices that are reusable. In reality, after a procedure, all cables (in some cardiology procedures, 5-6 cables are used, with some of them being single-use, others re-usable) are placed in a bin and sent down to SPD. It is an impossible task for SPD staff to recognize every single cable and to pull out the single-use models. However, to follow the regulations, these products should appropriately be moved from on-site reprocessing to reprocessing by a company that has FDA clearance to reprocess.

Not all devices can be reprocessed by the hospital and reused. Some are simply too technically complex, fragile, or physically/mechanically impossible to clean. Some devices should be disposable. The point is this: Manufacturers have, over the past decades, focused on making more and more devices disposable (or "single-use"), and this trend needs to be reversed. Over-reliance on disposable devices creates great vulnerabilities, increases environmental harm, and they simply cost too much. While manufacturers change their strategies, single-use device reprocessing provides a safe, regulated solution for hospitals when it comes to certain types of devices. Reprocessing has become a very advanced practice, and even delicate devices can often be reprocessed.



Reusable Medical Devices

Reusable medical devices are far more environmentally friendly than single-use devices. Reusable devices are designed by the manufacturer to be re-used a specified number of times, when instructions are followed for devices to be identified, cleaned, and re-sterilized. Device reuse varies considerably, from just a few uses to 10, 20, or even more uses.

Reusable devices are traditionally reprocessed by the hospital in their SPD department. This department's task is a critical one, both from a patient safety and an operational perspective. Unfortunately, SPDs are among the departments that have experienced the post-COVID staffing challenges, and their task is a monumental one, starting with the identification of the individual device to discover what specific cleaning and testing instructions are required. There are hundreds of different models of connector cables, for example, and it requires special training to be able to distinguish between them. In reality, most SPDs use the exact same process for wiping down devices and sterilizing them, regardless of model numbers and IFUs. Device identification happens at a very superficial level, devices are not tested, and counting the number of uses is problematic as well.

Hospitals are increasingly recognizing that SPD's limitations can mean Joint Commission requirements are compromised when reusable devices are reprocessed on-site. Again, reusable connector cables are a good example. Most connector cables are reprocessed on-site, but different manufacturers' cables come with very different IFUs that imply different cleaning requirements and different numbers of cycles. Should the Joint Commission see devices with different IFUs treated with the same process in on-site reprocessing, the hospital could face some grim oversight consequences. Add to this that connector cables vary in number of uses allowed, but most SPDs do not have the ability to track number of uses, and consequently, cables are simply used until they fail – with substantial regulatory, patient risk, and operational costs involved.

An alternative to SPD is to send the most difficult reusable device categories to third-party reprocessors who have the expertise and the routines to properly identify, clean, count, and sterilize the devices. A significant number of hospitals send their connector cables to third-party reprocessors. These companies reprocess extremely complex devices, like mapping catheters, and have proven expertise in reprocessing.

In spite of the challenges involved in device reuse, hospitals should put more pressure on manufacturers to design devices to be reused. Financial and environmental waste increase when the single-use mindset wins. On the other hand, when new reuse policies and practices are introduced into healthcare, hospitals win.





Reprocessable Medical Devices

The basic choice of medical device is between single-use devices and reusable devices. However, FDA operates with a third model that falls in-between in terms of environmental and financial impact: FDA provides clearances to reprocessors to collect, identify, clean, test, and sterilize used single-use medical devices – and sell them back to the hospital. Reprocessors sell them back to the hospital at about 50% of the price and carbon emissions footprint of a new device.

This practice has been regulated in the US since around 2000, and history has demonstrated that reprocessed medical devices are as safe and functional as new devices. The requirements for FDA to grant a clearance to reprocess a certain device are extremely strict, and as a result the practice is very safe.

A recent study by Fraunhofer in the journal Sustainability (see figure 2) showed that a reprocessed electrophysiology catheter produces less than half the environmental harm of a new catheter, so the impact on the environment from using reprocessed devices can be substantial.

