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Sustainable Infection Prevention Methods in Respiratory Therapy

In this feature interview, Respiratory Therapy addresses the topic of the operational implications surrounding sustainability, infection prevention and the costly plastic waste stream. Our conversation is with Richard Radford, who was a Director of RT and other clinical areas for over 30 years. Radford is the founder and CEO of Cenorin, which is focused on infection prevention, sustainability, and cost reduction in healthcare. Radford was also the founder of Clear Medical, an early entry into the FDA-regulated 3rd Party Reprocessor business.

The following questions are posed to inform and raise awareness, concern and feasible remedies that Respiratory Care and Sleep professionals can apply when addressing issues they face related to sustainability, infection prevention, healthcare waste and professional stewardship.

In your view what are the big issues facing health care managers that have the most impact on excellent patient care, Infection prevention and sustainability?
Well now, that's a big question to begin our discussion with and it's not a simple one. I am flattered that you'd ask me to share my views with your readers on such important topics. Healthcare is filled with many complex issues, and these are certainly in the top ten. Naturally, the solutions to challenges like these are multifaceted, and center around people, organizational structures, mission, and a commitment to finding quality outcome solutions.

Shaping the achievement of high quality of patient care, infection prevention and sustainability can only be done with focused programs for each. Leaders need to mold the working environment with defined outcomes and protocols for each process and modality of care. Having structures in place will form a foundation for defining what you do and how you do it. Protocols and defined outcomes are the basis of training staff and auditing their performance. The audit process will provide the data that is needed to determine the level of compliance to the desired outcomes.

With this in place, a retrospective review of performance can identify where performance needs improvement and then you can make appropriate changes. The entire process forms what is known as a 'Quality Circle'.

In my experience, staffing is always an issue managers face in producing good quality outcomes. Staffing begins with the hiring process. It probably goes without saying that you should hire the best trained and experienced people available. Onboard them with a structured and understandable process, including regular feedback and reviews. Maintain a positive learning environment and culture. Support local training programs and professional organization participation. Most people enter healthcare with a 'helping/caring' gene…support and nurture this trait and their training and commitment will be a personal guide to excellent patient care.

What infection prevention methods have been utilized in RT and Sleep?
Well, many have been used over the years and science, research, clinical evidence, failures and practical experience have moved us a great distance towards the methods we commonly use today. The Spaulding Principle outlines how various medical devices need to be disinfected based on the level of risk associated with their use. Critical devices, which contact the vasculature or sterile tissue, require sterilization. Semi-critical devices that contact intact mucous membranes need to be high-level disinfected. Non-critical devices, where they touch only intact skin, require only low- or medium-level disinfection. This structure is a simple and practical guide in shaping infection prevention practices.

Typical methods used to decontaminate RT and Sleep devices fall into these three categories:

Critical devices: Sterilization is the recommended process and is achieved with various methods such as steam, plasma, vaporized hydrogen peroxide and ETO. All of these provide terminal disinfection for bacteria, viruses, fungi and endospores. Surgical instruments are the typical items undergoing this process. The one exception to the rule of touching blood or sterile tissue might be high-risk endoscopes, which are technically categorized as semi-critical. Because of documented cases of high-risk endoscopes such as bronchoscopes transmitting infection, according to AAMI ST91, the preferred disinfection method for these scopes would be sterilization.

Semi-critical devices: High Level Disinfection (HLD) is the recommended process and can be achieved typically utilizing three different methods, each with its own pros and cons.

The first method is chemical. Chemical disinfectants (glutaraldehyde, peracetic acid, OPA) are well studied and deemed highly effective. This method is pretty convenient for small batches of devices; however, it is expensive and in respiratory departments typically relies on manual processes

If you would like to participate in this feature, as a company or healthcare provider, please contact Steve Goldstein at s.gold4@verizon.net.

and manual documentation. Another issue is potential 'residue' of chemicals on devices, which may not be eliminated due to poorly performed or non-validated manual rinsing. My observation is that the labor costs, lack of process control, and focus of Joint Commission auditors on process management can be challenging for departments which are still disinfecting manually. Furthermore, disposal of these chemicals may violate sustainability and toxic waste disposal standards in many municipalities.

Method two is thermal disinfection. Thermal disinfection is the accepted international standard for disinfecting critical medical devices—steam is an example of thermal disinfection that is used everywhere. Thermal HLD (THLD) utilizes the same methodology, killing the relevant microorganisms with high temperature over a specified time. Compared with thermal disinfection for critical devices, the time and temperature requirements are different for semi-critical device disinfection. In scientific terms, we would describe it as the required 6 log reduction in living organisms to conform to HLD standards is typically performed with full immersion in liquid water instead of steam.

