$7.00

February 2021 • Vol. 45 No. 2

HEALTHCARE PURCHASING NEWS®

CLINICAL INTELLIGENCE FOR SUPPLY CHAIN LEADERSHIP

www.hpnonline.com

Sponsored Content

Trade up for Accuracy

Trade in Your Non-Contact Thermometers for Proven Accurate Exergen TAT-5000 Temporal*Scanners*

Accuracy has never been more important in health care facilities than right now, due to the importance of accurate fever detection. Accuracy on patients cannot be guaranteed by laboratory tests alone – clinical studies are required.

Exergen TemporalScanner accuracy is supported by more than 80 peer reviewed published clinical studies, and is the only non-invasive thermometer with extensive clinical support for accuracy, and is the only thermometer backed by a lifetime warranty, and the only thermometer manufactured in the U.S.A.

For more information on trade-in program please go to: exergen.com/tradeup

Contact HPN:
email: hpn-subscriptions@endeavorb2b.com /phone: 941-927-9345 / fax: 941-927-9588

EXERGEN® Accuracy Matters

To evaluate, email: medical@exergen.com
For general information: www.exergen.com
For educational videos, clinical studies, & manuals: www.exergen.com/ww

Invented, designed, assembled, tested, and packaged in the U.S.A. by Exergen

Q&A's on Thermometer Accuracy

Q: What makes thermometers accurate? What should we know about thermometer accuracy? How about non-contact thermometers?

A: Published peer-reviewed clinical studies. Without such studies by medical professionals, there is no assurance of accuracy on children and adults in all settings.

Accuracy specifications by manufacturers of thermometers are laboratory accuracy, not accuracy in actual use on people being tested for fever. Laboratory accuracy tests do not include important physiological effects which vary from person to person, and setting to setting, which can affect the actual accuracy well beyond their laboratory accuracy.

Published peer-reviewed clinical studies are the gold standard for accuracy, since they include actual use on people in many settings, which automatically includes the physiological effects that vary from person to person and setting to setting. Only these studies can provide the assurance that the thermometer will provide accuracy in detecting fevers for all ages in all settings.

With more than 80 published peer-reviewed clinical studies attesting to the accuracy on all ages from newborns to geriatrics, in all settings where fever detection is needed, the Exergen Temporal Artery Thermometer is by far the most proven accurate, compared to thermometers which have no or very few clinical studies.

Q: How about non-contact thermometers?

A: Non-contact thermometers are highly inaccurate for detecting fevers, here is why:
Accuracy specifications by manufacturers of non-contact thermometers (NCIT) are laboratory accuracy, not accuracy in actual use on people being tested for fever. Laboratory accuracy tests do not include important physiological effects which vary from person to person, and setting to setting, rendering NCIT's unreliable, regardless of their laboratory accuracy. For non-contact devices, these physiological effects can overwhelm the normal laboratory accuracy of the device, to the point that its actual error is 2 deg C rather than 0.2 deg C.[1]

Studies have demonstrated NCIT's detected fever in from 4% to 90% of the people with fevers, and did not detect fever in from 75% to 100% of people who lacked fever.[2] Studies of real-world efficacy of fever screening at airports and borders found that almost no disease cases had been caught across several nations and pandemics.

Q: Have non-contact thermometers been compared to Exergen Temporal*Scanner* thermometers?

A: Yes, in a new study published in 2020.[3] Independent researchers conducted a prospective observational study on a sample of 265 non-infectious patients at two hospitals. When body temperatures read below 99.5 degrees Fahrenheit, the thermometers showed similar results, but as temperatures rose above that, non-contact scanners' accuracy decreased. Temperatures were farther apart as they rose. The non-contact scanners missed five out of every six fevers detected by Exergen temporal artery thermometers.

According to the authors, "This is the first study to compare the accuracy of non-contact infrared thermometers (NCIT) to TAT in adult patients. Although mass fever screening is currently underway using NCIT, these results indicate that the NCIT may not be the most accurate device for fever mass screening during a pandemic."

1,2,3: References at exergen.com/trade-in

Exergen Corporation
400 Pleasant Street
Watertown, MA 02472

For more information, please
call 617-923-9900 x6234,
email: medical@exergen.com,
or visit: www.exergen.com

Access clinical studies:

www.exergen.com/s

$7.00

February 2021 • Vol. 45 No. 2

HEALTHCARE PURCHASING NEWS®

CLINICAL INTELLIGENCE FOR SUPPLY CHAIN LEADERSHIP

www.hpnonline.com

IP - EVS Partnerships

Managing the microscopic battleground

Reusable vs. Disposable Supplies
Visual Instrument Inspections
OR Turnover & Scheduling
Value Analysis

GET WET STAY WET

FOR 72 HOURS

Can't get to that tray of dirty surgical instruments? NO WORRIES!

Ruhof's Prepzyme Forever Wet Pre-treatment, an enzymatic **pre-treatment** humectant spray, will keep your instruments and rigid scopes moist for up to **72 hours** – preventing organic debris from drying and hardening, **making cleaning easier!**

RUHOF
An ISO Registered Firm

For More Information and **GENEROUS FREE SAMPLES**

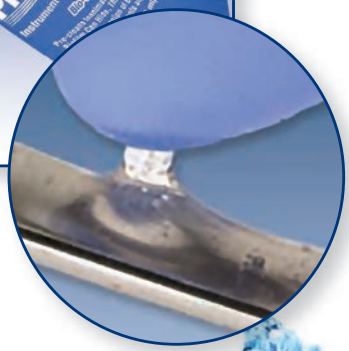
1-800-537-8463 • WWW.RUHOF.COM

393 Sagamore Avenue, Mineola, New York 11501

Tel: 516-294-5888 • Fax: 516-248-6456

Visit www.ksrleads.com/?102hp-007

Copyright ©2020 Ruhof Corporation



Prepzyme® Forever Wet creates a long lasting moisture barrier. As seen here, instrument remains wet to the touch for days after application.

Prepzyme® Forever Wet

INSTRUMENT TRANSPORT HUMECTANT SPRAY

The latest breakthrough in **enzymatic pre-cleaning** sprays, **Prepzyme® Forever Wet's** unique humectant properties form a **moist coating** over the instruments that lasts for days.

- The humectant formulation creates a moisture retention barrier which keeps soiled instruments and rigid scopes moist for a prolonged period of time – unlike a GEL which **HAS NO MOISTURE RETENTION** properties
- Operating room safe, non-aerosol, multi-tiered enzymatic spray helps prevent bio-burden from drying on the surface of soiled instruments and scopes
- Ideal for transporting soiled instruments that may sit for an extended period of time
- Reduces tray weight during transport compared to liquid presoaks
- Soiled sharps are visible through humectant
- Decreases spills and potential cross-contamination

AD-63 112320

IN THIS ISSUE...

February 2021 • Volume 45, No. 2

HEALTHCARE PURCHASING NEWS

Photo credit: nndanko | stock.adobe.com

Photo credit: NicoElNino | stock.adobe.com

Photo credit: Juan | stock.adobe.com

Photo credit: Roger | stock.adobe.com

Photo credit: tadamichi | stock.adobe.com

SPECIAL FOCUS

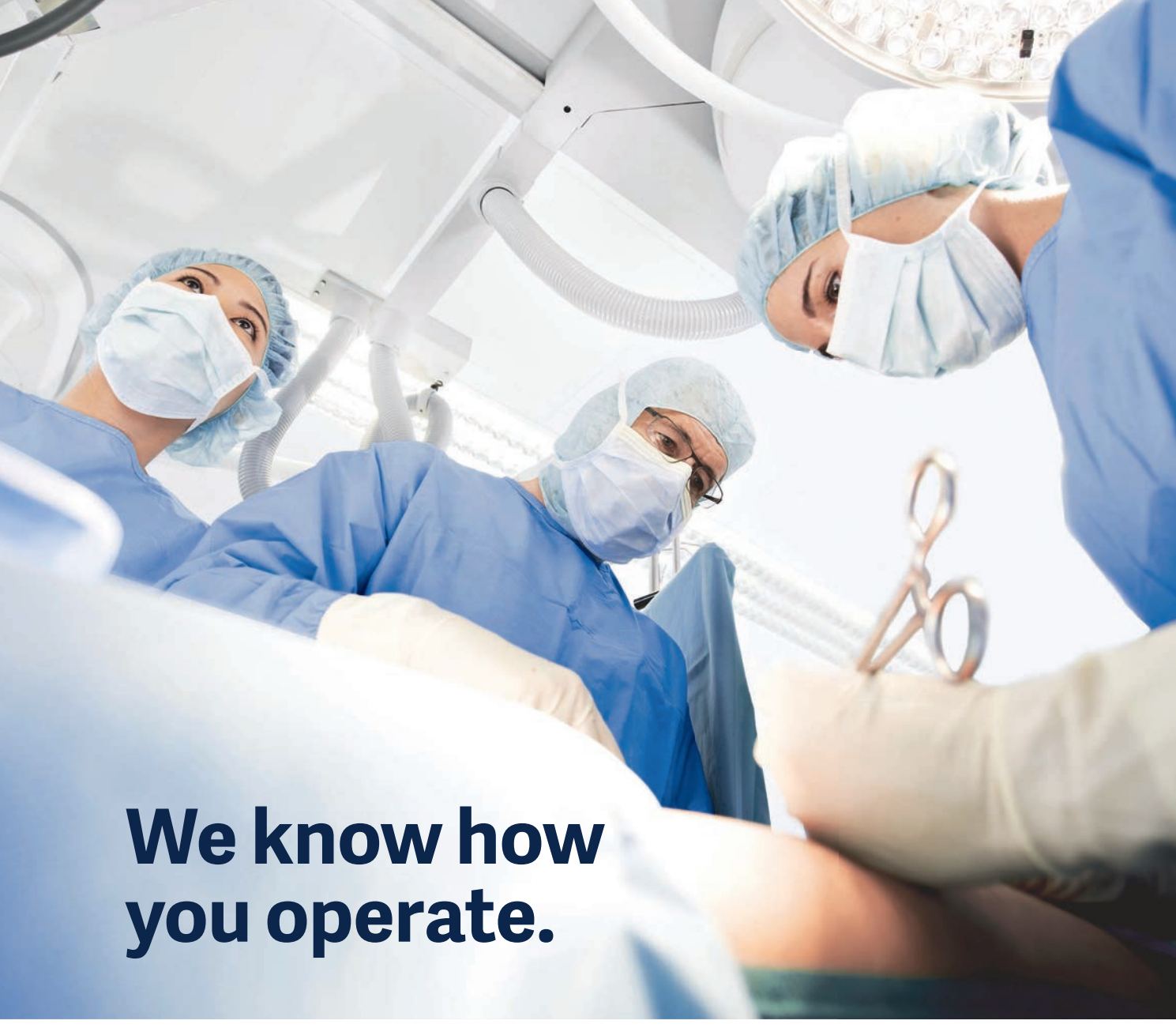
OPERATING ROOM

INFECTION PREVENTION

CS CONNECTION

PRODUCTS & SERVICES

EXPERT EXCLUSIVES



We know how you operate.

As the complexity and diversity of surgical procedures continue to increase in the ASC, more and more ambulatory surgery centers are turning to Getinge for single source financial, operating room and infection control solutions to help ensure superior operational efficiencies and positive clinical outcomes.

Getinge understands your needs and offers an unmatched portfolio of products and technologies that are aligned with cost containment, OR scheduling, space allocation, and patient care strategies that distinguish ASCs from inpatient hospital surgical workflows.

Getinge solutions for your ASC — We know how you operate.

Explore all we have to offer
getingeusa.com/AmbulatorySurgeryCenters

GETINGE

Getinge and Cardiosave are trademarks or registered trademarks of Getinge AB, its subsidiaries, or affiliates in the United States or other countries. • Copyright 2020 Getinge AB or its subsidiaries or affiliates. • All rights reserved. • MCV00106554 REVA

RESILIENT

The wish list

Armed with 2020 hindsight (pun intended), we acknowledge that the healthcare industry weathered the pandemic storm as well as it could, but it did seem to bring out a back-to-basics philosophy for the nerve-wracked Supply Chain that tried to keep pace like War Admiral chasing his nephew Seabiscuit at Baltimore's Pimlico in 1938.

In a survey of *Healthcare Purchasing News* readers last year as a prerequisite to *HPN*'s October feature on "Future-Ready Supply Chains," December's "Healthcare Product Hall of Fame" and January's "Healthcare Product All-Stars," we asked readers the following question: If they were provided the resources to research, adopt and implement one or two technology-oriented processes, products or projects in 2021, which one or two would they choose? We gave them a long list of options.

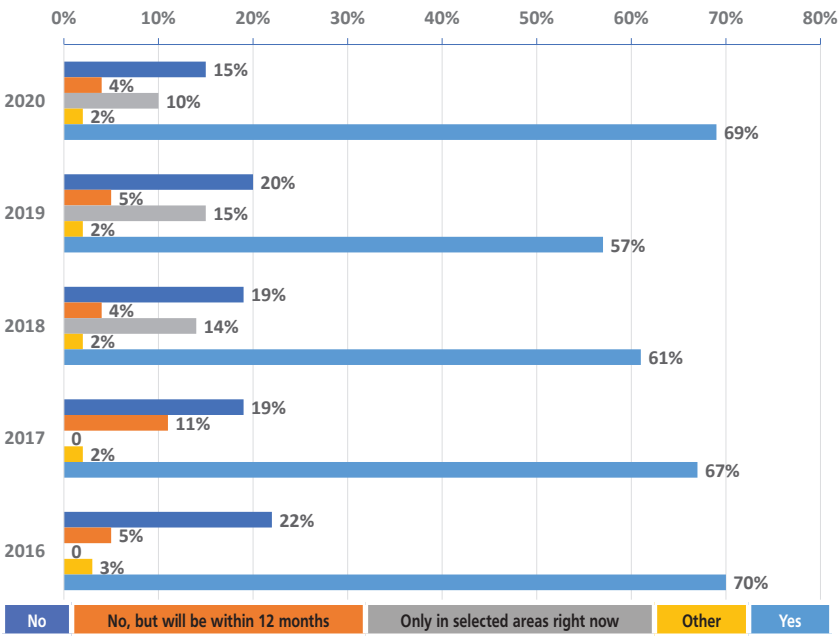
With all the hubbub and multimedia hubbaloo about artificial intelligence, blockchain and 3-D printing during the last two years, we figured the results would be … predictable and ordinary.

Surprisingly, we were wrong. The three anticipated/expected leaders were nestled snuggly in the middle of the list. The leaders were more … dare we say it? Old school. See below for the results and ponder.

1. **Wearables (e.g., computers, sensors, trackers) … 40.0%**
2. **Cybersecurity measure … 27.3%**
3. **4-D barcoding and/or advanced RTLS … 25.5%**
4. Drones for internal/external deliveries/distribution … 10.9%
5. Robotics/Robotics Process Automation (RPA) … 10.0%
6. Artificial intelligence (AI) … 8.2%
7. 3-D printing … 7.3%
8. Blockchain … 7.3%
9. Internet of Things (IoT)/Machine-to-machine (M2M) interoperability … 7.3%
10. Self-driving vehicles (e.g., AGVs, sensor-led tugs, etc.) … 3.6%
11. Virtual reality (VR) … 2.7%
12. Augmented reality (AR) … 0.9%

DATA BANK

Is your Item Master (IM) linked to your organization's Chargemaster (CDM)?



EDITORIAL

Publisher/Executive Editor *Kristine Russell*
krussell@hpnonline.com
Senior Editor *Rick Dana Barlow*
rickdanabarlow@hpnonline.com
Managing Editor *Ebony Smith*
esmith@hpnonline.com
(941) 259-0839
Contributing Editor *Kara Nadeau*
knadeau@hpnonline.com

ADVERTISING SALES

East Coast *Blake and Michelle Holton*
(407) 971-6286
Midwest *Randy Knotts*
(312) 933-4700
West Coast *Blake and Michelle Holton*
(407) 971-6286

ADVERTISING & ART PRODUCTION

Ad Contracts Manager *Tiffany Coffman*
(941) 259-0842
Graphic Design *Tracy Arendt*
List Rentals *Laura Moulton (941) 259-0859*

EDITORIAL ADVISORY BOARD

Jimmy Chung, MD, FACS, Associate Vice President, Perioperative Portfolio, Providence St. Joseph Health, Renton, WA; **Joe Colonna**, Chief Supply Chain and Project Management Officer, Piedmont Healthcare, Atlanta, GA; **Karen Conway**, Vice President, Healthcare Value, GHX, Louisville, CO; **Dee Donatelli**, RN, CMRP, CVAHP, Vice President Of Professional Services, symplr, and Principal, Dee Donatelli Consulting, LLC, Overland Park, KS; **Melanie Miller**, RN, CVAHP, CNOR, CSPDM, Value Analysis Consultant, Healthcare Value Management Experts Inc. (HVME) Los Angeles, CA; **Dennis Orthman**, Consulting, Braintree, MA; **Janet Pate**, Nurse Consultant and Educator, Ruhof Corp.; **Richard Perrin**, CEO, Active Innovations LLC, Annapolis, MD; **Jean Sargent**, CMRP, FAHRMM, FCS, Principal, Sargent Healthcare Strategies, Port Charlotte, FL; **Rose Seavey**, RN, BS, MBA, CNOR, ACSP, Seavey Healthcare Consulting Inc., Denver, CO; **Richard W. Schule**, MBA, BS, FAST, CST, FCS, CRCST, CHMMC, CIS, CHL, AGTS, Managing Director Synergy Health NorthEast at STERIS Instrument Management Services; **Barbara Strain**, MA, CVAHP, Principal, Barbara Strain Consulting LLC, Charlottesville, VA ; **Deborah Petretich Templeton**, RPh, MHA, Chief Administrative Officer, System Support Services, Geisinger Health, Danville, PA; **Ray Taurasi**, Principal, Healthcare CS Solutions, Washington, DC area

SUBSCRIPTION RATES

Annual Subcriptions (prepaid only) **Discounts:**
U.S.: $120.00 **Canada/Mexico:** $155.00 2 yrs: 10%
Foreign A/O: $221.00 **Digital Subscription**: $60.00 3 yrs: 15%
Current Issue
U.S.: $15.00 **Canada/Mexico/Foreign A/O:** $20.00
Back Issue
U.S.: $17.60 **Canada/Mexico/Foreign A/O:** $22.00

CHANGE OF ADDRESS

Subscribers: For change of address, send your old and new addresses to *Healthcare Purchasing News*, 2477 Stickney Point Road, Suite 315B, Sarasota, FL 34231. Fax: (941) 927-9588, Email: *hpn-subscriptions@endeavorb2b.com*. Allow 4 to 6 weeks for correction. All other inquiries, call Tiffany Coffman at (941) 259-0842.