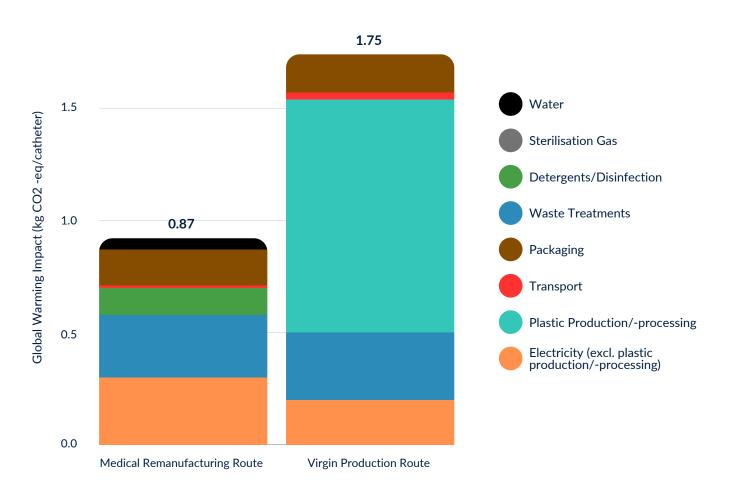


Figure 2: Comparing CO₂ impact of new and reprocessed EP devices⁶

Single-use device reprocessing reduces environmental harm in two ways:

- Devices that would normally be sent to incineration are captured and reprocessed for one or more additional uses. Each time this happens, environmental waste is reduced by the weight of the device.
- The manufacturing process for a reprocessed device has much lower emissions (CO₂) impact than the manufacturing process for a new device. In figure 2, the Fraunhofer study's results are shown the difference in greenhouse gas emissions is 0.88 kg CO₂ equivalent or 2.2046 pounds CO₂ equivalent.

If devices, by the nature of their use or the patient risk involved, cannot be made *re-usable*, manufacturers can work with reprocessors to make them *reprocessable*. Innovative medical device companies have come to single-use device reprocessors and said: "We have this new device, can you work with us to make them reprocessable? Here are the blueprints". They do this, so they can offer a quality product to hospitals while making its adoption environmentally sustainable and fiscally responsible. Meanwhile, none of the 4-5 large medical device suppliers that dominate the electrophysiology space have made this approach (one of them has a reprocessing division, but that is not enough to claim a change in financial and technological strategy, especially since several new, complex, and expensive devices are not included in their reprocessing program). There is little incentive to sacrifice profits for the environment when their market share is not really under threat. Hospital leaders should shift market share to suppliers that create circular economy solutions, and demand that dominant suppliers start collaborating with reprocessors – to the benefit of hospital economics as well as the environment.

This model has sometimes been termed "green servitization"⁷. Green servitization means that manufacturers complement their product offering with services to develop new revenue streams and generate greater value for customers throughout the life of the device. "Green" servitization refers to the trend towards such models being focused on services that are aimed at reducing healthcare's environmental impact. In a context where original medical device manufacturers have persisted in launching more and more "single-use" devices, green servitization means adding reprocessing services to the sale of single-use devices, reprocessing services that help the manufacturer deliver higher value and add new revenue streams while helping the environment.

Practically, adding reprocessing services can be accomplished by collaborating with reprocessing companies that can provide these services as a complement to the original manufacturers' device offering – or by integrating reprocessing services into the design and marketing of new devices, a much more effective solution. Integration can happen through the build-out of reprocessing capabilities or through the acquisition of reprocessing companies, which is what we have historically seen in the United States: In 2009, Stryker acquired Ascent Healthcare Solutions (the largest reprocessing company in the country), and in 2022, Johnson & Johnson (Biosense Webster) acquired SterilMed (the second-largest reprocessor in the country).





The ultimate success of single-use medical device reprocessing, which as an industry has always had an adversarial relation to manufacturers in the space, would be the true integration of reprocessing into the original manufacturing and marketing process. When it is taking so long (the industry is more than 20 years old), it is because large medical device manufacturers have a very short-term focus on protecting and growing existing revenue streams - a focus that lessens the appeal of solutions that drive long term value for the customer – because initial cannibalization of sales is always implied. Yet, visionary leaders in the medical device industry have tried for years to make this happen. The success has been limited. With today's focus on the environmental impact of healthcare, problems with supply chain resilience, and the unprecedented financial stress in the sector, the tide may be turning. At some point, the medical device industry will have to give in to customer pressure and regulatory demands.

Linear vs Circular Supply Solutions

Both reusable devices and reprocessable devices represent circular solutions to the linear solution of single-use devices (see figure 3).