It's interesting that with RT/Sleep devices, the time and temperature required to achieve THLD makes this process an excellent choice for the large family of medical devices made of plastic. RT and Sleep therapies typically use plastic devices and THLD is a superior choice for reprocessing them, given it does not cause structural deformation and retains the devices' intended functional use.

THLD systems have been used worldwide to process these devices for over 40 years with few, if any, reported failures. Furthermore, some of these systems are FDA cleared, automated for both cleaning and HLD in large batches. With automation, you get standardized documentation and hard copy records, which is perfect for a controlled system that will meet auditors' scrutiny. It's my understanding from RT and Sleep Departments who use that THLD batch-processing consumes minimal time, and the automation frees staff to attend to other duties. While these systems are a capital equipment item and subject to the typical bean-counter budget reviews, many users report the reduction in device costs that comes with device re-use has offset the capital purchase in less than one year.

The third method involves disposable Single Patient Use (SPU) devices. Disposable devices are part of an infection prevention strategy that assumes devices are decontaminated and determined safe for single use. It is a convenient choice. However, I should note that disposable SPU items are not without issues related to sustainability, waste stream, and costs. For your readers, continued use of disposable SPU devices should be analyzed from a cost/benefit perspective to confirm whether it's really a beneficial strategy. Examples of these disposable device categories include:

- Critical: Sterile surgical devices or syringes for ABG (SPU).
- Semi-Critical: Ventilator or CPAP circuits or masks.
- Non-Critical: Blood pressure cuffs.

The term 'Single Patient Use' has an interesting history. That term has evolved over the past two decades. Originally it was a term that manufacturers used as it presented a profitable marketing strategy as well as implying a significant improvement in patient safety for some applications. An example of this is the simple disposable plastic syringe. This innovation replaced the calibrated glass syringe that required staff to clean the barrel and plunger, then match the engraved numbers on both parts to assure the custom fit and finally sterilize it. If you haven't done it, you can probably imagine the labor and time that went into it. I recall it as being time-consuming and a source of worry. Furthermore, if you can believe it, the needles were individually cleaned and 'sharpened' during this process and sterilization followed. What a relief to have very inexpensive SPU packaged syringes without all that work.

In the early 2000's the FDA began addressing the issue of SPU and determined that reprocessing them was safe, if conducted under the auspices of FDA oversight, GMP's, and formal registration of 3rd party reprocessors. The FDA required 3rd party reprocessors to file for a 510(k) clearance for each device they reprocessed. Being able to reprocess SPU devices has saved hospitals millions of dollars and assured safe reuse of many devices. However, the term Single Patient Use began to evolve given various ways it was used. Did this designation mean, "use on a single patient for a single 'event' (sterile syringe)"? Or did it mean, "use for several events on a single patient (a ventilator circuit used over several events/days)"? The FDA has now made this term 'official' and provided guidance in its use.

Many companies started using the term "Disposable" to describe these devices, as they didn't want to lose money by having hospitals realize they could be reprocessed. That change in description, in turn, has led to a huge increase in the costs to manufacture an endless supply of plastic devices that end up in the waste stream. All of this is a reaction to your question about infection prevention methods. Disposable or Single Patient Use devices haven't proven any safer from an infection prevention standpoint than properly processed reusable devices, but they sure have caused a lot of purchasing, inventory and waste management problems for the facilities that use them. If a hospital complies with safe reprocessing protocols for a surgical pack, why is it unsafe to reprocess a sleep mask using safe reprocessing protocols?

Why is documentation of Procedure and Process important?
Documentation is the bane of providers in medicine today. Healthcare depends on and is required to keep documentation. It's a never-ending activity to generate and maintain information. And there is a lot of it! Objective data for audits and quality reviews, patient information systems, financial process, and reports. Staff productivity, device clinical information, laboratory reports. Your readers deal with this all the time - I'm sure they could come up with other examples. We do trend analysis and improvement plan development using a variety of tools and forms. In some ways documenting these various types of information shapes the 'consciousness' of an organization. And of course, we use it to guide patient care and how we go about moving forward, keeping track of activities and processes to promote good outcomes and safety.

Daily operation of RT and Sleep requires productivity and budgeting information tools like the RT-validated Relative Value Unit system and patient assignment slips from which staffing assignments can be planned and budgeted. Documentation is also essential for benchmarking department and individual performance and improvement. Charting and ABG data are present in documentation activities every day. If you don't have

a plan for where you're going, and a tool to measure change, you won't know whether you ever got there. Or if your hospital is sued, you want to be able to prove you followed the correct protocols or procedures. As they say: if it isn't documented, it didn't happen.