CORPORATE TEAM

Healthcare Purchasing News (ISSN: 1098-3716) is published monthly by Endeavor Business Media, 2477 Stickney Point Road, Suite 315B, Sarasota, FL 34231, Phone: (941) 927-9345, Fax: (941) 927-9588,

ENDEAVOR BUSINESS MEDIA

CEO Chris Ferrell
CRO/CMO June Griffin | **CFO** William Nurthen
COO Patrick Rains | **Chief Administrative and Legal Officer** Tracy Kane
EVP Special Projects Kristine Russell
EVP Key Accounts Scott Bieda

www.hpnonline.com, Business hours: 8:00 a.m.-5:00 p.m. EST.

Copyright 2021 by Endeavor Business Media. All rights reserved. No part of this publication may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopy, recording, or any information storage-and-retrieval system, without permission in writing from the publisher. *Healthcare Purchasing News* is a registered trademark used herein under license.

Office of publication: Periodicals Postage Paid at Nashville, TN 37209 and at additional mailing offices.

Postmaster: Send address changes to: *Omeda (Healthcare Purchasing News)*, PO Box 3257, Northbrook, IL 60065-3257.

VERIFIED AUDIT CIRCULATION

Printed in USA
Paper manufactured in USA
Soy ink made in USA

facebook.com/hpnonline
twitter.com/hpn_online
linkedin.com/company/healthcare-purchasing-news/

See how Mölnlycke delivers möre to **your bottom line.**

At Mölnlycke, we strive to **Deliver Möre** to healthcare organizations, aiming to boost profitability by **improving every part of the care cycle.**

Enhancing patient experiences
Protecting clinician safety
Improving outcomes
Generating higher efficiencies
Supporting you with a reliable, robust supply chain

That's what we call

TÖTAL VALUE™

Learn more at www.molnlycke.us/totalvalue

The Mölnlycke trademarks, names and logo types are registered globally to one or more of the Mölnlycke Health Care Group of Companies. Distributed by Mölnlycke Health Care US, LLC, Norcross, Georgia 30092.
© 2020 Mölnlycke Health Care AB. All rights reserved. 1-800-843-8497. MHC-2020-78805

Mölnlycke®

FAST STATS

Vaccine rollout and development

50

states and the District of Columbia are prioritizing healthcare workers and long-term care residents and staff in Phase 1a of their plans as recommended, though 16 states depart from the recommendations in some way.

14

of the 44 states that have updated their Phase 1b priority groups follow the CDC's recommendations exactly and will prioritize people ages 75 and older and frontline essential workers outside of healthcare, including first responders, corrections officers, food and agriculture workers, postal workers, manufacturing workers, grocery store workers, public transit workers, teachers and education support staff and childcare workers.

23

of the 30 states that depart from the Phase 1b recommendation include a broader range of older residents (generally ages 65 and older), and 18 use modified definitions for eligible frontline workers, including several that limit frontline workers to educators and/or first responders.

17

of the 33 states that have updated their Phase 1c priority groups follow the CDC's recommendation to prioritize people ages 65 to 74, younger people with high-risk medical conditions, and any essential workers not included in earlier phases.

3

mRNA vaccine candidates were announced by Moderna's development programs, including Flu vaccine (mRNA-1010, mRNA-1020, mRNA-1030), HIV vaccine (mRNA-1644 & mRNA-1574) and Nipah virus (NiV) Vaccine (mRNA-1215).

Citations:

New Analysis Takes In-Depth Look at How States are Prioritizing Who Gets a COVID-19 Vaccine, Jan 11, 2021, https://www.kff.org/coronavirus-covid-19/press-release/new-analysis-takes-in-depth-look-at-how-states-are-prioritizing-who-gets-a-covid-19-vaccine/

Moderna Provides Business Update and Announces Three New Development Programs in Infectious Disease Vaccines, January 11, 2021, https://investors.modernatx.com/news-releases/news-release-details/moderna-provides-business-update-and-announces-three-new

Photo by Karolina Grabowska from Pexels

NEWSWIRE

AHRMM adds 20 additional keys for supply chain excellence

AHRMM has added 20 Keys for Supply Chain Excellence to its Key Performance Indicator (KPI) repository. The initial Keys released in July 2020 focused on the areas of Finance and Operations; the 20 newly released Keys expand into four new categories: Environmental Sustainability, Patient Safety, Resiliency and Data Standards. Healthcare supply chain professionals play a critical role in driving high-quality care, at a more affordable cost, to deliver greater value to patients; this is the essence of Cost, Quality and Outcomes (CQO). To achieve this, you must monitor and measure the health of your supply chain. The Keys are a way for organizations to evaluate its supply chain performance over time in fundamental areas.

The AHRMM Keys will help:

- initiate continuous process improvement dialogue with key stakeholders
- demonstrate supply chain performance
- change the conversation with the C-suite to make supply chain more strategic partners
- unlock healthcare supply chain excellence
- operate from the intersection of CQO

For all Keys, visit AHRMM at https://www.ahrmm.org/keys.

Bellwether League to expand with educational offerings and scholarships

Bellwether League Inc. announced they officially became Bellwether League Foundation on Jan. 1, 2021 and now will be offering the healthcare supply chain industry and profession several new opportunities. Among the newly added improvements include:

- Bellwether League Foundation now operates as a 501(c)3 nonprofit organization so donations and sponsorships qualify as tax-deductible charitable contributions. Previously, Bellwether League Inc. operated as a 501(c)6 not-for-profit corporation for 13 years so donations and sponsorships only could be deducted as business expenses.
- Bellwether League Foundation plans more educational content online and on-demand through its "Leaders & Luminaries" podcasts, publication and webcasts, as well as through the annual Healthcare Supply Chain Leadership Forum.
- Bellwether League Foundation plans a variety of educational scholarships to qualified college-bound high school students, qualified current collegiate students and qualified active professionals.
- The annual Bellwether Induction Dinner Event, which went virtual last October due to the pandemic, has been rebranded the Bellwether League Foundation Induction & Recognition Event (BLFIRE) to provide multimedia flexibility – whether live or streaming on-demand. Bellwether League Foundation continues to honor and recognize supply chain excellence through its Future Famers, Ammer Honoree and Bellwether Honoree awards that span and celebrate entire careers from beginning to middle to end.

2021 EVENTS INCLUDE:

- BLFIRE 14 currently is scheduled for Monday, Oct. 4, 2021. Depending on pandemic developments, the fourth quarter 2021 event either will be a hybrid or live-streaming and on-demand virtual event.
- Bellwether League Foundation's 8th Healthcare Supply Chain Leadership Forum is scheduled for May 2021 as a virtual event.
- Bellwether League Foundation's *Leaders & Luminaries* publication is scheduled for online posting twice this year in late winter and late summer.

APIC issues statement regarding new COVID-19 strain

The Association for Professionals in Infection Control and Epidemiology (APIC) is urging the public to 'Stay the Course,' and Continue Infection Prevention Measures.

The following statement comes from Connie Steed, MSN, RN, CIC, FAPIC, 2020 President of APIC:

"APIC urges the public to continue practicing the infection control measures we know are effective in preventing the spread of COVID-19, no matter what strain of the virus is circulating.

With reports that a new variant of COVID-19 is infecting people in Europe, Americans may be worried about how to protect themselves. The nation's infection preventionists want the public to know that they should continue to wear face masks, practice social distancing, get a flu shot, and wash their hands frequently.

These steps are effective in stopping the spread of infection regardless of the strain currently in circulation. Because the virus spreads via droplets that are expelled from the respiratory tract when we talk, cough, and breathe, wearing face masks and staying six feet away from each other are the best ways to prevent the spread of this disease. And because the new strain of COVID-19 appears to be highly transmissible, following these practices is more important than ever.

Until the new COVID-19 vaccines are widely available, it is imperative that we all do what we can to prevent illness. This is especially critical given that many, if not

Page 8

NOW PATHOGENS HAVE NOWHERE TO HIDE

Not under the tray. Not under the bed. There's no evading new Clorox Healthcare® Spore[10] Defense™ Cleaner Disinfectant, the first sporicidal solution available for the Clorox® Total 360® System. Now you can have unparalleled electrostatic coverage and the disinfecting power to eliminate *C. diff* and 38 additional pathogens in 5 minutes or less.

Under. Over. And on all sides of surfaces, in every room.*

Learn more at CloroxHealthcare.com

[10]Clostridium difficile spores only *Hard, nonporous surfaces

© 2020 Clorox Professional Products Company. NI-50972

CLOROX HEALTHCARE™

most, U.S. hospitals are stretched beyond capacity.

APIC asks the public to take the #PreventTheSpread pledge to continue masking and social distancing — even after being vaccinated. Until enough people have received the required vaccine doses, we cannot risk spreading COVID-19 in our communities."

Global scientists double down on SARS-CoV-2 variants research

Global scientists are intensifying research into COVID-19, as the World Health Organization (WHO) moves to expand its scientific collaboration and monitoring of emerging variants of SARS-CoV-2, the virus that causes COVID-19, reported WHO.

A virtual meeting of scientists from around the globe brought together more than 1,750 experts from 124 countries to discuss critical knowledge gaps and research priorities for emerging variants of the virus.

Dr. Tedros Adhanom Ghebreyesus, WHO Director-General, said: "Science and research have played a vital role in responding to the pandemic since day one and will continue to be the heartbeat of everything WHO does."

The consultation was structured around six thematic areas covering epidemiology and mathematical modelling, evolutionary biology, animal models, assays and diagnostics, clinical management and therapeutics and vaccines. Scientists noted the importance of research to detect and understand early on the potential impact of emerging variants on diagnostics, treatments and vaccines. There was a consensus on the importance of integrating the new SARS-CoV-2 variants research into the global research and innovation agenda while enhancing coordination across disciplines.

"Our collective goal is to get ahead of the game and have a global mechanism to quickly identify and study variants of concern and understand their implications for disease control efforts," said Dr. Ana Maria Henao Restrepo, Head of WHO's R&D Blueprint.

It is normal for viruses to mutate, but the more the SARS-CoV-2 virus spreads, the more opportunities it has to change. High levels of transmission mean that we should expect more variants to emerge.

Of the variants reported so far, some are associated with increases in transmissibility but not disease severity. Research is ongoing to address whether the changes impact public health tools and measures. Genomic sequencing has been critical in identifying and responding to new variants.

"So far an astounding 350,000 sequences have been publicly shared, but most come from just a handful of countries. Improving the geographic coverage of sequencing is critical for the world to have eyes and ears on changes to the virus," said Dr. Maria Van Kerkhove, WHO Technical Lead on COVID-19.

Increasing sequencing capacity across the world is a priority research area for WHO.

Better surveillance and laboratory capacity to monitor strains of concern needs to be accompanied by prompt sharing of virus and serum samples via globally agreed mechanisms so that critical research can be promptly initiated each time. Scientists highlighted the importance of national data platforms to document critical clinical, epidemiological and virus data that facilitates the detection and assessment of new SARS-CoV-2 variants.

STERIS announces agreement to acquire Cantel Medical

STERIS and Cantel Medical Corp announced that STERIS has signed a definitive agreement to acquire Cantel, through a US subsidiary. Cantel is a global provider of infection prevention products and services primarily to endoscopy and dental customers.

"We have long appreciated Cantel, which is a natural complement and extension to STERIS' product and service offerings, global reach and Customers," said Walt Rosebrough, President and Chief Executive Officer of STERIS. "Combined, we will offer a broader set of Customers a more diversified selection of infection prevention and procedural products and services."

Cantel's largest business, its medical portfolio, will strengthen and expand STERIS' endoscopy offerings, adding a full suite of high-level disinfection consumables, capital equipment and services, as well as additional single-use accessories. Cantel's dental business extends STERIS into a new customer segment where there is an increasing focus on infection prevention protocols and processes.

Hospital ISM Report On Business shows seven months of continued growth

Economic activity in the hospital subsector grew in December for the seventh consecutive month, say the nation's hospital supply executives in the latest Hospital ISM Report On Business, announced the Institute for Supply Management (ISM).

In the report issued by Nancy LeMaster, MBA, Chair of the ISM Hospital Business Survey Committee, "The Hospital PMI registered 62.6 percent in December, unchanged from November," the report stated. This was the seventh month of growth following two months of contraction.

The Business Activity, New Orders, and Backlog of Orders indexes grew in December, while the Employment Index contracted. The Case Mix Index decreased to 62 percent, down 0.5 percentage point compared to the November reading of 62.5 percent. The Days Payable Outstanding Index increased to 52.5 percent, up 1.5 percentage points from the November reading of 51 percent. The Technology Spend Index registered 52 percent, a decrease of 6 percentage points from the November reading of 58 percent.

"December comments from Business Survey Committee panelists echoed and reinforced the same issues highlighted in November. COVID-19 spikes account for most of patient volumes, and elective procedures are once again being delayed due to lack of capacity. Availability of personal protective equipment (PPE) continues to be a challenge, but staffing has become an even bigger issue. Such comments as, 'Having a difficult time finding employees, especially environmental services department (EVS) and other support staff' and 'COVID-19 burnout is causing vacancies across the system' were typical," said LeMaster.

HHS launches locator for COVID-19 treatment sites with monoclonal antibodies

A web-based COVID-19 outpatient treatment locator maintained by the U.S. Department of Health and Human Services (HHS) is now available to assist healthcare providers and patients in finding potential locations for treatment with monoclonal antibody therapeutics, reports HHS.

These medicines are authorized for emergency use in treating patients with mild or moderate COVID-19 who are at high risk of developing severe symptoms and requiring hospitalization.

The COVID-19 therapeutics distribution page shows locations where these monoclonal antibody therapeutics have been delivered, including the facility name and address and which monoclonal antibody therapeutic has been delivered to the site. Only facilities that are open to the general public are listed. The locator does not include facilities that receive the monoclonal antibody therapeutics for outpatient treatment of specific groups, such as for patients in long-term care facilities, skilled nursing facilities, psychiatric facilities, or prisons.

For the locator, visit https://protect-public.hhs.gov/pages/therapeutics-distribution #distribution-locations. HPN

CleanSpace®

RESPIRATORS

EVERY ANGEL DESERVES A HALO

PROTECTING HEALTHCARE WORKERS FROM AIRBORNE CONTAMINANTS

- No belts and hoses usually associated with Powered Air Purifying Respirators (PAPRs)
- High protection P3/TM3 99.97% against biohazards (APF 50 & 1000)
- Reusable and cost-effective
- Comfortable to wear for extended periods – Only 400g/0.9lb
- Simple and fast to don
- NIOSH approved

Available in half face and full face masks.

sales@cleanspacetechnology.com

WWW.CLEANSPACETECHNOLOGY.COM

NIOSH APPROVED ✓ CE IP66

Has pandemic poked holes in reusable vs. disposable product debate?

COVID-19 cannibalizes consumption, causing utilization conundrum

by Rick Dana Barlow

Photo credit: nndanko | stock.adobe.com

One of the more controversial issues lurking within the Sterile Processing realm as far back as a decade or two ago involved the reuse of single-use devices (SUDs) with the industry cleverly considering certain disposables as "reposables" regardless of Food and Drug Administration (FDA) classification.

Provider proponents justified the practice by claiming the "disposable" label helped manufacturers pad their profits from healthier sales even though manufacturers declared the disposable products they made included components and raw materials that likely could not withstand a rigorous cleaning, disinfection and/or sterilization process, which would render those single-use-only products fragile, unsafe and a potential danger to patients if used more than once.