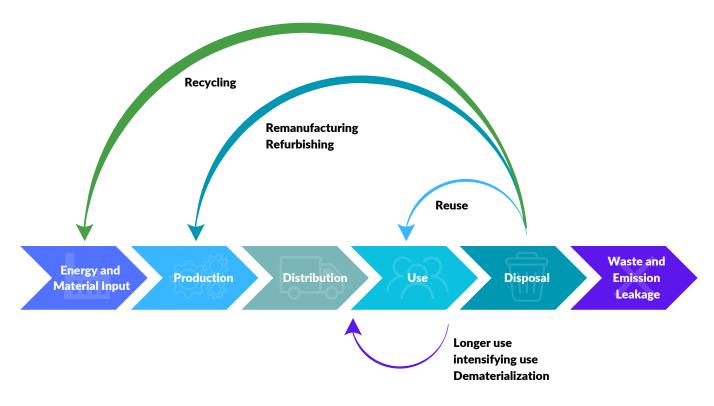


Figure 3: Circular and linear utilization models⁸

The single-use medical device goes through production, distribution, and use. Following this, it is disposed of. Medical device reuse is preferred to single-use because the carbon footprint of the in-hospital sterilization process is minimal compared with the carbon footprint of a new device. It is a circular model because the device is not simply destroyed after one use.

As a circular solution with a higher carbon footprint than a reused device, a *reprocessed* device is preferable to a *new* device (in cardiology, the carbon footprint is about 50% of a new device). The farther to the left in figure 3 the used device travels, the higher the carbon emissions "bill". When a device cannot be designed for reuse, reprocessing becomes the most attractive solution from an environmental perspective.

Recycling, as an alternative to reprocessing, is the most "expensive" solution from a carbon emissions standpoint, except for the single-use device. It is the least favorable circular solution, because recycling (and downcycling) involves a lot of energy consumption and because only a small part of a typical medical device can actually be recycled. The industry has suggested⁹ that about 23% of surgical waste can be recycled. Many parts of a typical cardiology device simply cannot be recycled. Recycling of medical devices is really not a very good solution in healthcare. There are at least three reasons for this:

- 1. Recycling is a lesser solution from an environmental standpoint than other available circular use solutions, such as re-use, remanufacturing/reprocessing, repair, and repurpose. These are solutions where the device is not re-captured for a different use (which involves a lot of waste), but maintained for another use, avoiding immediate incineration.
- 2. When a device is recycled, some materials (but not all) are re-cycled. However, the hospital still needs to purchase a new device. Reprocessed devices have less than half the environmental impact of a new device in terms of carbon emissions.
- 3. When used devices are broken down to their component parts and recycled, these devices are taken out of the supply chain. At a time where hospitals experience backorder on some of their most critical devices, recycling seriously threatens supply chain resilience.

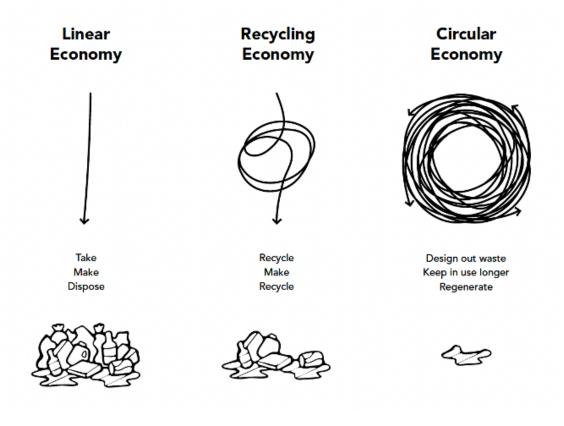


Figure 4: Linear, recycling and circular economy¹⁰

Legacy sustainability programs in healthcare were straight-out recycling programs where used items were broken down to component parts and inserted into ill-equipped recycled parts manufacturing – in a very expensive process. The fact is that in terms of circular utilization, recycling is a very poor solution.

Today's emerging circular programs combine environmental sustainability with financial upside. When an item is not broken down into its component parts, but rather made ready for a second use, there is balance in the sustainability-cost equation: Tomorrow's circular solutions reduce costs and environmental impact. Single-use device reprocessing, for example, retains the value of devices while reducing carbon footprint by 50% or more. Recycling solutions are the enemy of financially and environmentally responsible reuse. High-value circular solutions achieve both because they are about bringing extra life to items, not piecing out their death.

Recycling, Reprocessing or Reusing – Are the Manufacturers on Board

So how should hospital supply chains utilize this information? Single-use devices are bad for the environment and for hospital economics. Reusable devices represent the most environmentally responsible solution. When single-use devices are all that is available, reprocessable devices should be preferred. Recycling solutions are the least valuable from both an environmental and a financial perspective.