You mentioned medical waste and sustainability as issues for RT and Sleep Departments. What is the extent of US medical waste and specifically waste attributable to single-use, disposable plastics?
Let me tell you, the enormity of the plastics issue is staggering and the downstream effects on waste disposal costs and the effects on the environment and biosphere are astonishing. Waste in the US healthcare system leads the world—not exactly the leadership position we're seeking, in my view. Here are a few statistics for perspective:

- Plastic waste in the US averages 33 pounds, per bed, per day.
- There are 350 million metric tons of plastic medical waste per year.
- 25% of healthcare waste is plastic.
- 91% of this waste ends up in landfills or natural environments and may take hundreds of years to degrade.
- 85% of plastic waste could be recycled. Less than 10% is recycled.
- Most devices that touch or connect to a patient in RT/Sleep are plastic.

Maybe the saddest aspect of this is, plastic devices thrown into the waste stream will not completely disintegrate over time, they'll just become 'micro particles' that enter living structures and persist with mostly unknown effects. While disposable SPU devices can have a positive contribution to infection prevention for a select set of devices, the general overuse practice found in healthcare institutions results in a significant contribution to the waste stream. Reprocessing reusable devices could have a big impact on the environment by decreasing the amount of plastic medical waste.

How can managers of RT and Sleep participate in efforts to improve Sustainability and Waste/cost reduction?
As a long time RT observer/practitioner, I'm astounded that disposable SPU plastic devices are the norm today compared to a few decades ago, when devices were typically reprocessed. This reliance on single use plastic devices is, in my opinion, antithetical to the clinical mission 'to do no harm.' It is apparent that many in healthcare share my opinion and are making great efforts to deal with the plastics issue and many other waste reduction opportunities. The increasing participation in sustainability-focused organizations like AMDR (the Association for Medical Device Reprocessing), Practice Greenhealth and CleanMed are excellent examples that RT and Sleep Departments can follow.

At the CleanMed annual conferences, I've learned that cost and waste reduction strategies can be straightforward. An obvious one: Choose a re-use solution in place of disposable SPU devices and significantly reduce plastic consumption. Re-use strategies will also reduce the large portion of packaging waste attributable to SPUs. Additionally, re-use will reduce associated costs in logistics (like shipping and fuel costs, inventory storage costs and waste disposal costs). Where possible, reprocess it locally, within the hospital, and add to savings.

I'm encouraged to see RT/Sleep departments that practice re-use and onsite reprocessing have found the labor and capital costs for many reusable devices are minor compared to the savings from eliminating plastic SPUs. These hospitals utilize FDA-cleared cleaning and disinfection systems, along with automated drying systems, which are simple to operate and provide controlled and automated process management, including documentation of disinfection.

We all know budgeting and acquiring capital equipment can be difficult in healthcare, and it's no different in RT. Fortunately, acquisition strategies to implement onsite reprocessing have proven to be ROI positive and need to be applied in RT and Sleep. Capital equipment acquisitions are typically made for three reasons:

- Required by statute or governance for operations
- Provide state of art technology
- Create savings (ROI) that pays for the device over a short time

One or all of these strategies should be included in a justification for capital acquisitions. I also think that AMDR is a terrific organization - this is the Association for Medical Device Reprocessing. Their website has a number of resources, and they have a quarterly newsletter that provides insights into strategies that real people are using in real-life scenarios. Your readers might find some ideas there to help them improve their sustainability profile.

How can re-use of devices support the durability of the supply chain?
During COVID, we all experienced that Supply Chains were severely tested. This very trying time served as a real lesson in supply chain durability. Re-use and localization of reprocessing protected hospitals from supply shortages. Including reusable devices over single patient use items is insurance against future supply disruptions. Sleep and RT, with shortages of masks and tubing, all managed better if they were already prepared to reprocess and reuse their devices. Patient care and inventory frustrations were mitigated with re -use and local device processing. Longer term policies and practices paid off.

Like so many issues in our society, advocacy in improving patient care and improving sustainability profiles is the only way to effect positive change. Today these advocacy efforts are a growing opportunity for RT and Sleep professionals. Sustainability challenges are found in all departments and services in healthcare. National organizations have addressed this challenge and have supported the structure and venues for collaborative initiatives and real solutions. Advocacy can be as simple as having discussions among staff and department managers on simple changes that might reduce waste or a change in select devices from disposable to reusable devices. Furthermore, expanding these discussions to include Sterile and Central Processing, Material Management and the hospital Infection Prevention team may result in new and helpful approaches.