For the last decade at least, the concept of SUDs and reposables seemed to ebb along with the concept of flashing or immediate-use sterilization – carried out on a desperate, last-resort, need-to only basis.

Early last year, as healthcare organizations began to anticipate product demand spikes due to a rapidly spreading regional epidemic in East Asia that exploded within months to a full-blown, world-wide pandemic, the last resort re-opened for business for a select number of products.

Nothing like surging demand to empty shelves, clog back-order channels, magnify shortages and amplify tensions with supply chain around the access to and availability of personal protective equipment (PPE) and other related products.

To make ends meet, desperate times called for desperate measures, such that a number of providers and suppliers figured out creative ways to encourage and implement the reprocessing of specific SUDs, such as N95 respirators, for example.

This leads to a fundamental procedural question worth asking: How has the provider and supplier response to the pandemic in terms of reusing SUDs – no matter how limited or specialized – changed opinions about the practice even as the specter of deadlier crises looms?

Bobbing and weaving

Melinda "Mindy" Benedict, CIC, CFER, Global Senior Manager, Infection Prevention, Olympus Corporation of the Americas, acknowledges the apparent mixed messaging but urges caution before changing behaviors.


Melinda Benedict

"COVID-19 has created an unprecedented need for reprocessing SUDs, such as N95 respirators," Benedict noted. "The supply of these protective facemasks has not met the ongoing demand for these essential safety tools for healthcare workers, and emergency use authorization (EUA) was provided by the FDA to reprocess these masks, provided that the reprocessor conducts cleaning and sterilization/disinfection of the SUDs in an appropriate manner – per FDA guidelines for decontaminating respirators.

"Temporary allowances that may have been made to enable the continuation of patient care and meet care demands could be misinterpreted as permanent solutions," Benedict warned. "The current EUA is a temporary solution to the pandemic-related problem of personal protective equipment shortages. Single-use devices are engineered and manufactured to be used one time only. While some single-use devices, like the N95 facemask, are considered low-risk devices, other single-use devices are classified as high-risk as reprocessing these high-risk devices could present a significant risk for infection unless the original equipment manufacturer (OEM) has data supporting that the device can be reprocessed and used multiple times."

Still, she emphasizes the increased legal liability on part of providers and service companies that carry out reuse practices.

"Firms and hospitals that are reprocessing SUDs are considered by the FDA to be manufacturers and as such must comply with all of the following statutory and regulatory requirements: Reprocessors of SUDs should be able to demonstrate:

1. That the device can be adequately cleaned and disinfected or sterilized
2. That the physical characteristics or quality of the device will not be adversely affected by these processes
3. That the device continues to comply with applicable FDA requirements."

But navigating through the winding and seemingly circuitous justification for reusing certain SUDs during a crisis when few other options exist leads to frustration and peril.

"As a nurse and as an Environment of Care/Infection Prevention Director for many years, there was a strong focus on reusable vs. disposable supplies," acknowledged Janet Pate, JD, MHA, RN, Nurse Consultant and Educator, Ruhof Corp. "For many products, it was obvious that they shouldn't be reused. From a user's perspective, for the products that were permissible to be reused, it was often a struggle to educate them that if an item was labeled single-use, under no circumstances should it be reused. This was ongoing education for an extended period of time.


Janet Pate

"With the development of reprocessing facilities for some of these items it became even more confusing," Pate admitted. "It was difficult to educate everyone on which items could be reprocessed by these facilities and why it was acceptable. After all, everyone had been educated that disposable/single-use items meant just that, the item should be disposed of after use. With the onset of the pandemic, suddenly it is acceptable to reuse many of these items. Although most people understand the impact of the pandemic regarding the reuse of supplies, in the future the Infection Preventionists and other regulatory experts will now be faced with changing back to the practices before the pandemic. This definitely will be challenging, and perhaps research should be performed to evaluate if the change in practices related to certain products should remain even after the pandemic."

As a veteran healthcare supply chain and sterile processing executive, consultant Jean Sargent knows plenty about the intricacies of reuse as she worked with the FDA in 2000 on educating Sterile Processing, Supply Chain and Infection Preventionists about the federal agency's new policy on reusing SUDs.


Jean Sargent

"It was quite a process to get people to understand the significance of the policy," said Sargent, Principal, Sargent Healthcare Strategies. "There are many today who do not know it exists. This will create much more confusion. We need direction from the FDA, and then manufacturers need to update their instructions-for-use (IFUs) to include reuse of single-use devices. Otherwise, leaving the choice to each facility may affect the safety of [the patients] on whom the reprocessed product was used. I also know firsthand how difficult it has been to find PPE that meets the approval of Infection Preventionists, clinicians, human resources, finance and supply chain."

Still, the pandemic reaction remains an effective reminder of the fundamental tenets behind reuse, product integrity and sterility, according to Stephen Kovach, CFER, Educator Emeritus, Healthmark Industries.


Stephen Kovach

"For me, it brings to light what I refer to as 'The Science of Reprocessing,'" he noted. "Staff who work in the medical device reprocessing department [know] how important of a department we are. We are no longer just the department that 'cleans utensils.' We know thousands of medical devices, and we have more than only steam sterilization technology at our fingertips."

The pandemic illuminates this context.

"[Sterile Processing] staff today understand the importance of what they do and the impact they have on patient outcomes," Kovach said. "This pandemic has shown how vital we are to any facility, not just to prepare something for surgery. When you read the peer-reviewed literature, you will notice that members of the department are part of those papers, so in my view, it has helped change in the C-suite the perception of the people in the basement. They have and will be vital to the facility's survival.

"The shortage has caused all departments to work together and see how they each dovetail into each other, and with science, they can make changes," he continued. "It raised each department's awareness within its facility, making everybody stronger, and then the patient is the winner. So from something sour, we made something sweet."

Hits and misses

Few deny that Supply Chain took a hit when the pandemic caused demand to outpace availability of products and under pressure may have missed opportunities to change processes on the fly.


Gregg Agoston

"The pandemic has brought laser focus on the supply chains," observed Gregg Agoston, Vice President, Business Development, SPD Transformation Services,

Page 12

SpecialtyCare. "Everyone who purchased goods from a grocery store witnessed the effects of supply chain disruption caused by the pandemic. For hospitals, most began in January to stockpile supplies in anticipation of the disease's arrival. We saw that inventories were quickly depleted. Manufacturing capability, dependability and logistics became the pinch points. As shortages began to be felt, our creativeness allowed for workaround solutions, such as reprocessing N95 masks, etc. Fortunately, the pandemic was not as devastating as predicted and did not result in an overrun of hospitals' capacity to treat patients."

But K. Mark Wiencek, Ph.D., Lead Microbiologist, Contec Inc., points to the pandemic-driven supply shortages as introducing some "new dynamics into the classic debate" of reusables vs. disposables.

Mark Wiencek

"In some cases, healthcare associates switched from whatever type they were using before the pandemic to any option they could procure," Wiencek recalled. "The switch from the preferred disposables to reusable options usually was associated with PPE. However, there have been situations, like with cleaning textiles (e.g., mop pads, wipers), where the opposite occurred – personnel switched to domestically produced disposables due to issues with off-shore supply chains for reusable items.

"Regardless of the drivers, reprocessing textiles can be a challenging process, even for products that are designed to be re-cleaned or re-laundered and possibly re-sterilized," he continued.

Visit www.ksrleads.com/?102hp-009

"It is important that healthcare institutions properly audit the reprocessing operations, whether they are conducted internally or through an outside contractor. Improper laundering can lead to damage that can compromise the performance of the item or increase the risk of cross-contamination if hazardous microbes, chemicals or drugs are left on the items after processing."

When examining the notion of reusable vs. disposable supplies – and more narrowly, whether to disinfect disposable supplies – much of the debate centers on four factors, according to Don Lowe, Spokesperson, ProTEC-USA.

Cost: "Material used to make reusable gowns is in very tight demand; therefore, not only making it extremely difficult to source but driving up the cost of goods to a premium that is substantially higher than disposable counterparts," Lowe indicated. "Much of the material itself is imported, leading the countries of manufacture to commonly prohibit export of said goods.

"Disposable gowns can be procured more readily and typically at a lower cost versus that of reusable alternatives," he continued. "Utilizing domestic manufacturers of disposable gowns allows healthcare organizations to shorten supply chains and reduce exposure for potential delivery disruptions."

Maintenance: "Reusable gowns carry a life span," he said. "This raises several challenges: How can one be sure the exact number of washes that a gown has gone through? How can one be sure that the safeguards and protections built into the gown don't start to diminish after 10, five or even two washes? Furthermore, the scorecard is left in the hands of laundry operators, opening the possibility of human error on a wash count of gowns. Great care must be taken as part of any gown maintenance program."

Risk: "Picking up from maintenance, there is an inherent risk associated with using a reusable gown that while cleaned, can only be donned with the assumption that it was washed as per manufacturer specifications and that it has not reached its recommended end-of-use state," he noted. "On-shored supply chains are a factor here too, as there is inherent value in saving time and reducing the potential to received tainted orders."

Confidence: "Healthcare organizations can feel a sense of assurance knowing that the disposable gowns that they've procured for their team will provide superior performance and protection as they work with patients in high-contamination risk situations," he added.

Lowe recognizes the challenges the topic of reusing disposable gowns brings.

"It's critical that hospital administrators implement and follow all FDA guidelines and procedures when looking to extend the use of reusable and disposable gowns," he said. "There should be strict oversight to ensure that the safety of medical professionals and patients are never compromised."

For the record, the FDA does not condone the reuse of a variety of products and, in fact, advises against the reuse of disposable gowns. But the federal agency does make an allowance for certain types of respirators.

Still, the pandemic taught healthcare organizations some valuable lessons. Four key wake-up calls should have been learned so far, according to Agoston.

1. "Even with an effective and efficient supply chain, it can be quickly disrupted and depleted," he said. "For this reason, back-up supplies and alternative products are a must. In addition, having dependable manufacturing capability and logistic support are a national requirement for critical medical supplies.

Page 14 ▶

How's Your Supply Chain Holding Up?

ProTEC-USA
Built with integrity.

ProTEC-USA is a full-service resource for domestically-produced, 100% Made-in-USA ***EZDoff medical gowns***, designed and manufactured by our teams at our American-based facilities.

In-stock, quick order turnaround • Volume-level pricing
Highly responsive customer service • AAMI PB70 Level 1, 2 and 3-compliant

Available through your preferred distributor or at:

ProTECUSAProducts.com
inquiries@protecusaproducts.com

Scan here to view our product sheet:

2. "Disposable items have a place, but if there is a safe and effective reusable device, this should be preferred or at least held in reserve to hedge against shortages," he noted. "Environmentally, reusable devices tend to have a much lower impact vs. disposable supplies. Think of all the single-use water bottles that now litter the earth.
3. "The biggest challenge that the pandemic created for supply chains is how they balance carrying inventory to avoid shortages versus 'just-in-time inventory management systems' that rely on matching inventory to demand," he indicated. "Significant spikes in demand caused by a pandemic or other catastrophe are not fully accounted for. Without dependable manufacturing capabilities and logistics, there is great risk of future shortages.
4. "The opportunity for industry is in the creation of local manufacturing capability for medical devices, supplies and pharmaceuticals and in the development of reusable supplies that could be used in place of disposable items," he concluded. HPN

For more information visit the following links:

- **Coronavirus (COVID-19) Update: FDA Reissues Emergency Use Authorizations Revising Which Types of Respirators Can Be Decontaminated for Reuse | FDA** https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-reissues-emergency-use-authorizations-revising-which-types
- **Investigating Decontamination and Reuse of Respirators in Public Health Emergencies | FDA** https://www.fda.gov/emergency-preparedness-and-response/mcm-regulatory-science/investigating-decontamination-and-reuse-respirators-public-health-emergencies
- **FAQs on Shortages of Surgical Masks and Gowns During the COVID-19 Pandemic | FDA** https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/faqs-shortages-surgical-masks-and-gowns-during-covid-19-pandemic
- **Surgical Mask and Gown Conservation Strategies - Letter to Health Care Providers | FDA** https://www.fda.gov/medical-devices/letters-health-care-providers/surgical-mask-and-gown-conservation-strategies-letter-health-care-providers
- **Questions About Personal Protective Equipment (PPE) | FDA** https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/questions-about-personal-protective-equipment-ppe

Experts urge healthcare to plan now for next pandemic, crisis

Reusing single-use devices draws concerns amid creativity

by Rick Dana Barlow

As the COVID-19 pandemic depleted storeroom shelves to the point that manufacturing scrambled to catch up to demand, the Food and Drug Administration (FDA) granted "Emergency Use Authorization" for certain products to solve short-term supply problems and the federal agency granted a limited green light to reusing certain single-use products, such as N95 respirators.

When it comes to the oft controversial issue of reusing single-use devices (SUDs), at best the FDA can point to its policy on the practice put in place in 2000 – two decades ago. At worst, however, the agency's leaving the door cracked open may demonstrate the need for some flexibility during a crisis nearly spinning out of control, but it also leaves any hard line open to interpretation long-term once the crisis abates.

Experts argue the providers and suppliers perhaps should be equally confused and concerned.

K. Mark Wiencek, Ph.D., Lead Microbiologist, Contec Inc., acknowledges that the ongoing tizzy primarily focuses on the reuse of certain personal protective equipment (PPE) designed to be disposable, but does that lead to more harm than not?

"While any measure that can help reduce the risks to short-term issues of protecting healthcare workers and patients should be explored, there are several concerns if these measures were adopted longer term," Wiencek told *Healthcare Purchasing News*. "Disposable items that include textile/fabric components are designed to meet the requirements of protection through single- or short-term use while minimizing durability to reduce cost. They are not designed or constructed to withstand reprocessing.

"Some studies may have been able to demonstrate that certain items can be cleaned and decontaminated without destroying the minimum filtration, barrier or cleaning properties, but if all disposables were forced to meet the stringent requirements for products that are designed to be reusable, the disposables would no longer be affordable," he continued. "Cleaning textiles presents its own set of challenges as the products that provide superior performance contain 'microfiber.' The delicate microfibers are excellent at grabbing and holding onto particles but make it difficult to effectively remove the particles during reprocessing without damaging the fibers. This becomes an acute issue in the cases where the products are contaminated with pathogens and must be re-laundered at high temperatures or with bleach to effectively decontaminate the products before returning to use."

Even in the face of future crises and pandemics in 2022 and beyond, Wiencek questions whether the FDA should update its policies to enable limited reuse of SUDs to relieve the pressure from pent-up demand and lackluster supply.

"Caution is advised if facilities or regulatory agencies relax their guidance on re-using single-use items after the emergency

Page 16 ▶

SpecialtyCare®

SPD

SPECIALTYCARE'S STERILE PROCESSING IS INSTRUMENTAL IN

SURGEON SATISFACTION REDUCING RISK AND KEEPING COSTS DOWN

SPECIALTYCARE IS A LEADER WHEN IT COMES TO BUILDING AND MANAGING STERILE PROCESSING DEPARTMENTS FROM THE GROUND UP.

LEARN HOW SPECIALTYCARE'S STERILE PROCESSING DEPARTMENT CAN BE INSTRUMENTAL IN YOUR HOSPITAL'S SUCCESS.

WWW.SPECIALTYCAREUS.COM

SpecialtyCare®

from the COVID-19 pandemic subsides," he insisted. "Some will make the argument that if it was acceptable during the pandemic, it proves these items are capable of multiple uses. However, just like approval of novel drug therapies under FDA's Emergency Use Authorization, this short-term approval does not involve the same level of scrutiny as an official approval or registration.

"Formal approval for reusing items designed to be disposable would require new standard methods and specifications to first be developed and validated," he continued. "Products would have to be tested to these new standards and demonstrate sufficient performance after reprocessing. Novel reprocessing methods might have to be developed that can effectively decontaminate these items without causing damage to the filtration, barrier or cleaning properties for items such as respirators, gowns and wipes, respectively. All this could create a slippery slope where many products are considered reusable after processing. Some can withstand a few cycles whereas others can be reused for more cycles. How will the number of use/processing cycles effectively be tracked and documented for each type of item?"

Jumping through hoops

Melinda "Mindy" Benedict, MS, CIC, CFER, Global Senior Manager, Infection Prevention, Olympus Corporation of the Americas, traces the reprocessing of SUDs back to the 1970s, and even though the FDA regulated these activities by official policy nearly three decades later, compliance among healthcare facilities varies. Further, the FDA allows the reprocessing and reuse of certain SUDs, but only when that task is performed by an authorized company or service provider, she added. This means that hospital sterile processing departments would be classified as remanufacturers of the devices.

The FDA wisely remains concerned about the public health risk presented by a reprocessed SUD, according to Benedict, who refers to and cites from the FDA policy.

"Some devices, which are low-risk when used only one time, may present an increased risk to the patient upon reprocessing," Benedict noted. "Other SUDs are low risk when used for the first time and remain low risk after reprocessing, provided that the reprocessor conducts cleaning and sterilization/disinfection of the SUD in an appropriate manner. Other SUDs, however, cannot be reprocessed safely and should not be reprocessed and reused under any circumstances."