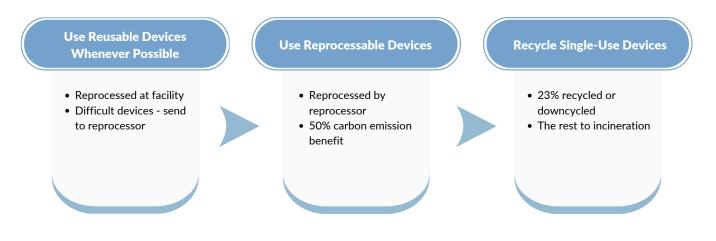


Figure 5: A decision-making model for medical device reusability

Physicians are becoming more committed to responsible environmental solutions to their device utilization. As an example, a recent study¹¹ found that Electrophysiologists are highly motivated to reduce the environmental impact of electrophysiology procedures. A total of 278 physicians from 42 hospitals were polled and 62% were motivated to work towards more sustainable solutions - and re-use of catheters was the most commonly cited potential sustainability solution by the respondents. This is great news in labs where more than half of catheters used are discarded to medical waste, and less than 20% of catheters are re-used. There are two ways to increase re-use in the EP lab: Manufacturers can design and market reusable catheters instead of single-use catheters - or hospitals can work with reprocessing companies to use reprocessed single-use catheters.

So, how are manufacturers responding to this desire from physicians to become more sustainable? We have seen some of the largest manufacturers start "sustainability programs" based on recycling of medical devices. It seems like they are responding to an increased demand for environmental sustainability in the hospital. However, the problem is that these types of programs just are not as good as they sound. In fact, they work counter to the intention and further exacerbate some rather serious problems in the supply chain. They do, however, ensure that the companies can continue to grow its revenue.

Let's start with the environmental aspects of these recycling programs. From an environmental perspective, recycling is a far less valuable circular solution than reprocessing – as illustrated in figure 3 above. Devices from these programs will not be re-used, but rather broken apart, and the recyclable parts (less than 30% of residual hospital waste) will be used in the manufacture of other products. If, instead, the devices were reprocessed, the entire catheter would be salvaged and made available for another use with the use of very few resources. Since many single-use devices can be reprocessed and re-used, putting in place a recycling program simply means that the environmental benefit is lessened. Some reprocessed medical device have less than half the carbon emission impact than a new device. This impact is lost with a recycling program which implies that a new catheter will be needed. In other words: Every time a catheter is recycled rather than reprocessed, the hospital increases CO_2 emissions significantly.

So why would some of the largest suppliers of medical devices put a program in place that increases CO₂ emissions and makes supplies scarce? We are not sure, but math might help. Every time a medical device is recycled rather than reprocessed, the manufacturer increases its revenue while the hospital increases its costs. This is because the hospital cannot buy a reprocessed medical device at the lower price but must buy a new one. Possible supply shortages, environmental harm and hospital economics are collateral damage. This is how medical device recyling programs make a lot of sense. For the manufacturer. Not so much for the environment and the hospital – and the patient.



A Roadmap to Supplier Accountability

So, how do hospital leaders get the suppliers on board with more environmentally friendly solutions? Recently, the National Academy of Medicine (NAM) hosted a series of webinars to teach healthcare organizations effective carbon accounting - including for scope 3 emissions. "Carbon accounting is the process of measuring, tracking, and reporting an organization's greenhouse gas emissions. This helps organizations understand how they are contributing to climate change and how they can most effectively reduce their emissions." NAM says. The pre-recorded webinar series covers the basics of carbon accounting to the Greenhouse Gas (GHG) Protocol, including what data to collect, how to measure and report data, and real-world examples. Hospitals and health systems can browse the Carbon Clinics and related resources for steps to reduce their carbon footprint.

More recently, Practice Greenhealth has taken this even further by providing their own emissions impact calculator for healthcare. This powerful tool will allow health systems and facilities to measure scope 1, 2, and 3 emissions, helping them "take their first step on the path to emissions measurement, reporting, and reduction efforts." It is the first free, publicly available tool of its kind for health care organizations. The calculator was developed following the GHG Protocol, the world's most widely used GHG accounting standard.

These initiatives are helpful, and they demonstrate the need for healthcare to become accountable for their carbon emissions footprint. They also make a critical point: You can't effectively address the climate impact of healthcare until you can put NUMBERS on carbon emissions. Up until this point, there is no accountability, only talk.

To operationalize carbon emissions reductions in healthcare, we need four things:

- 1. Standards and goals for carbon emissions reductions in hospitals probably defined at the federal level
- 2. More LCAs (Life-Cycle Analyses) that are applicable across the hospital supply chain
- 3. Calculators like the one provided by Practice Greenhealth to quickly and accurately attach numbers to carbon emission footprint
- 4. Diligent governance by hospital of their supply chain to favor supplies with the lowest carbon footprint

Hospitals use a vast number of very different types of supplies, and it is unrealistic to expect that each product will come with its own LCA. However, based on LCA studies of major product categories, we can arrive at fairly healthy approximations. The point is, to create climate accountability in healthcare, we need carbon emissions calculators and we need more LCA studies. And since hospitals today have zero visibility into scope 3 carbon emissions, good approximations are better than nothing.