How does professional stewardship enter the mix?
Well, maybe we could coin a new phrase: Do no harm…and do good.

Continuing Education is personal stewardship. Participating in policy reviews and implementation with changes in technology

and standards can move the ball in a more sustainable way. Seeing quality patient care beyond an individual patient and envision it encompassing the larger healthcare system and its impact on society can shape the continuum of care, professional standards, and the effects on the larger healthcare environment.

Give us a few examples of practice changes in RT and Sleep that have impacted sustainability and improved patient outcomes.
Early in my RT career I became aware of the significant waste created using multiple suction kits to remove secretions from the trachea of ventilated patients (also at significant patient risk, discomfort, and daily costs). Attempting to address this problem, I developed the original 'Trach Care' in-line suction system marketed by Ballard Medical. When Trach Care came to market not only did costs go down, but patient care and practitioner safety was significantly improved. This is an example of safe re-use and of reducing the volume of SPU's by using the same device on the same patient several times. It became commonplace to see this done with devices like ventilator circuits.

Sleep centers have improved patient outcomes by maintaining a large inventory of reusable CPAP masks so patients can try on as many as necessary to find the optimal fit. Finding the best fit achieves better comfort and compliance. These centers can afford to maintain this inventory because they reprocess each mask after its use, even if it was just five minutes long, at a very low cost. Again, better patient outcome and reduced costs via re-use. And, as I've been noting, choosing re-use also results in a reduction in packaging waste because you're purchasing many fewer devices than before—perhaps as many as 20 or 30 times fewer for each mask.

Many hospital RT and Sleep departments are committed to device reuse; they choose to clean and THLD many of their devices. The estimated cost saving is reported to be in the six-figure level annually. There was a case study published in RT magazine last spring that illustrated this outcome.

What activities are available that would assist managers to adopt policies and practices that would enable more re-use of medical devices?
Forgive my personal advocacy …. Do your research! Become informed about the abundant sources of waste and waste reduction options that exist in hospitals and at the national level. Advocate to your professional societies to develop a national cost-benefit analyses protocol of single use vs. reusable devices. Collaborate with other professional groups (like HSPA, the Hospital Sterile Processing Association, and AMDR, the Association for Medical Device Reprocessing) for accepted and validated reprocessing practices, training standards, global standards and certification processes. Contact other RT and Sleep 'early adopters' about their device re-use strategies.

Become engaged in how you and your department can become a part of the solution to improve sustainability, while maintaining patient safety and reducing healthcare costs. Share this opinion piece with your supervisor. Include Sustainability and device re-use in the curriculum of RT and Sleep training programs. Not to beat a dead horse, but also share this opinion piece with a RT/Sleep instructor.

What changes could RT and Sleep professionals make that will improve their ability to enhance sustainability, infection prevention, reduce waste, reduce costs, and streamline workflow?
There are many things we can change and improve to strengthen each of these. To begin, develop a personal philosophy and assume a personal responsibility for sustainability, supply chain durability and patient safety, to strengthen your commitment to advocacy.

Collaborating with others to create principled, rational guidance for the use of reusable semi-critical medical devices in RT and Sleep is a large step in the right direction. As a caring profession we can innovate and create platforms that can be employed to improve not only the clinical outcomes for patients but the economics of device reuse and their capital payback rationale.

Recognize these are big payback activities that will take a plan, time and an expanded vision. Progress will be made with support and collaboration with fellow professionals. Assume personal responsibility for sustainability, supply chain durability and patient safety to strengthen your advocacy commitment.

We know that safe and proven tools are available for processing reusable devices in RT and Sleep. Early adopters have many examples and data to document the feasibility of these choices and how they implemented the changes they made. Be smart and future-focused, and make sustainability, infection prevention and related subjects a required subject in RT and Sleep training … not just in school training, but every day.

How would you summarize the key outcomes you'd expect to see if people in RT and Sleep implement your ideas about infection prevention and sustainability?
My friends would tell you it's a challenge for me to be brief, but in short, I'd say that RT and Sleep departments would enjoy an equivalent or even better standard of infection prevention for their plastic devices if they move to reprocessing reusable devices with an eco-friendly method such as thermal high-level disinfection. They will also enjoy a major positive impact on their operating expenses and on their sustainability efforts. They'll be purchasing less, managing less inventory, throwing away fewer devices, and helping to minimize the damage that's done by "forever plastics" that never leave the environment.

Thank you for an interesting discussion and the opportunity to share my views with your readers. If your readers would like more information on sustainability in RT and Sleep reach out: **sustainability@cenorin.com.** I would be happy to talk with them.

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