Establishing a course of action

"The long-term public health consequences of reprocessing single-use devices will be determined through process audits, identification of hospital-acquired infections and monitoring the efficacy of SUDs that have undergone multiple episodes of reprocessing," she said. "At present low-risk devices such as N95 respirators are being successfully reprocessed during this pandemic. However, it is important for anyone considering reprocessing a single-use device to know which devices can and cannot be safely reprocessed and who should be doing the reprocessing. Certain SUDs cannot withstand the same material stress during cleaning, disinfection and sterilization."

Just because a policy door may be ajar doesn't necessarily mean it should be kicked open in desperation in the future, according to Janet Pate, JD, MHA, RN, Nurse Consultant and Educator, Ruhof Corp.

"Although exceptions are made during a pandemic to assist with supply shortages and for Emergency Use Authorization, it should not be forgotten why these stringent processes are in place," Pate indicated. "The approval process is to ensure that adequate research has been conducted to allow the use or reuse of the product in a safe manner. It gives adequate time for the discovery of unforeseen problems/concerns with the new product or process to be revealed that otherwise might not be immediately obvious. There needs to be a balance of critical need and safety for products and medications that are released for use.

"In the future, it may be difficult to convince the public that it is in everyone's best interest that the long process of research and development is necessary," she continued. "This may be debated especially if there were no adverse reactions or problems during the pandemic. The FDA and manufacturers may be encouraged to shorten the time currently required for manufacturing medications and products, and the actual time they are released. Perhaps the pandemic will enhance the production and approval of medications and supplies if it can be done in a safe, reasonable manner and delete the significant wait time between development and implementation. If this is done in a safe, reasonable method, it could benefit everyone in the future."

Jean Sargent, Principal, Sargent Healthcare Strategies, and a former hospital supply chain and sterile processing executive, dismisses the idea that Sterile Processing and Distribution (SPD) departments are as qualified to be manufacturers as the device manufacturers themselves, which is how they would be classified and considered under FDA policy.

"In the end, sterile processing is not a manufacturer and must have IFUs that state specifically how to complete the process," Sargent said. "This must come from the manufacturers that have to complete testing to ensure their IFUs are providing appropriate direction for safe use of the devices. This is not something they have at hand and must develop."

Like Sargent, Stephen Kovach, CFER, Educator Emeritus, Healthmark Industries, remembers the battle over reuse of SUDs and working with the FDA to address the issue some 20 years ago.

"Unfortunately, the shortage of many products has shown how dependent we have become on certain supplies from outside our border for medical facilities to give the care they need regardless of a pandemic," Kovach noted. "This has forced us to be creative, to work together and to use science to find solutions. If one reads the various studies done on this subject, they are based on science, which is the difference. Before, facilities were reprocessing single-use items with not much data or information behind them.

"Short term, it helps us out while we get the supply chain for various products," he continued. "Where it goes from there is anybody's guess. But the future we can see is unlimited because this pandemic has shown we can solve any issue, even ones that we were told we should not do – such as reprocessing single-use devices – but with teamwork and science behind us."

Turning point

If anything, the pandemic has brought healthcare providers and suppliers to an inflection point regarding supplies and supply chains, insists Gregg Agoston, Vice President, Business Development, SPD Transformation Services, SpecialtyCare.

"For supplies, we know that reusable items that can be safely reprocessed are more economical and environmentally friendly in most cases," he indicated. "Disposable items offer the convenience of use and provide a 'feeling' of greater safety because the item is new. Evidence of our society's reliance on disposable items is [shown] by the number and size of our landfills.

"Sterile Processing departments across the country process millions of reusable instruments and clean thousands of pieces of durable medical equipment daily," Agoston continued. "When reprocessed correctly following the manufacturer's guidelines, reprocessing is safe and effec-

Page 18 ▶

Quickly take control of unmanaged equipment service spend with a first-of-its-kind platform for clinical engineering.

We've developed an evidence-based service solution that allows supply chain leaders to embrace easier methods and control category spend. Improve the quality of the hospital supply chain with increased visibility, consolidation and automation of the entire vendor procurement process.

Learn more at: **PartsSource.com/OnSiteService**

Your connection to better service

PARTSSOURCE®
On-Site Service

tive. The excuse that disposables should be used to avoid the risk of inadequate reprocessing is often an excuse for poor technician performance, staff/ equipment shortages, poor training and/or management support and should not be accepted. SPD staff reprocess millions of items daily. If there are errors made, one should look at the systems, management and staffing to determine why the error occurred and correct the problem. If we can't trust SPD to process one item effectively, how can we be confident in any of the work? Alternatively, imagine a system where every medical instrument was disposable. Imagine the impact that this would have on our environment and associated costs."

Agoston recommends homing in on reusable equipment and supplies.

"Facilities that I am familiar with that reprocessed N95 masks labeled them with the name of the user so that the user received their mask back and not someone else's. Even with this, there was still great apprehension in reusing the single-use devices," he observed. "There was also apprehension by the staff who was responsible for transporting and reprocessing the mask. This latter concern was more related to the processes being new and unproven versus fear of handling contaminated items as hospital staff – including SPD – handle contaminated items all of the time. I believe that the pandemic has created an opportunity for industry to look at all disposable devices to see if there is a way to make them reusable or perhaps a version that has a reusable component and a small disposable component."

Any optimal solution will center on the financials and total costs of ownership, Agoston acknowledges.

"Economics will determine what is best," he said. "For disposables, they tend to have lower purchase prices than a reusable device, but have a much higher cost of disposal. There also are the reoccurring costs associated with the [purchase order] process and costs for inventory management, etc. Reusable devices tend to have higher purchase prices and a reprocessing, repair and disposal cost. The overall costs of ownership should include all costs divided by the number of uses to determine the total cost per use."

Agoston warns that the industry should anticipate the reality of the next pandemic and prepare now. "Whether reusable or disposable or a combination, Supply Chain managers should evaluate total cost per use, current and future needs and build stock to avoid shortages when the next pandemic or disaster strikes. Having dependable manufacturing capability and logistic systems are a must," he added. HPN

Editor's Note: Healthmark Industries recommended the following podcasts as useful references:

- ***Finding a Safe and Effective Way to Process PPE.*** *Two physicians from the University of Michigan Medicine, share their story of multidisciplinary collaboration that led to finding the safest and most effective way to process N95 masks: https://pod.co/hmark/20-finding-a-safe-and-effective-way-to-process-ppe*
- ***Interview with Michelle Hoste.*** *Michelle Hoste, SPD Manager and military veteran shares how her team collaborated with other departments and Infection Control to come up with a way to safely process N95 masks, keeping their frontline equipped with the PPE they need to combat the pandemic: https://pod.co/hmark/6-bonus-episode-interview-with-michelle-hoste*

NOW IS THE TIME FOR

SINGLE-USE STERILE

SURGICAL INSTRUMENTS AND PROCEDURE PACKS

SAFE. RELIABLE. READY.

- Packaged sterile, thus reducing the risk of cross-contamination
- Offered as individual instruments and procedure packs
- 3-year shelf life
- Samples available

FOR USE IN:

- EMERGENCY ROOM
- URGENT CARE CENTERS
- CRITICAL CARE TRANSPORT
- MATERNITY CENTERS
- OB/GYN CLINICS
- OPERATING ROOM
- OFF-SITE CLINICS

Contact your STERIS IMS Account Manager for more information or go to steris-ims.com to view the full catalog.

Distributed by

STERIS ims
Instrument Management Services

steris-ims.com | 1.800.783.9251

Instrapac is a registered trademark of Robinson Healthcare Ltd.
AV-61R Edition 1/13/21

Visit www.ksrleads.com/?102hp-031

Surgical resiliency in surge and shortage

Managing OR and hospital scheduling, turnover and supplies in times of crisis and beyond

by Ebony Smith

Photo credit: NicoElNino | stock.adobe.com

One thing is certain, the healthcare landscape constantly is revolving. In more "normal" times, operating rooms (ORs), emergency rooms (ERs) and hospitals may churn around the clock, scheduling patients and moving them in and out for the critical care they need. The ongoing COVID-19 pandemic, however, propelled a new level of changes and complications in patient volumes, staffing, supplies, flow, and bottom lines in care.

"Healthcare facilities are facing a backlog of elective surgeries, less availability and rising costs of supplies, staffing shortages, and maintaining a safe environment during this pandemic," addressed Gina Gilbert, Senior Director of Professional Education & Clinical Affairs, Ansell.

Scheduling procedures is a difficulty in care, observes Shawn Sefton, MBA, BSN, RN, VP of Client Operations and CNO, Hospital IQ.

"A consistent theme I've heard from perioperative leaders is that many challenges arise from scheduling procedural cases and then creating an efficient throughput process that optimizes both patient care and business objectives," Sefton shared. "COVID has definitely increased these challenges and all perioperative services are impacted like other areas."

So, how else is the crisis affecting procedure scheduling, room turnover, and OR, elective surgery or hospital care? And what are the effects on patients, staff and facilities?

Patient volume shift

During the pandemic, there has been a decline in the numbers of patients going to hospitals for care or procedures.

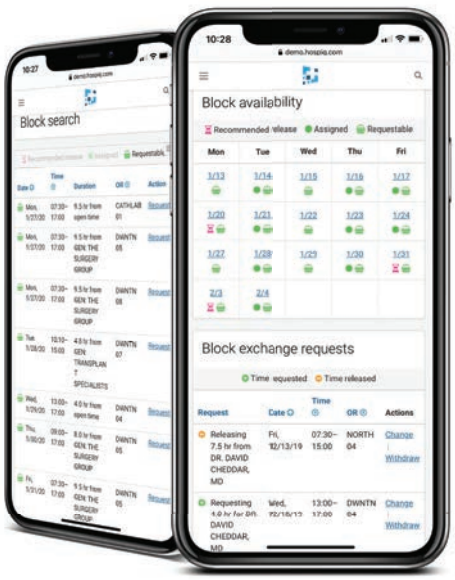
"Volume is clearly down for 2020," Sefton indicated. "Mandated cancellations in the spring are the most significant factor, but even with those restrictions lifted, caseloads in many areas haven't returned to previous levels. You also have patients reluctant to come to the hospital, those that have lost their insurance coverage, or those that test positive for COVID before the scheduled procedure, which causes a cancellation."

Keerthi Kanubaddi, CEO, ReadySet Surgical, adds that as levels of patients in hospitals are lower, staff has been reduced and affected by the crisis.

"Even with the most recent COVID-19 surge, we are seeing that hospital volumes overall are still down by single digits, which have recovered slightly due to the massive influx of COVID-19 patients," he addressed. "Capacity of care is still a challenge, given that hospitals have laid off or furloughed staff to manage the significant volume losses in 2020. Existing staff are severely taxed, and staff have been impacted by COVID-19. Overall care has been impacted as well."

Critical surgeries also have decreased and elective surgeries are backed up, continues Kanubaddi.

"Specific procedure areas, like orthopedic replacements and cardiac procedures, have markedly declined by double digits year over year," he explained. "Some estimates point out that elective procedure volumes will be at 75 percent to 85 percent of pre-COVID capacity by the end of 2020, but that might even be too optimistic depending on infections in the local area. Add to this an anticipated backlog of elective procedures that is anywhere from six to 18 months by some estimates."



Hospital IQ's block schedule solution

Scheduling, inventory concerns

The crisis has disrupted the availability of supplies and the coordination of scheduling.

"Capacity of care has been hindered due to challenges with supply and demand," Gilbert said. "Scheduling priorities drasti-

Page 22

medela

Enjoy Administrative Freedom

We make NPWT easier.

Medela's tailored billing model provides **administrative freedom** with consistent costs regardless of the ebb and flow of your NPWT needs. Never worry about having enough NPWT devices or tracking therapy usage again, and get back to what you do best, caring for your patients.

Learn more at medelahealthcare.us

Visit www.ksrleads.com/?102hp-004

Medela wordmark and logo are registered in the U.S. Patent and Trademark Office. 1549554 A 0620 © 2020 Medela 4551363

cally have changed globally, depending on the virus surge level. Patients with time-sensitive conditions may be prioritized over those considered elective, and others have been postponed altogether."

Changes in business operations and care during the pandemic have impeded scheduling and turnover, expresses Sefton.

"Scheduling cases is more difficult now because so many contingencies are subject to a quick change, whether from government guidelines, hospital capacity, testing requirements, or patient issues," she explained. "COVID-induced constraints and an increased emphasis on sterility and cleanliness are all causing breakdowns in scheduling, flow, and turnover, increasing the hurdles for the OR desk."

Managing clinician time is essential for enhancing scheduling, workflows and care.

Sefton points to Hospital IQ's technology system to help provide real-time transparency in scheduling surgeries.

"Surgeries will continue to rebound through 2021 but will face COVID-related inpatient capacity challenges as many perioperative departments are siloed from the inpatient units," she indicated. "OR leaders lack visibility into real-time or future capacity as they move patients through the OR. Using AI, our solution prompts block-holders to release time they likely won't need so other surgeons have adequate time to request that open time. This summer when elective cases again were permitted in New York, a customer of ours used this capability to turn a majority of their existing block schedule into open time, and then surgeons and perioperative leaders worked together to prioritize and schedule cases to work through their backlog of rescheduled cases."

Facilities must remain flexible in handling changes in scheduling and care, according to Kanubaddi.

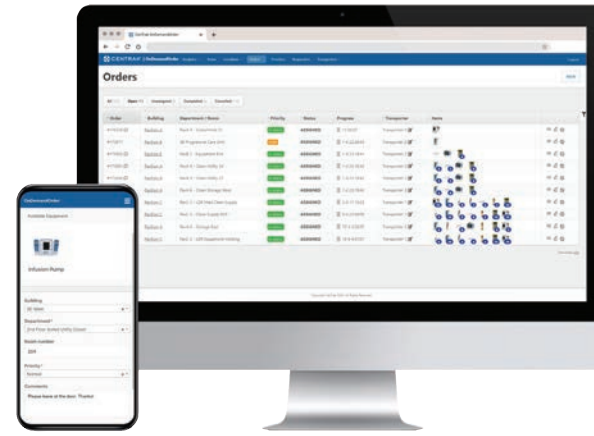
"The massive influx of COVID-19 patients has stressed normal operating procedures at hospitals, including elective procedures," he stated. "While those procedures are down significantly year over year, hospitals are prioritizing procedure types to manage given the current shifting environment. Patient turnover also has been impacted notably, as COVID patients are sicker and take longer to recuperate in many instances."

Kanubaddi highlights ReadySet Surgical's technology to help manage device tracking, patient scheduling, and room turnover.

"Our first application, RS Track, has provided asset tracking functionality around surgical trays and implants," he explained. "Given extremely taxed supply chains, this visibility has proven very effective in supporting scheduled procedures. Our RS Coordinate solution, which includes RS Track, provides automated advanced scheduling and vendor notification, which has helped improve scheduling efficiency and turnover. A leading Children's Hospital increased notification lead time by 66.3 percent to 14.3 days and loaner tray arrival time by 500 percent to 48 hours before the case."

A new portal by CenTrak provides automated management of inventory and care assignments.

According to a CenTrak press release[1], "CenTrak has announced the availability of OnDemandOrder, a centralized portal for managing requests for mobile medical equipment and other support services across the healthcare enterprise. The portal can be used as a standalone SaaS (software-as-a-service) solution or incorporated into a more robust RTLS (real-time location system) that uses a combination of sensors and software to automate procurement when supplies run low."



CenTrak's OnDemandOrder portal

The company continued, "For clinicians, it offers a convenient tool for submitting requests for equipment and support. The ordering tool's user interface is designed to mimic the online consumer shopping experience and features configurable product categories, such as PPE (personal protective equipment) and environmental services. It allows staff to designate a level of urgency to each request and view the real-time status of their orders, which are automatically routed to delivery teams and prioritized for fulfillment. OnDemandOrder also automates regular work assignments related to inventory management, including PAR level replenishment and the retrieval of soiled equipment. Supply chain managers and other healthcare administrators can use the system's backend to monitor PAR levels in real time and use its advanced reporting and analytics capabilities to identify inefficient workflows or inventory utilization."

ReadySet Surgical's technology additionally includes a system for managing OR equipment and purchases, shares Kanubaddi.

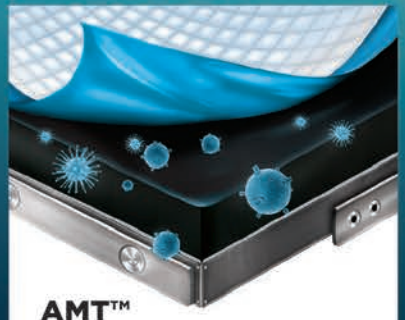
"Equipment shortages also have impacted care of COVID-19 patients, but supply availability has improved," he noted. "Up to 85 percent of OR delays are equipment-related issues. RS

ReadySet Surgical's applications

Page 24

Ansell

BLOCK INCOMING RISKS



SANDEL®

STAT-BLOC™ Antimicrobial Table Linens

Cross-contamination is calling but your impervious, antimicrobial linens won't stand for it. STAT-BLOC O.R. table linens provide complete protection against bacterial migration and now show efficacy against COVID-19. Create a custom pack with your STAT-BLOC linens and a variety of other components to improve turnover time and help prevent cross-contamination in your O.R.