Barriers to Carbon Emission Reductions in Healthcare

Supply chain professionals in healthcare today will tell you that even though hospital leadership is pushing for greater environmental sustainability, they will default to an uncompromised focus on cost when push comes to shove. The cheapest product wins, whether it is green or not.

For decades, the healthcare supply chain has been focused solely on one thing: driving down costs. This came with efforts to negotiate single-source contracts and pushing for just-in-time inventory policies. With this sole task, healthcare purchasing has played a less-than-glorious role in the hospital, which has increasingly struggled with severely strained bottom lines.

The pandemic changed that – for a minute. Supply chain shortages in vital product categories like gloves and face masks shone a light on the healthcare supply chain and suddenly made the purchasing and inventory function of the hospital the arguably most important function in healthcare. Healthcare purchasing, having lived a life out of the limelight, became critical in the acquisition and availability of products.

In this way, the pendulum shifted from just-in-time inventories to just-in-case inventories, and the cost focus shifted to a focus on resource availability. Sole-source contracting (in some cases) was abandoned and changed to dual-source arrangements to enhance the resilience of the supply chain. During the pandemic, in other words, the sole focus on price faded. Other procurement criteria, such as environmental considerations, were invited to play a role.

However, since the pandemic, the pendulum has swung right back to where it started, with the healthcare supply chain solely focused on cost savings. We are back to single-source contracting and procurement decisions made to reduce costs.

Of course, the environmental and resilience discussion has not completely disappeared, and hospital leaders are eager to demonstrate that their hospitals are making an effort to combat climate change. After all, doing so helps to comply with political signals, to build the hospital's "brand," and to strengthen their hiring and retention efforts. To this end, most hospitals have hired sustainability directors.

Given the pervasiveness of this theme and the focus of hospital leadership, why is the healthcare supply chain still struggling with notions such as environmentally preferred purchasing? There are two main reasons why:

- 1. Supply chain executives do not drive all procurement decisions. Specifically, physicians and nurses often have the clout to insist on buying new or preferred technologies for clinical reasons and otherwise. <u>Some</u> have suggested that physicians' incomes and the fact that physicians direct most healthcare spending (80 percent is a frequently used number) are the real culprits in rising health care costs. We call this "physician-induced demand, a documented phenomenon that results in overtreatment and contributes to high health care costs." So, for some of the most expensive products, supply chain staff is left to simply execute not question.
- 2. When supply chain staff does drive procurement decisions, they are focused on their main task: to drive down costs. In the minds of supply chain decision-makers, the environment is considered when the environmentally friendly alternative is cost neutral or reduces costs. Otherwise not. And in many cases, the environmentally preferable product is also the more expensive one. (A noteworthy exception is single-use device reprocessing, which reduces the carbon emissions footprint by up to 50 percent and reduces costs by at least 40 percent.) When hospital leaders ask the supply chain to demonstrate effort to combat climate change, they are essentially giving hospital supply chain executives conflicting instructions, since environmentally preferable purchasing often runs counter to the standing instruction to reduce costs. As a consequence, supply chain executives will ignore hospital leadership's calls for greening the hospital.

Given the importance of costs, what can supply chain executives in U.S. hospitals do to reduce their hospital's environmental footprint? It must be recognized that they have to apply a common-sense approach; costs cannot be ignored. However, some basic initiatives would help:

Vendors typically don't provide information about the environmental impact of their products. Why? Because the hospital does not ask. Simply asking for sustainability performance metrics for every supplier, contract, and product to appear alongside price would go a long way toward creating the conditions for balanced or "common sense" decision-making. Ideally, sustainability metrics would be based on life-cycle analyses (LCAs).

More fundamentally, while most hospitals have value analysis committees designed to balance clinical, operational, and financial considerations in contracting, they do not play the role they should in showing environmental stewardship. Simply bringing together the right people and providing sustainability metrics is well within the power of the supply chain professional. As usual, knowing the facts helps.

A joint platform for decision-making that considers – among other things – climate impact can be the foundation for supply chain leaders to "democratize" the procurement decision and create shared

responsibility and accountability among different hospital functions. It may be time to re-write the charter of the value analysis committee.

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