99.9% effective against MRSA, CRE and E. Coli

Kills 99% of COVID-19 that comes into contact with the antimicrobial backing

For more information or to receive a sample, visit www.Ansell.com/STAT-BLOC or call 866-764-3327

Ansell,® and ™ are trademarks owned by Ansell Limited or one of its affiliates. US Patented and US and non-US Patents Pending: www.ansell.com/patentmarking
© 2021 Ansell Limited. All Rights Reserved.

Ansell's STAT-PAC O.R. Turnover Solutions

Analyze, our 'bill only' charge capture solution, has provided 100 percent charge accuracy, decreased lag time 97 percent for 'bill-only' submissions, and decreased surgical invoice processing time by 75 percent. RS Analyze provides deep insight into non-compliant purchases by physicians and staff, as well as graded vendor and vendor rep performance."

Safety and turnover priorities

The pandemic has increased concentration on cleanliness, disinfection, and timing of throughput in surgical care, according to Gilbert.

"Surgeries are being performed with a greater emphasis on safety, environmental hygiene and a heightened focus on turnover," she stated. "Detailed infection control protocols are being expanded to minimize risk of exposure, including OR cleaning, use of disposable kits and supplies, in addition to expanded education and training. Cleaning procedures are more involved and time consuming. As surgeries ebb and flow during various surges of the pandemic, improving OR turnover speed is critical. Utilizing standardized products, procedures and processes translates into providing a safer and more effective surgical environment."

Cleaning and turnover products from Ansell help support protection, safety, and flow in care, continues Gilbert.

"Ansell's STAT-BLOC disposable linens are the only antimicrobial offering available, recently tested to show 99 percent effectiveness against COVID-19, in addition to 99.9 percent effectiveness against E. coli, MRSA and CRE," she indicated. "Ansell's STAT-PAC Room Turnover Kits help to improve efficiency, reduce the risk of cross contamination, reduce lint, prevent skin breakdown and eliminate costs associated with reusable linens. In addition, Ansell offers a new clinically based program – AdvisOR – where facility turnovers are evaluated against AORN best practices through observational surveys, turnover time, and ATP (adenosine triphosphate) testing data in a collaborative effort to improve room turnover outcomes and effectiveness."

A new report by Fact.MR shows a rise in healthcare procedures, patient volumes, and risk of infections on a global scale.

According to a Fact.MR press release[2], "Growth rate of the global healthcare industry has been around seven percent in recent years, which is expected to increase to over nine percent over the next five years. With a growing healthcare industry, including multi-specialty hospitals, clinics, and others, there has been an increase in the number of patients. This also means increased chances of acquiring hospital-associated infections while being treated."

The prepackaged item market is increasing, noted the company.

"While the COVID-19 pandemic affected production across manufacturing units for a while, contrary to this, there has been surge in demand due to the rush of patients in clinics, ambulatory surgical centers, and others. This has fueled the growth of the prepackaged medical kits and trays market and is anticipated to drive the market further over the next few years."

The disposable product market also is expanding, added the company.

"The global medical disposable market size was estimated at US $248 billion in 2019 and is rising steadily to cross US $280 billion in 2020. As the healthcare industry, especially the multi-specialty hospital industry, is growing at a steady pace, demand for prepackaged medical kits and trays is skyrocketing. Increase in awareness among patients, doctors, medical staff, and others is further catering to market growth." **HPN**

References

1. CentTrak Announces OnDemandOrder to Automate Inventory Management, December 15, 2020, https://centrak.com/ondemandorder-to-automate-inventory-management/

2. Prepackaged Medical Kits and Trays Market Surging at 8.5% CAGR; COVID-19 Pandemic Crisis Lending Impetus to Market Growth: Fact.MR, Dec 14, 2020, https://www.factmr.com/media-release/1762/global-prepackaged-medical-kits-and-trays-market

CHOOSE Biogel®

Standardization to synthetic Biogel surgical gloves can reduce clinical risks and related costs[1]

As part of a LEAN project, the University of Rochester Medical Center standardized to Biogel synthetic surgical gloves decreasing SKUs from 13 to 3 and regaining 111 cubic feet of storage space in the center core. The clinical risks associated with latex glove use were eliminated, resulting in related cost savings of over $43,000 in one year.[2]

Improved O.R. efficiency — that is one way Biogel gloves deliver Tötal Value.

To review this poster publication or learn more about Biogel surgical gloves, visit www.molnlycke.us/choosebiogel

References: 1. Data on file, MHC-2019-T000010 **2.** Utilizing the Lean Process in Surgical Glove Standardization, Samuel E. Sullivan RN CNOR, Published Poster, AORN 2020

The Mölnlycke® Health Care and Biogel® names and logos are registered globally to one or more of the Mölnlycke® Health Care Group of Companies. Distributed by Mölnlycke® Health Care US, LLC, Norcross, Georgia 30092.©2020 Mölnlycke® Health Care AB. All rights reserved. MHC-2020-78718

Mölnlycke®

Managing the microscopic battleground

EVS, IP united mindset needed for cleaning, hygiene practices

by Ebony Smith

Photo credit: Juan | stock.adobe.com

As hospitals and healthcare systems march forward in care through the COVID-19 crisis and other public health emergencies, they must work together to keep their environments decontaminated, safe and approachable for patients.

"I spoke with Halosil customer Iris Verdi, EVS Director at Beebe Healthcare in Lewes, DE, about just that the other day," shared Maryalice StClair, Chief Commercial Officer, Halosil International, Inc. "She feels that with the COVID-19 pandemic and the impending flu season, now more than ever, patients are concerned about safety when coming to a hospital. That fear keeps patients away from seeking treatment and can cost lives. Healthcare systems need to demonstrate that their facilities take patient concern seriously and are providing a safe, clean and sanitary environment."

Two vital departments dedicated to the common goals of cleanliness, hygiene and protection from pathogens for patients, staff and visitors are environmental services (EVS) and infection prevention (IP) departments. They need to routinely perform high levels, monitoring and compliance of cleaning, sanitation, and infection control measures.

So, just how do COVID-19, the flu and other such major health events impact environmental cleaning, safety and quality in care? And how specifically do EVS and IP teams work to consistently create cleaner and safer operating, patient and common rooms, support personal hygiene and protective protocols, and, ultimately, help keep people safe from the spread of pathogens and infectious diseases?

Supporting EVS, IP staff needs

In order to safely and adequately perform their essential duties during COVID-19, EVS workers must have access to personal protective equipment (PPE), cleaning and disinfectant products and systems, and any other necessary resources and support.

"Of greatest importance is keeping EVS team members safe while working in what can only be classified as the front lines of a healthcare battle zone," stated Mike Short, a Rubbermaid Cleaning Advisory Board Member and Director of Safety and Environmental Services at Maury Regional Medical Center.

Short continued, "Hospital EVS team members and other healthcare workers continue to test positive, which places additional burden on other exhausted and over-taxed team members. Facilities need to maintain a high level of training and open lines of communication with their staff, while not letting their guard down in completing the EVS mission of cleanliness and disinfection. One break or failure can have devastating consequences. This is where arming teams with products that are highly efficient and effective is critical. They provide an added level of assurance to both staff and patients that the job will get done."

Yet, the ongoing crisis has caused significant personal and workplace strain on many healthcare personnel, stresses, Doe Kley, Senior Infection Preventionist, Clorox Healthcare.

"One of the biggest challenges is healthcare worker fatigue – fatigue with isolation, PPE, and general physical and mental fatigue," Kley addressed. "Another challenge is staff who are not trained in cleaning and disinfection are increasingly being asked to take on this task during this resource-scarce time."

As healthcare supply chain interruptions have been far reaching, Acute Care Pharmaceuticals has responded with additional manufacturing resources and supplier communications, indicates Brian Martin, Vice President, Sales & Marketing, Acute Care Pharmaceuticals, a member of Hospeco Brands Group.

Brian Martin

"The exponentially higher demand for PPE and cleaning and disinfecting products has reshuffled the deck, with existing companies stretched to the limit and

Page 28

Defend with Profend®
nasal decolonization swabs to reduce the **risk of SSIs*.**

60-second application with Profend® nasal swabs before surgery kills 99.7% of *S. aureus* at 10 minutes and 99.9% at 12 hours.[1]

More than 90% of healthcare providers surveyed prefer Profend over other PVP-Iodine products because it can be applied 2.5x faster—just snap open and use[2†]. Profend is clinician-administered for 100% compliance, with a compact design for patient comfort. It's the efficient, mess-free way to defend against SSIs.*

Learn more at www.DefendwithProfend.com

References: 1. PDI *in vivo* Study PDI-0113-CTEV01
2. PDI user acceptance study *Surgical site infections
†From 11 acute care facilities with 50 beds

PDI®

BE THE DIFFERENCE®

©2021 PDI PDI11207194

new players entering the market," Martin emphasized. "It creates increased competition for already limited resources. The result is that many, if not all, healthcare facilities are in a situation where they will take anything they can get —and that's not a position you wish upon those challenged with caring for others. We talk to hundreds of hospitals every day and we hear they are suffering. We've also reached out to foreign and domestic suppliers to ramp up production. We've made strategic moves to vertically integrate. We've invested in new machinery and expertise to maximize production of necessary cleaning, wiping and disinfecting products."

PDI Healthcare's portfolio of environmental products

High hygiene standard

Constant surface cleaning with the right products is required to create a safe environment, expresses Deborah Chung, Regional Marketing Manager, Essity Professional Hygiene, North America, part of Tork.

"With typical flu season patient intake compounded by COVID-19 cases, hospitals' and medical facilities' staff are working tirelessly to maintain a safe environment that supports a high level of care," Chung explained. "Given the pandemic-driven strain many facilities faced in 2020, EVS and IP staff continue to play a critical role in maintaining a high hygiene standard, so care providers can work effectively and know that stringent cleaning and disinfecting efforts are taking place to help prevent the spread of infection or cross contamination. In addition to hand hygiene, cleaning and disinfecting environmental surfaces, such as bedrails and door handles, is a fundamental part of hygiene protocols. The newly launched Tork Microfiber Cleaning Cloths provide options between disposable and reusable cloths for heavy and lighter duty tasks."

Tork Microfiber Cleaning Cloths

For cleaning surfaces, the HYGEN Disposable Microfiber System is newly available from Rubbermaid Commercial Products, shares Michelle Olsen, Senior Product Manager, Rubbermaid Commercial Products.

"Our system is a perfect example in assisting EVS departments by removing 99.7 percent or more of tested viruses and bacteria[1, 2] with water alone to help improve cleaning efficacy," Olsen indicated. "The disposable nature of the cloths and pads encourages use of a new cloth or pad for each area to avoid cross contamination and is a direct response to the safety concerns highlighted by COVID-19."

Rubbermaid Commercial Products' HYGEN Disposable Microfiber Cloth System

Larger volumes and adapted settings of care during the pandemic have elevated cleaning and disinfection responsibilities, observes Debra Hagberg MT (ASCP), CIC, Director, Clinical Affairs, PDI Healthcare.

"Makeshift ICUs, field hospitals, and triage areas expand the locations that require robust environmental disinfection," Hagberg explained. "EVS personnel need to be flexible but competent in handling increased demand for services while maintaining compliance with appropriate PPE, disinfectant IFUs, efficient turnover of rooms, patient privacy, and waste management operations."

Other surface cleaning products are offered by PDI Healthcare, including a majority of disinfectants that are included on the EPA List N, Disinfectants for COVID-19, continues Hagberg.

"PDI's portfolio of environmental products offers a wide array of low to intermediate level, sporicidal, and continuously active disinfectants, and soft surface sanitizers in disposable wipes and sprays available in tubs, pails, and individual packages," she shared. "PDI utilizes customer feedback when creating new products illustrated by the launch of Sani-HyPerCide disinfectants. This product was developed to satisfy customer requests for a non-bleach, sporicidal solution."

Floors, in particular, are major high-contact sites for contaminants, addresses Nancy Huber, Product Manager, NoTrax.

"With the expansion of critical care units within (and sometimes outside of) the facility, the need for adequate environmental services and infection prevention has expanded," Huber emphasized. "An early study by the CDC[3] has shown COVID-19 is easily spread on floors. When they tested

Clean-Step tacky mats by NoTrax

Page 30

100 years of infection control. We've got this.

Your partner in dialysis infection prevention.

ALCAVIS 50®

High-Level Disinfectant Compatible with Catheters, Caps and Connectors

2 minute contact time kills bacteria, fungi, viruses and mycobacteria

Catheter material compatibility confirmed

30 month shelf life; 180 days once opened

2 MINUTE | COMPATIBLE | STABILITY

EXSEPT PLUS®

Antimicrobial Catheter Exit Site, Skin and Wound Cleanser

Non-sensitizing and non-irritative

Broad-spectrum activity against contamination

30 month shelf life; 180 days once opened

HYPOALLERGENIC | BROAD SPECTRUM | STABILITY

ANGELINI PHARMA

www.angelini-us.com | (800) 726-2308 | ©2021

areas of the hospitals where no patients were present, like the hospital pharmacy, they had a 100 percent positivity rate for presence of the virus. Without a way to disinfect their shoes, critical care workers were tracking the virus across the hospital and out the door."

Mats and shoe sanitizer systems by NoTrax can help to protect against pathogen spread from floors, points out Huber.

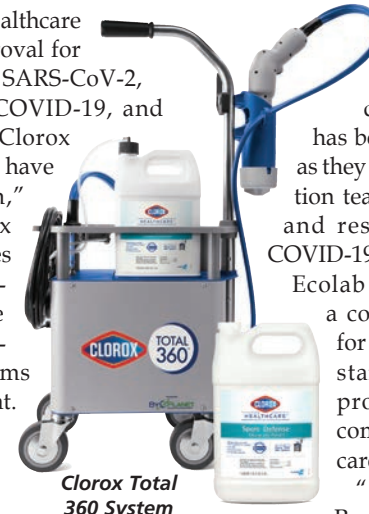
"The adhesive surface of the CleanStep tacky mat traps dirt, germs, dust, and any kind of particulate that may be present on shoes or equipment wheels," she indicated. "It can help prevent cross contamination by anyone moving through sensitive sterile areas, like ICUs. In addition to tacky mats, our zoned shoe sanitizer systems are great for simple shoe sanitizing before entering sensitive areas or when exiting contaminated areas. They have dedicated sections for cleaning, sanitizing and drying. These products can reduce the type of cleaning that needs to happen facility-wide because the mess is contained on the mats. It allows EVS professionals to focus on facility sanitation instead of sweeping."

Rooms and equipment that are frequently touched by patients, staff and visitors are other areas for germ cross contamination, emphasizes Kley.

"Even in the best of times, only 30 to 40 percent of healthcare surfaces are cleaned and disinfected," Kley stated. "Couple this with current challenges, resulting in a greater transmission risk, particularly of pathogens, such as influenza and *C. difficile*, which are easily transmitted via environmental services."

Clorox Healthcare's disinfectants and systems can be used facility-wide for comprehensive surface disinfection against many contaminants, adds Kley.

"At the start, Clorox Healthcare worked to get EPA approval for product claims against SARS-CoV-2, the virus that causes COVID-19, and as of today, nearly all Clorox Healthcare disinfectants have the SARS-CoV-2 claim," she noted. "Our Clorox Total 360 System provides an efficient and effective way for healthcare facilities to disinfect waiting rooms, patient rooms and transport equipment. Clorox Healthcare also launched Clorox Healthcare Spore Defense Cleaner Disinfectant, available through the Clorox Total 360 System. Spore Defense is a low fragrance bleach that kills *C. diff* in five minutes in addition to 42 other pathogens, including influenza and SARS-CoV-2, and can be used in sensitive patient settings."



Clorox Total 360 System and Clorox Healthcare Spore Defense Cleaner Disinfectant

Supporting hygiene compliance

COVID-19, of course, raised more attention on cleaning, hygiene and sanitation practices and infection control.

"At the onset of COVID-19, every health system had to evaluate its protocols to ensure it met the safety concerns related to the pandemic for team members, patients and the community," said Linda Homan, RN, BSN, CIC, Senior Manager of Clinical Affairs, Ecolab Healthcare. "Despite waived inspection requirements and suspended infection reporting, maintaining vigilance with cleaning and hygiene standards grew increasingly important. Objective performance monitoring technology that provides real-time actionable data to identify potential gaps in cleaning and disinfection programs has been a help to hospitals, as they allow Infection Prevention teams to focus their time and resources on emergent COVID-19 needs."

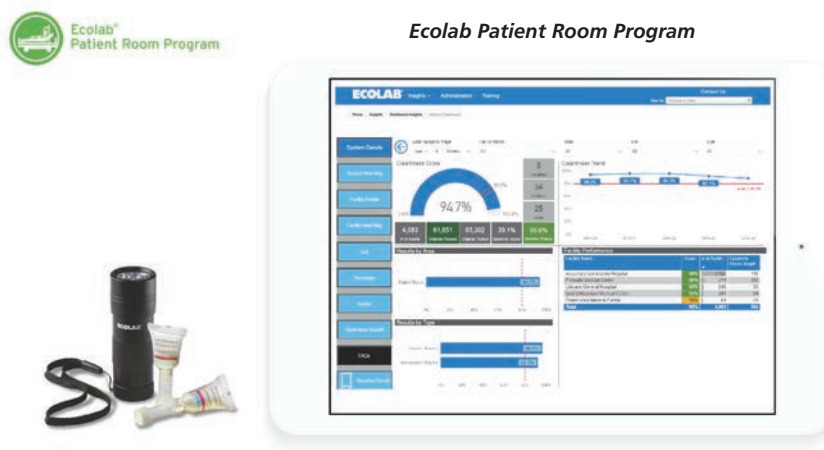
Ecolab Healthcare provides a comprehensive solution for environmental hygiene standard processes and protocols, training, and compliance to aid safety in care, shares Homan.

"The Ecolab Patient Room Program provides standardized cleaning workflows that help minimize the opportunity for objects to be missed and for pathogen spread, while improving operational cost savings," explained Homan. "EVS and non-EVS personnel who are taking on a cleaning role have access to professional training based on industry best practices. And the Observational Survey Tool and DAZO Fluorescent Marking Gel provide objective methods to evaluate the thoroughness of cleaning processes and consolidate audit data. This provides visibility into the hospital's process so EVS can pinpoint where corrective action is needed before errors put a patient at risk."

Tork's hygiene products and educational resources focus on helping EVS and IP staff achieve a high hygiene standard among staff and patients, Chung notes.

"Tork Clean Care, an online resource hub for healthcare and long-term care facilities, offers free, downloadable resources with education and best practices for EVS and IP teams, including surface cleaning resources, which is a critical component of any cleaning checklist," Chung expressed. "Additionally, Tork Clean Care offers downloadable guides for how to strategically place hand sanitizer dispensers throughout facilities. Strategic dispenser placement can boost hand hygiene compliance by 50 percent[4] – contributing to mitigating the spread of germs, viruses and other bacteria."

She continued, "Tork PeakServe Continuous Hand Towel Dispensers can hold up to 2,100 towels per dispenser, helping reduce the time EVS staff spend restocking dispensers, and in turn, increase time hospital staff need to focus on maintaining a clean and safe environment in other



Ecolab Patient Room Program

Page 32

Double Down on Disinfection

RD™ UVC System

The RD™ UVC mobile, touch-free system is transportable and designed to provide measured, proven disinfection throughout every area of your medical facility.

RD-Fx™ UVC System

The RD-Fx™ UVC fixed system is ceiling/wall mounted and simple to operate, providing rapid disinfection in under 2 minutes.

Proven disinfection has never been more critical—and now it comes in two advanced systems.

The COVID-19 pandemic is rapidly changing the healthcare landscape. With hospitals running at full census and IP/EVS teams short staffed, proven disinfection has never been more critical for safety—and rapid, precise, disinfecting technology like the RD™ UVC and RD-Fx™ UVC systems have never been more essential to our most essential workers.

Call **855.882.2013** to get the PROOF you demand.

RD UVC
Proof. Delivered.

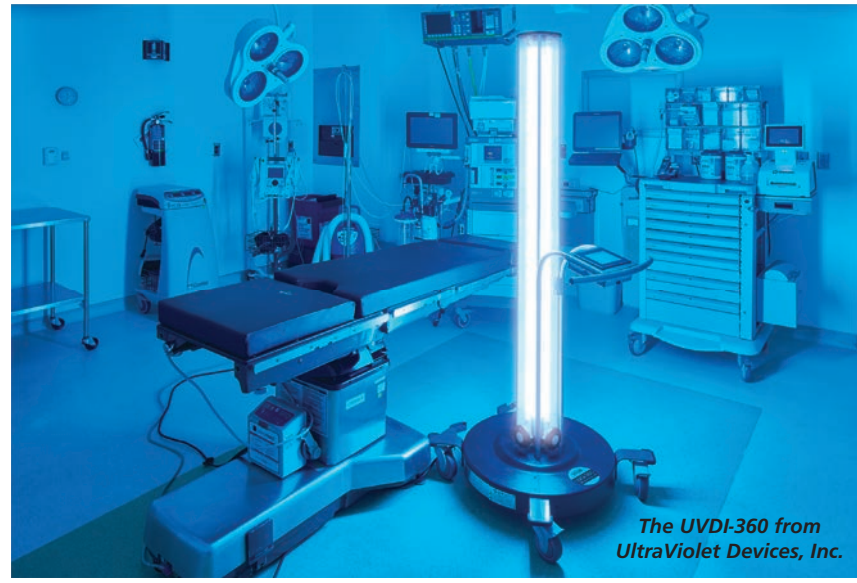
RDUVC.com

areas. Tork offers a range of skincare formulations that maximize cleanliness while being mild on the skin."

Enhancing room disinfection

During COVID-19, managing hospital and healthcare staff time and care settings are crucial for meeting the demand in care and preventing infections. Many facilities are looking to increase efficiencies in cleaning, disinfection and turnover of rooms, such as adding room disinfection systems to complement practices.

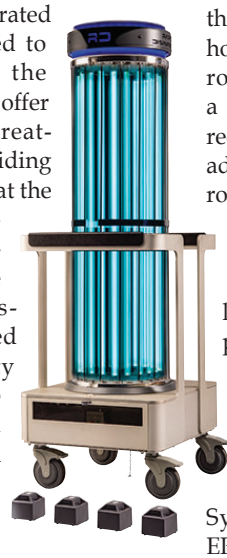
"As a result of the COVID-19 pandemic, most hospitals are operating at full census and IP/EVS teams are often short staffed and functioning at or above their capacity," emphasized Sam Trapani, President & CEO, Steriliz UVC. "Consequently, there is no time to waste when disinfecting contaminated areas."



The UVDI-360 from UltraViolet Devices, Inc.

Trapani points to UV technology for helping to disinfect entire rooms in hospitals or healthcare facilities in rapid time.

"Mobile and fixed UVC disinfection systems that utilize UVC sensors to measure the actual or calibrated dose of UVC delivered to targeted surfaces in the space being disinfected offer the fastest possible treatment time while providing proof of compliance that the proper dose was actually delivered," Trapani explained. "The RD UVC mobile system is easily deployed throughout all facility environments to help reduce airborne and surface contamination of harmful pathogens. The new RD-Fx fixed mount UVC system treats COVID-19 in two minutes between room uses. Environments that require rapid turnover and increased throughput between cases are able to provide UVC dose assurance for a cleaner and safer environment."



UVC - RD UVC System by Steriliz

Richard Hayes, President, UltraViolet Devices, Inc., adds how UV disinfection systems for whole rooms help support cleaning and ease staff that medical environments are safe and ready for care.

"The need to have technology in place providing reliable surface disinfection with as little disruption to their workflow as possible has been repeatedly expressed," Hayes indicated. "We've also seen a spike in requests for HVAC systems to have automated UV disinfection technology in place to relieve concerns that the air systems can be contributing to the transmission of viral incidences. With hospital capacity stretched, turning over rooms quickly and safely is vital. For a typical patient room, the UVDI-360 requires two five-minute cycles (and one additional five-minute cycle for the bathroom). There is proven third-party validation of pathogen inactivation claims at times and distances indicative of whole room disinfection from independent laboratory testing and peer-reviewed published clinical studies."

Another option for whole room disinfection and peace of mind for infection control in healthcare settings is fogging technology, suggests StClair.

"The Halo Disinfection System combines Halosil's EPA-registered HaloMist (EPA Reg.# 84526-6) disinfectant applied with the HaloFogger to create a dry-mist fog that kills 99.9999 percent of *C. diff* spores in a whole room," StClair explained. "Touchless fogging with our hydrogen peroxide and silver-based HaloMist disinfectant ensures reliable and repeatable disinfection, and because fogging with HaloMist kills spores, it meets EPA Guidance for effective disinfection against the SARS-Cov-2 virus."

Halo Disinfection System from Halosil International

One healthcare system, she notes, has used the fogging system to help disinfect many spaces, including those with SARS-CoV-2 exposure, supporting cleaner and safer care environments.

"Per Iris, at Beebe Healthcare, every patient room that has had a positive SARS-CoV-2 patient is treated with the Halo Disinfection System," StClair stated. "In common areas where the system cannot be used, Beebe performs the same level of cleaning and disinfection and follow-up with electrostatic spraying utilizing an activated hydrogen peroxide-based EPA-registered N-listed disinfectant. These protocols are used in all areas including surgical areas, procedural areas, and even waiting rooms, as it is critical that Beebe provide the safest facility possible for everyone who enters." HPN

References

1. Based on third-party testing on VCT surface with water only | EPA Est. No 92100-CHN-1

2.† HYGEN™ Disposable Microfiber Mop Pads remove 99.91% of Feline Calicivirus (surrogate for norovirus), 99.99% of Common human coronavirus OC43, 99.99% of Pseudomonas aeruginosa (Pseudo), 99.91% of Clostridioides difficile (C. diff), and 99.97% of Methicillin-resistant Staphylococcus aureus (MRSA). HYGEN™ Disposable Microfiber Cloths remove 99.97% of Feline Calicivirus (surrogate for norovirus), 99.99% of Common human coronavirus OC43, 99.99% of Pseudomonas aeruginosa (Pseudo), 99.79% of Clostridioides difficile (C. diff), and 99.70% of Methicillin-resistant Staphylococcus aureus (MRSA).

3. CDC, Volume 26, Number 7—July 2020, Dispatch, Aerosol and Surface Distribution of Severe Acute Respiratory Syndrome Coronavirus 2 in Hospital Wards, Wuhan, China, 2020, https://wwwnc.cdc.gov/eid/article/26/7/20-0885_article

4. Thomas BW, Berg-Copas GM, Vasquez DG, Jackson BL, Wetta-Hall R. Conspicuous vs Customary Location of Hand Hygiene Agent Dispensers on Alcohol-Based Hand Hygiene Product Usage in an Intensive Care Unit. *J Am Osteopath Assoc* 2009;109(5):263-267.

Page 34

It starts with safe care environments

Prepare your EVS staff with the right surface cleaning tools

The importance of hygiene in healthcare has become even more evident. In a healthcare system under pressure, keeping the healthcare environment a clean and safe place is top priority – making you and your staff the first line of defense and the guardians of safety for patients and staff alike.

Introducing our free online Tork Interactive Clean Hospital Training, Education tools and New Tork Microfiber Surface Cleaning Cloths— all to support you in securing safe healthcare environments.

Learn more at torkusa.com/surfacehygiene

Tork, an Essity brand

TORK®
Think ahead.

Looking past the pandemic for cleaning and infection prevention success

HPN asked industry professionals what they envisioned as the future of IP and EVS needs and practices. Here are their thoughts and predictions.

"Among other things, 2020 taught us just how unpredictable the future can be. We do know the pandemic will continue into 2021. We don't know what impact vaccines will have, or when. But I think it's reasonable to assume that, at some point in the future, there will be a glut of product in the market. But prices won't necessarily come down because that product will have been manufactured using source materials priced at peak. As far as practices are concerned, I believe the touchless trend will continue, even after the pandemic subsides."

— Brian Martin, Acute Care Pharmaceuticals, a Member of Hospeco Brands Group

"At some point, we will arrive on the other side of this pandemic. Once we all catch our breath, we need to take an inventory of the lessons learned. First, being the heightened awareness of the importance of both hand hygiene and environmental cleaning and disinfection – it is vital that we keep this positive momentum going. We have learned some hard lessons this past year and by now we should understand the critical importance of being continuously prepared for the next emerging microbial threat or pandemic. This preparation should include having the right products and technologies available."

— Doe Kley, Clorox Healthcare

"SARS-CoV-2 is taxing the traditional infection control infrastructure. Recent publications suggest hospitals are experiencing an increase in some healthcare-associated infections as a result. The trend may continue unless resources are made available to maintain a consistent level of environmental cleanliness. Using a robust environmental hygiene program may help. To be effective, this programmatic approach should incorporate efficacious and efficient products, clear and evidence-based processes and training, and objective performance monitoring technology to provide real-time actionable data back to infection prevention staff."

— Linda Homan, Ecolab Healthcare

"Needs and practices for EVS and IP personnel will intensify post-pandemic. I envision innovative technology and solutions being a must; perhaps increased automation so there is less dependency on human factors, innovative equipment/surfaces that have sustained antimicrobial effects, improved audit/surveillance tools for disinfection compliance, or improvements in surface compatibility materials or environmental design. I also see the increased need for strong relationships between IP and EVS. EVS personnel have eyes on the institution daily and can provide important feedback regarding potentially problematic situations before problems arise."

— Debra Hagberg, PDI Healthcare

"In working with the Rubbermaid Commercial Products' Cleaning Advisory Board, we believe there are several key areas of focus: protecting and supporting EVS staff, maintaining vigilance across all areas of the hospital—not just COVID units, and anticipating a potential shift towards disposable cleaning products with proven efficacy. Another important focus is working to ensure that facilities have adequate supplies of cleaning products and PPE to meet their needs. This was a critical issue earlier in the pandemic and one that Rubbermaid is prepared to address for the future."

— Michelle Olsen, Rubbermaid Commercial Products

"COVID-19 will have an everlasting impact on hospitals and medical facilities. In 2021 and beyond, proper training for surface cleaning and hand hygiene will be key in ensuring EVS and IP staff are up to speed on proper hygiene protocols. We'll continue to see the integration of technology in EVS and IP practices across training and products. Additionally, we'll see technology implemented into physical products to improve efficiency."

— Deborah Chung, Essity Professional Hygiene, North America, part of Tork

"I and many healthcare professionals with whom I have spoken agree that COVID-19 may not be the last pandemic we see in our lifetime. In the past decade, every year has brought new and emerging pathogens. Many spore-producing bacteria are nasty pathogens, like Bacillus anthracis, the cause of anthrax and Clostridium difficile."

— Maryalice StClair, Halosil International, Inc.

"Every industry is going to be concerned with how to keep their employees and consumers safe and because of that, products like our zoned shoe sanitizing systems, disinfectant mats, and shoe wash stations will become more commonplace. I think we've only scratched the surface of what our needs will become. The widespread nature of this pandemic, combined with a high threat of seasonal illnesses, has opened our eyes to a gap in the plan. This will eventually force companies to display their ingenuity and engineer more products to meet the needs of the healthcare industry and beyond."

— Nancy Huber, NoTrax

"An important new need in healthcare environments is the ability to rapidly disinfect high-turnover procedure rooms and ORs between cases without a dedicated FTE. This requires high-powered fixed mount systems, that are not moved from room to room, which employ high-efficacy germicidal UVC at 253.7nm."

— Sam Trapani, Steriliz UVC

"More seamless collaboration than ever. The example of PPE and N95 sourcing challenges underlines how core environmental safety equipment plays a key role in infection prevention. Products and devices that provide automated user data and analytics to empower in-the-moment efficiency, decision making and partnership between EVS and IPs are especially key."

— Richard Hayes, UltraViolet Devices, Inc.

Image by athree23 from Pixabay

Raising the Standard for **Whole Room Disinfection**

Healthcare and community-acquired infections, such as COVID-19, are a universal concern for today's healthcare facilities. While spray-and-wipe and UV-based systems eradicate many pathogens, they miss those lurking in shadowed or hard-to-reach areas. At Halosil, our dry fogging HaloMist™ disinfectant (EPA Reg. No. 84526-6) eliminates pathogens on hard, non-porous surfaces, **achieving the highest standard for efficacy, safety, affordability, and longevity on the market today.**

Halosil™
INTERNATIONAL

It's time to disinfect beyond a shadow of a doubt.

Contact Halosil at halosil.com/shadow to get started.

Tel: +1 302.454.8102 | **Email:** info@halosil.com

Bioburden – more than meets the eye

Inspecting surgical instruments visually must evolve

by Kara Nadeau

Photo credit: Roger | stock.adobe.com

While the quality of Central Service/Sterile Processing and Distribution (CS/SPD) operations is highly dependent upon those individuals performing the processes, in most cases equipment and tools are a critical part of the equation. This is particularly true in the visual inspection of surgical instruments as microscopic bioburden and/or biofilm is invisible to the naked eye. Furthermore, as instruments become more complex to facilitate minimally invasive procedures, internal components such as lumens make them more difficult to clean and impossible to thoroughly inspect without magnification and other visual aids.

"Year after year, the job has become increasingly challenging as new devices and technological advancements increase both the sheer numbers and the complexity of these devices," said Lee Ann Purtell, Owner, Capital Medical Resources. "Minimally invasive techniques drive the demand for smaller and smaller instruments that, by nature, are more complex and require special knowledge and processes to clean, inspect and sterilize. Having tools to aid in visual inspection and functional testing help keep damaged and dirty instruments out of use, thus reducing incidences of healthcare-acquired infections (HAIs)."

Times have changed

As instruments have changed so have the standard teaching points on visual inspections, as well as the equipment available to perform them, says Sharon Greene-Golden, BA, CRCST, CER, SME, FCS and oneSOURCE consultant. She stated:

"Standard teaching points given over the years focused on six review points used for visual inspection of instruments: Scissors, needle holders, suction devices, retractors, hemostatic forceps, and tissue and dressing forceps. Times have changed and how we meet the review points have changed in our visualization process because of the delicate, hard to check and minimally invasive instruments used in surgeries done in hospitals today."

"Today, we have different equipment designed to aid a technician in the visualization of all instruments, Greene-Golden added. "These technologies include insulation testers, lighted magnifying glasses, borescopes for checking lumens, and the testing developed to aid in verifying cleaning quality standards are being met. The verifying methods in place in the sterile processing department are needed because microorganisms are not seen, so we have a protein test and adenosine triphosphate (ATP) bioluminescence, which test for residual soils."

"Visual inspection has come a long way in the past few years," said Jonathan A. Wilder, Ph.D., Managing Director, Quality Processing Resource Group. "Gone are the days when finding the nearsighted person in SPD was how you improved visual checks for residual soil and debris. When I do audits with my associates, there are a few things that are high on the list of things we advise clients to use to properly do a visual inspec-

Page 38

OPERATE WITH GREATER PRECISION

Who Benefits from an Optimized Periop?

HE DOES.

Quality surgical instrument readiness is critical to patients like this little guy.

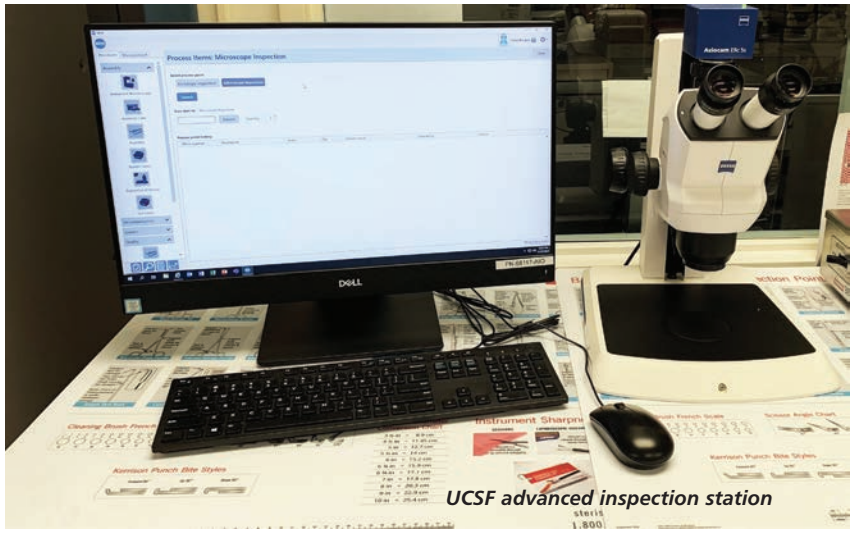
Our experts can help ensure your team has access to the tools they need, when and where they need them, all without adding to your staff's workload.

We'll apply data-driven workflow analytics to optimize your instrument usage and streamline your sterile processing workflows so that you are prepared to support surgery.

Start operating with greater precision. Visit **aesculapusa.com/greaterprecision** to learn more.

AESCULAP®

Aesculap, Inc. - a B. Braun company


UCSF advanced inspection station

tion. These are: Enough light, magnifying glasses - preferably lighted and at least 5x magnification - and borescopes."

Making the case for investment

From the purchase of a new visual inspection tool to the complete transformation of inspection processes, CS/SPD leaders must present the case for change to their healthcare organization's C-suite. Improved quality, reduced costs, greater efficiency and lower risk for infection are some key benefit areas that can help secure the necessary resources.

The University of California San Francisco (UCSF) Health is currently implementing an advanced visual inspection program for its CS/SPDs, which includes visualization using a dedicated workstation, borescope and high resolution digital microscope. They are also working with a software developer that will be commercializing an artificial intelligence (AI)-based application that identifies functional defects or potential soils, which integrates with the equipment in real time.

"As we have three campuses and require a uniform standard of care, this initiative is somewhat costly. Our approach to securing executive support involves monetizing the cost of quality," said Gene Ricupito, CRCST, CIS, CHL, CFER, PMP, Sr. Project Manager, Sterile Processing, UCSF Health. "When looking at defects, we can determine the costs associated with rework and OR case delays."

When looking at quality events where undetected soils are found at the point of use (POU), organizations can quantify the costs associated with patient safety, such as breakdown of the sterile field and replacement of the potentially contaminated instruments and supply items, as well as the costs of infection control review, explains Ricupito. He adds that in a worst-case scenario, the costs of patient notification or litigation are "staggering."

A single surgical site infection (SSI) costs a hospital an estimated $36,000 per infection (in 2020 adjusted dollars),[1] while legal defense for just a single lawsuit costs a hospital an estimated $83,000 per claim with indemnity payments.[2] Commenting on these figures Ricupito stated:

"A well-developed justification, which includes the economics of the factors stated above compared to the frequency of internal incidents, can easily create a picture where the investment in technology to prevent defects is easily recognized as cost-effective."

Before a new surgical instrument enters the doors of a facility, CS/SPD professionals must have the opportunity to evaluate whether it can be effectively and safely processed with the department's current equipment, says Ken Pichulo, BSN, RN, CRCST, CER, CHL, Manager, Central Services, AdventHealth in Orlando. If it cannot, then the facility's leadership must be willing to provide the CS/SPD with what it needs.

"I recommend that facilities have SPD representation on purchasing committees to assure that the items can be cleaned as validated and that the purchase of said items doesn't require additional up-front cost in SPD processing equipment if required in the manufacturer's instructions for use (IFU)," said Pichulo. "It's not uncommon for an item to be approved for purchase, yet the facility does not possess the equipment necessary to process it in compliance to the IFU."

Greene-Golden urges CS/SPD leaders to also involve infection preventionists when evaluating visual inspection tools and making the case for these resource investments, stating:

"The importance of visualizing while inspecting instruments has grown exponentially as technicians work with delicate minimally invasive products. What is done in the inspection of instruments is most important because our process as sterile processing technicians has a direct correlation with the end purpose to have no patient acquire a surgical site infection due to our inefficiency. Each processing department should work with their infec-


AdventHealth performs direct visualization in decontamination

Page 40

Did you know endoscopy could be this colorful?

Endoscopic procedures require the right tools and support from beginning to end; and back around again. Key Surgical now offers an improved line of products for clinical procedures and endoscopic infection prevention. From bite blocks to biopsy valves and from snares to sponges – think of us as your (very colorful) scope sidekick.

KEYSURGICAL

Visit Keysurgical.com to learn more

Inspection at every stage

"Visual inspection is a critical factor to assure the function and safety of a surgical instrument. This inspection should be performed each time an instrument is handled," said Gregg Agoston, M.B.A., VP Business Development, SPD Transformation Services. "It includes visual inspection of the packaged product so in essence, visual inspection is critical to every function that SPD performs in reprocessing and transporting the instruments."

He describes the following "critical touch points" for instrument inspection in healthcare facilities:

- ***Decontamination***: The instrument must be inspected for any damage or missing parts. Damage can be in the form of dents, bends, cracks, mechanical malfunctions, insulation damage, broken wires or cables, broken lenses in telescopes, leak in flexible endoscopes, etc. Should a missing part be discovered the operating room (OR) must be notified to ensure that the missing part was not retained in the patient.
- ***Assembly***: Inspection here includes all of the same types of visual inspections performed in the decontamination area plus checks for cleanliness and functional testing (e.g. mechanical operation, sharpness, optics, etc.). Testing supplies should be readily available at each workstation to perform these critical tests.
- ***Quality assurance (QA)/quality control (QC) process***: A QA/QC process is critical to ensuring that the sets are complete and accurate. This final visual inspection prior to sterilization is critical to ensure that the set is complete as described on the count sheet, all of the necessary integrators, filters and locks are in place, and that there are no contaminates in the set. Agoston strongly recommends that this inspection be performed by a qualified person other than the technician who assembled the set.
- ***Sterilization/storage/transport***: In each of these steps, visual inspection is critical to ensure that the packaging/contents have not been damaged or compromised. Each time that the set is moved, it should be visually inspected for holes and tears in the wrap. Rigid containers also require visual inspection; locks and the lid should be inspected. Both rigid containers and wrapped sets must be inspected to ensure that the package has not been compromised by water, dirt or any other contaminant.

"In addition, visual inspection is also critical in the OR as the nurse or surgical technician opens the packaged instruments and prepares them for use and when she or he receives a used instrument from the sterile field," Agoston added. "These visual inspections must look for form, fit and function."

tion control team members to help in the procurement of equipment that aids our natural eyes as we process instruments for surgery."

Boosting visual inspection efficiencies

Visual inspections are a vital but time consuming process that can place a significant burden on CS/SPD technicians. At AdventHealth, Pichulo and his team have taken a Lean approach to streamline decontamination and pack and prep processes from a direct visualization perspective.

"I teamed up with a Lean expert and we partnered on developing an SPD process and facility that addresses the work that these professionals are tasked to complete yet had been under-supported for many years," said Pichulo. "The result has been a department that lends itself to good work and provides the technicians the tools necessary to achieve that goal."

In the department, technicians first inspect point-of-use preparation. Nonconforming trays that arrive from the OR are recorded in the health system's quality module in CensiTrac, its instrument tracking program. Staff members track non-conforming practices from both the OR and the CS/SPD and report this information on a monthly basis back to these teams.

Next, all lumened stainless steel instruments and other materialled instruments (if supported by the IFU) must pass through an ultrasonic process in the decontamination area. Once the ultrasonic process is complete, instruments with lumens are then flushed with a high pressure reverse osmosis (RO)/deionization (DI) water source. Prior to entering the washer/disinfector, staff members perform direct visualization using a lumen inspection scope. In the department, each third sink in decontamination has a borescope with monitor to support this task.

"We decided to perform this activity in decontam as the assembly area tends to lag behind decontam due to the time it takes to assemble and inspect a tray appropriately," said Pichulo. "Instruments that do not pass direct visualization in decontam do not go to the washer but are manually cleaned until the defects are eliminated. We use direct visualization for endoscopes in decontam as well. Each of our sink lines have a free-standing ultrasonic unit built into the line, so the technician does not have to move to another part of the room to use an ultrasonic."

Once instruments arrive in the prep and pack area, CS/SPD technicians take the instruments through a full inspection to test for cleanliness and function. For lumened instruments that have lumens that are too small to pass a borescope through, technicians flush them with sterile water to validate that cleaning was effective. Any instrument that does not pass visual inspection, along with the entire tray, is sent back to decontamination to be reprocessed there.

"We utilize high magnification digital magnifiers in addition to analog lighted magnifiers in the assembly area for hard to inspect instruments," said Pichulo. "These provide an amazing image many times greater than our analog units can provide. We also have additional borescopes on the clean side for further direct visualization of lumened instruments if the technician desires a second look. We also perform traditional inspections for function, which are part of an annual competency the staff must complete."

Visual inspection advances

Recognizing the limitations of the human eye, equipment manufacturers offer a variety of products aimed at helping CS/SPD professionals detect and destroy dangerous bioburden, identify and address instrument damage, and verify that cleaning processes have been effective.

"First, we need to add adequate illumination for better viewing, which will enable visual inspection of internal surfaces for debris and damage," said Ron Banach, Director of Clinical Training, Ruhof Healthcare. "Secondly, there needs to be magnification of the image for easier identification of debris and damage. Then, there needs to be several lengths and diameters appropriate for many different types of devices. During inspection both still and video documentation and archive storage are necessary. Finally, added training that will support and comply with manufacturers' IFUs."

Light it up

A well-lighted work area is essential, explains Gregg Agoston, M.B.A., VP Business Development, SPD Transformation Services. "Lighted magnifiers should be at each workstation, as well as visual cues to reinforce proper inspection techniques."

Wilder points to ANSI/AAMI ST79: 2017 Comprehensive guide to steam

Page 42

Is moisture in your instrument channels attracting unwanted guests?

Don't give them a place to stay. Dry channels with Airtime!

Properly dried channels reduce the risk of infection. Studies indicate there is a strong correlation between moisture and microbe colonization within flexible endoscopes. The Airtime Instrument Channel Dryer dries flexible endoscope channels, as well as channels in other cannulated surgical instruments.

airtime™
instrument channel dryer

Cygnus Medical | 800.990.7489 | www.cygnusmedical.com

sterilization and sterility assurance in healthcare facilities where section 3.3.5.6 defines the range of light levels for each working area.

"How to you measure the light level? There's an app for that, free ones, and for both Android and iPhone," said Wilder.

Get closer

"Visual and enhanced inspections are more critical now than ever in the sterile processing and endoscopy areas," said Cheron Rojo, AA, CRCST, CIS, CER, CFER, CHL, Clinical Education Coordinator for Healthmark Industries. "The technology advances alone in the power of magnification have skyrocketed by offering more advanced and specialized visualization from the magnification to the design. This can be used to view areas like lumens that cannot be seen with the naked eye or the standard magnification that sterile processing and endoscopy was used to over the years."

"The purchase of enhanced magnification technologies and specific magnification stated in the IFU of the instrument or device is essential," Rojo added. "But consideration also needs to be placed on the amount of magnification you purchase to maintain compliance with front-line technicians at each workstation. One type of magnification cannot be the save all and placed in the dark corner of the sterile processing department on either the decontamination or prep-n-pack areas. The type of magnification is determined by the type of instrumentation and devices in your inventory and all their IFUs."

"Manufacturers have added not only the use of magnification to their IFUs, but also specific power of magnification," said Rojo. He points to Intuitive robotic instrumentation, noting how the product's IFU specifies 4x magnification in the decontamination area. Rojo adds that numerous arthroscopy shaver manufacturers specify the use of an endoscopic camera or (borescope) in their IFUs as well.

Specific to scopes

As noted by the U.S. Food and Drug Administration (FDA), clinicians perform over 75 million endoscopic procedures in the U.S. each year.[3] While endoscopes are essential to many minimally invasive procedures, their use comes at a cost – the risk for contamination and infectious disease spread among patients. In studies performed by manufacturers on endoscopes used in clinics, about 2-5 percent have bacterial contamination.[4]

"In response to the spread of infections by contaminated devices, government agencies, standards committees and medical societies are calling for visually inspecting the internal mechanisms and lumens," said Banach. "They advocate the use of inspection scopes for this purpose."

With regards to rigid endoscopes used in visualization during laparoscopic procedures, Rojo says most manufacturers' IFUs recommend visual inspection by looking through the eyepiece and rotating the endoscope. "This is a very subjective test," he says. "There are better verification tools to identify damage to the optics that can obstruct the surgeon's view during the procedure."

Video borescopes are recommended in ANSI/AAMI ST79:2017 sections 7.6.4.5 and D.1, explains Wilder: "Borescopes can get into places where you can't see, the same places that can hide patient soil residues. They belonged to the previous patient. We don't want to give them to the next patient as a gift. And with the advent of better visual inspection, there is less of an opportunity to do that."

"Borescopes are a great tool to see inside lumens and other small areas of an instrument," said Agoston. "In addition, the various tests for cleanliness such as Healthmark's ChannelCheck that test lumens for protein, carbohydrates and hemoglobin is an excellent way to verify cleanliness."

For example, Ruhof Corporation's VIB (Visual Inspection Borescope) features an HD digital camera to allow for instant visual detection of internal debris and damage inside the channels of an endoscope, reducing the risk of device-related infections. Ruhof VIB's intuitive software provides high-resolution images and can build a reference-based library of images to assist CS/SPD to determine conditions of medical devices and instruments. The Ruhof VIB's software labels and archives both images and videos for emailing and reporting.

A note on IFUs

As Greene-Golden explains, a manufacturer's IFU is the official playbook for effectively and safely reprocessing instruments in the CS/SPD.

"All products found in our field of service help us in our quest to perform inspections of instrumentation used in surgical procedures," she said. "It is our main goal to give our patients world class service by doing our due diligence to ensure instruments sets are meeting the parameters of cleanliness and workability. It is about reading and understanding IFUs. A digital tool like oneSOURCE makes accessing IFUs easy 24/7, as they guide you in what you are looking for as you check each instrument. All instruments are not created equal, what you see is important and we need the human factor to make the call."

But as Pichulo points out, following the steps outlined in the IFU is not enough. CS/SPD professionals must validate that

Healthmark EPRO-001SK (EndoPro-Cam) is used to identify damage to the optics in rigid endoscopes

Page 44

FLEXIBLE INSPECTION SCOPE

VISUALLY INSPECT WITH REMARKABLE CLARITY

The **FIS** includes a distal tip composed of a light source and camera lens at the end of a 110cm flexible shaft, which features graduation marks. The Flexible Inspection Scope is a perfect tool to get a visualization of any potentially soiled device. Software is included and allows viewing and recording.

FIS-005SK
110CM LONG
2.0MM DIAMETER

FIS-006SK
110CM LONG
1.3MM DIAMETER

HEALTHMARK OFFERS MANY OPTICAL INSPECTION TOOLS TO SUIT YOUR NEEDS

MAGIC TOUCH
MAGNIFIER

HANDHELD
MULTI-MAGNIFIER

MADE IN AMERICA
MAGNIFIER

4X LED
MAGNIFIER

healthmark

HEALTHMARK INDUSTRIES CO. | HMARK.COM | 800.521.6224 | HEALTHMARK@HMARK.COM

Visit www.ksrleads.com/?102hp-012

McGan Insulation Tester used to detect defects in laparoscopic insulation

these steps resulted in a clean and sterile instrument.

"We've found that IFUs frequently do not adequately address cleaning procedures. SPD leaders must ask themselves 'How do we validate that our cleaning and disinfection processes are effective?' Additionally, 'Is it enough that we follow the IFU…should we do more to verify that the process we utilize to decontaminate and then sterilize is effective?' I believe the answer to that question is a resounding 'yes'. We must validate our processes, even when those processes are part of the IFU. We must leave nothing to chance."

Invest in people

"Tools are very valuable, but they rely on the competencies of the technician," said Agoston. "This is where many fall short, as we have witnessed technicians who do not use the tools or test correctly. The complexity of instrumentation, combined with typical high turnover in SPD, makes ensuring that every set is visually inspected at all stages of preparation a very difficult job. Training and competency assessments are absolutely necessary."

According to Agoston, 30 to 40 percent of a typical hospital's surgery volume is comprised of minimally invasive surgery (MIS) procedures, with orthopedic procedures using implants representing another approximately 25 to 30 percent.

"Thus, approximately 60 percent of all surgical cases are performed using complex instruments," notes Agoston. "It is generally accepted that for a technician to become competent with non-complex instruments (basic stainless steel handheld instruments) across all specialties is at minimum a 12-month process. The advanced skills required for complex instrument processing (robotics, flexible endoscopes, MIS instruments, power tools and complex orthopedic instruments) have a much longer learning curve."

To help ensure the effective and safe processing of minimally invasive equipment, Purtell recommends healthcare facilities consider having dedicated CS/SPD endoscopy technicians who are trained and specialize in MIS instrumentation, such as rigid and flexible scopes, laparoscopic instruments, powered surgical devices, etc.

"Having a dedicated area equipped with a variety of inspection tools is also worthwhile to round out a well-equipped testing station," she added.

Agoston notes how SpecialtyCare offers CS/SPD full staffing solutions, including specialists with the skills required to prevent common problems associated with MIS instruments, video equipment and robotics.

"Our specialists support instrument reprocessing, OR set up, troubleshooting and take down," said Agoston. "We can also provide the MIS instruments and video equipment. Through our services we ensure that these cases are not delayed due to instrument availability, function or safety and that they go well for the nurses, surgeons and patients." **HPN**

Tools for the job

Lee Ann Purtell, Owner, Capital Medical Resources, offers the following list of visual inspection tools that can "enhance" the inspection process when visual inspection may be challenging, or even impossible.

- ***Insulation testers*** for validating the integrity of laparoscopic insulation that may not be seen with the naked eye (visual inspection alone is NOT adequate). Insulation testing should be done after every use. If defects are found, the device should be removed from service and repaired to prevent patient burns.
- ***Lumen inspection*** for looking inside small channels not visible to the naked eye on flexible scopes, shaver handpieces, suction tubes, etc. Use to validate the effectiveness of cleaning and detect damage and comply with manufacturers' instructions for use (IFU).
- ***EndoScan rigid scope internal optic scanner*** to look "inside" rigid scopes to visually detect moisture, chipped/broken lenses, debris, etc.
- ***EndoLume or Lux Meter*** for measuring light output on scopes, light sources and light cords (visual inspection may not be adequate).
- ***Endoscope leak testers*** for testing and checking for leaks in flexible endoscopes.
- ***Magnifiers and USB microscopes*** for up-close inspection and documentation.
- ***Video tower, wireless camera or testing consoles*** (or access to) for image and functional testing of scopes and powered surgical devices.
- ***Adenosine triphosphate (ATP) or other biological detection*** to measure the amount of organic materials in surfaces not visible to the eye.

"The purpose is so CS and Endoscopy technicians can confidently validate the cleaning process, detect defects and comply with IFUs," said Purtell. "Doing so helps reduce end-user complaints and aids in staff education/training, departmental communication, patient-care follow-up and repair vendor interaction."

References

1. [1] The Direct Medical Costs of HAIs in US hospitals and the benefits of prevention, R. Douglas Scott II, 2009)

2. N Engl Jrnl of Med 2012, 366:1354-1356, April 2012

3. Quality Control: Stopping infections before they happen through safer endoscope reprocessing, FDA, January 9, 2020, https://www.fda.gov/science-research/fda-grand-rounds/quality-control-stopping-infections-they-happen-through-safer-endoscope-reprocessing-01092020

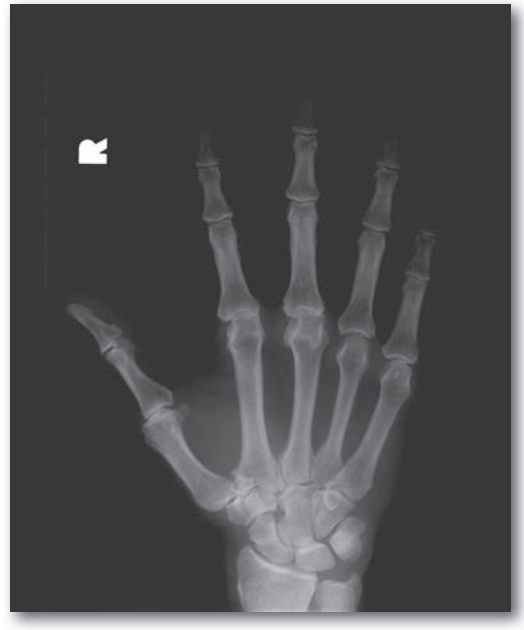
4. Quality Control: Stopping infections before they happen through safer endoscope reprocessing, FDA, January 9, 2020, https://www.fda.gov/science-research/fda-grand-rounds/quality-control-stopping-infections-they-happen-through-safer-endoscope-reprocessing-01092020

R & L SPOT® Disposable X-Ray Markers for Anatomical Orientation

The Sanitary Alternative to Permanent Markers

When used over and over, permanent anatomical orientation markers and the tapes used to secure them can harbor and spread opportunistic and pathogenic bacteria.

Beekley Medical's single-use, self-adhesive disposable x-ray markers are a sanitary alternative to permanent markers.



Ideal for use with:

- Immune-Suppressed or Compromised Patients
- Neonatal / Newborn
- Trauma Cases
- Isolation Wards
- Burn Units
- Portable Units

R-SPOT®

REF 113 QTY 64 / Box

- lead-free radiopaque R for documenting right side on film
- for isolation, trauma; neonatal and burn units

L-SPOT®

REF 112 QTY 64 / Box

- lead-free radiopaque L for documenting left side on film
- for isolation, trauma; neonatal and burn units

Start using R & L SPOT® disposable x-ray markers as a part of your infection control protocols.

Call 1.800.233.5539 • Fax 1.800.735.1234
Visit beekley.com • Email info@beekley.com

Customers outside the U.S. – Contact your local distributor for pricing and product availability.
To locate a distributor call +1.860.583.4700 or email international@beekley.com

Visit Beekley.com for product safety information

Manufactured by Beekley Corporation
One Prestige Lane, Bristol, CT 06010 USA
Tel: 1.800.233.5539 or +1.860.583.4700 Fax: 1.800.735.1234 beekley.com

BEEKLEY, BEEKLEY MEDICAL, SPOT, and WHEN YOUR DIAGNOSIS MUST BE RIGHT are Reg. U.S. Pat. & Tm. Off.
BEEKLEY and SPOT are Registered Community Trademarks. BEEKLEY is a registered trademark in Canada.
PIK-UP is an unregistered trademark of Beekley Corporation.
© 2020 Beekley Corporation. All rights reserved.

Beekley Medical®
when your diagnosis must be right®

REV: RLS_AD_HPN_1120

HEALTHCARE PURCHASING NEWS

February 2021
The self-study lesson on this central service topic was developed by 3M Health Care. The lessons are administered by Endeavor Healthcare Media.

Earn CEUs

After careful study of the lesson, complete the examination at the end of this section. Mail the completed test and scoring fee to *Healthcare Purchasing News* for grading. We will notify you if you have a passing score of 70 percent or higher, and you will receive a certificate of completion within 30 days. Previous lessons are available at www.hpnonline.com.

Certification

The CBSPD (Certification Board for Sterile Processing and Distribution) has pre-approved this in-service for one (1) contact hour for a period of five (5) years from the date of original publication. Successful completion of the lesson and post-test must be documented by facility management and those records maintained by the individual until recertification is required. DO NOT SEND LESSON OR TEST TO CBSPD. For additional information regarding certification, contact CBSPD - 148 Main Street, Suite C-1, Lebanon, NJ 08833 • www.sterileprocessing.org.

IAHCSMM (International Association of Healthcare Central Service Materiel Management) has pre-approved this in-service for 1.0 Continuing Education Credits for a period of three years, until January 15, 2024. The approval number for this lesson is **3M-HPN 211501**.

For more information, direct any questions to *Healthcare Purchasing News* (941) 259-0832.

LEARNING OBJECTIVES

To explain:

- *the variety of sterilization processes used to sterilize medical devices and relevant standards.*
- *the approaches used to validate and routinely control sterilization processes.*
- *how CIs are categorized into different types.*
- *how CIs can be used in validating and routinely monitoring VH_2O_2 sterilization processes.*
- *the results of some new studies examining the performance of VH_2O_2 CIs.*

Sponsored by:

3M Health Care

SELF-STUDY SERIES

Current evidence

Monitoring vaporized hydrogen peroxide sterilization processes using chemical indicators

by Dr. Brian Kirk

Sterile single-use and reusable medical devices must be sterilized by a validated sterilization process.[1,2] There are many microbicidal agents and figure 1 shows some which have been used in sterilization processes using physical methods or chemical agents.

Physical methods include hot and cold processes. Hot processes use high pressure steam in an autoclave or dry heat in an oven. Cold processes employ ionizing radiation and are used at an industrial scale for bulk sterilization of single-use devices.

Chemical sterilization methods include those which use alkylating chemicals such as ethylene oxide (EO), formaldehyde and glutaraldehyde. Chemical sterilization also uses oxidizing agents such as hydrogen peroxide vapor, chlorine dioxide, peracetic acid and ozone gas. Many of the chemical methods operate at low temperatures (*ca*<80°C) and are used for small scale sterilization in hospitals and some, e.g. EO, in industry. In hospitals >90 percent of theatre sets are processed using steam sterilization, however there is a need for low temperature processes for instruments which cannot withstand high temperatures, e.g. flexible endoscopes. The three most popular low temperature methods used in hospitals would be EO, low temperature steam with formaldehyde (in Europe) and vaporized hydrogen peroxide (VH_2O_2).

Validation and routine control of sterilization processes

All processes used to sterilize medical devices must be validated. Validation involves proving that what we want is what we get; sterility being one such attribute. Validation involves three steps. The first is installation qualification (IQ), and this involves checking the physical status of equipment installed in the hospital, including supplied services, to make sure they are correct. The second is operational qualification (OQ) and this involves operating the sterilizer, often empty or using standardised test loads, to make sure the equipment runs correctly. The final step is performance qualification (PQ) involving tests carried out to ensure the sterilizer can process loads that the hospital wishes to sterilize.

Sterilization Process Covered (following 14937 format)	International Standard	AAMI Standard (Hospitals)
Generic Standard for any Process	EN ISO 14937	N/A-I
Moist Heat (Steam)	EN ISO 17665	ST 79
Ethylene Oxide Gas	EN ISO 11135	ST 41
Irradiation	EN ISO 11137	N/A-I
Low Temp Steam with Formaldehyde	EN ISO 25424	N/A
Dry Heat	EN ISO 20857	N/A-I
Vaporized Hydrogen Peroxide	EN ISO 22441 [a]	ST 58

Table 1: International standards for the validation and routine control of various sterilization processes used in industry and hospitals and their ANSI/AAMI equivalents for hospital sterilization. N/A-I indicates a standard for industrial sterilization exists.

aEN ISO 22441 is in development.

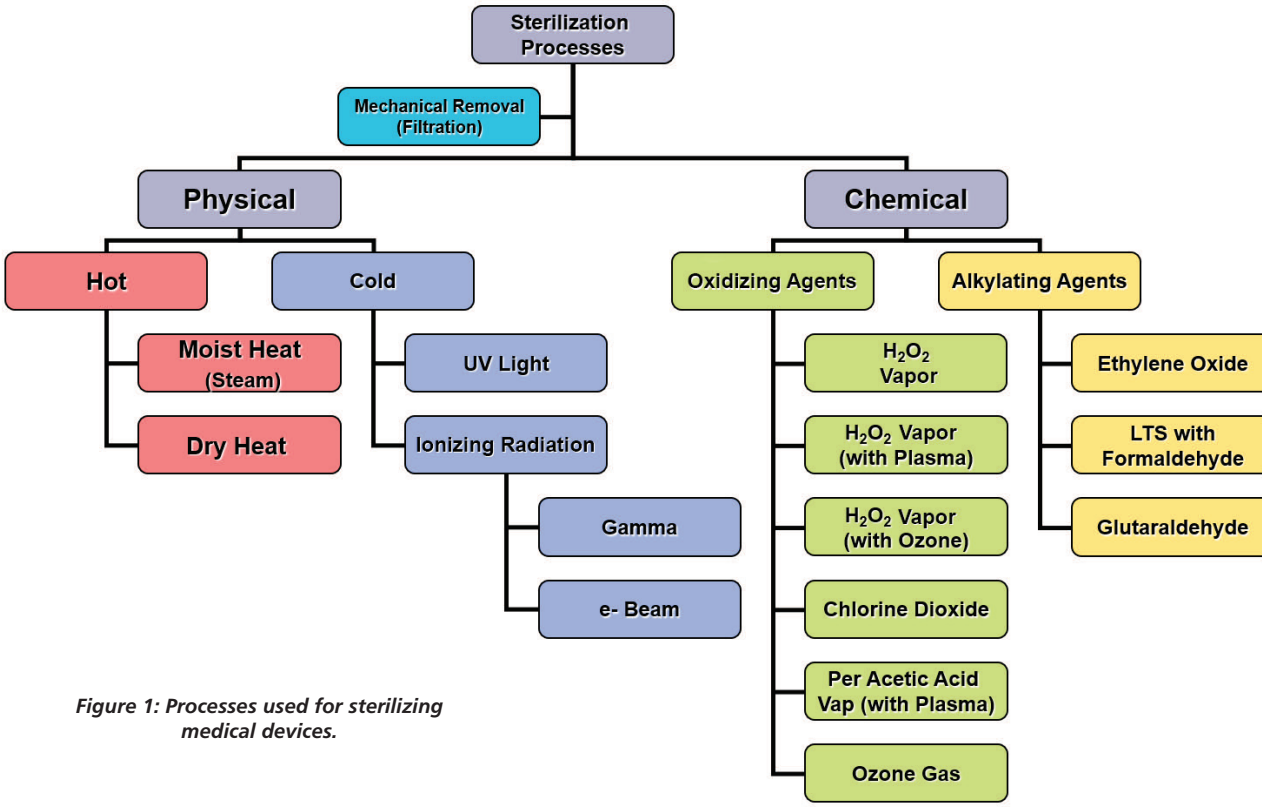


Figure 1: Processes used for sterilizing medical devices.

There are international standards describing the validation of a number of sterilization processes. These are shown in table 1 along with U.S. national equivalents. It is worth noting that there is no internationally agreed standard for validating VH_2O_2 processes; these are in development, so in the absence of a specific process standard, EN ISO 14937 applies.

In hospitals, IQ and OQ are normally undertaken by the sterilizer manufacturer or supplier and will form part the commissioning process of new equipment at the site of use. PQ is a site-specific exercise. Medical device manufacturers must provide re-processing instructions including the sterilization processes to be used. During PQ, hospitals might rely on these instructions or they may carry out some practical assessment of performance using a variety of monitoring tools.

Having validated our process, we must then ensure routine monitoring takes place to make sure the sterilization process remains efficacious, and a number of tools can be used for this purpose.

Routine monitoring of VH_2O_2 sterilization

Any sterilization process will have certain characteristics which contribute to microbial kill. These are called the "process variables." For VH_2O_2 sterilization, the process variables are the temperature and time of exposure at a specified concentration of VH_2O_2. In order to ensure every sterilization process has been effective, the process variables must be routinely monitored, and there are three basic methods for achieving this. Physical Indicators (PIs) employing instruments which measure a process variable. For a VH_2O_2 process, temperature and time are easily measured. VH_2O_2 chamber concentration can also be measured using UV light spectroscopy. PIs only provide information for one process variable, so a combination are required to get a full process picture. PIs provide no information about what is happening inside the packs being sterilized.

Biological Indicators (BIs)[3] are a preparation of a living microorganism, usually a bacterial spore, which has high resistance to, but is inactivated by, an effective process. BIs react to all of the process variables.

Chemical indicators (CIs)[4] are mixtures of chemicals which, when exposed to specified process variables (called their stated values; SVs) will change color. For example, a CIs SVs may be 2.3mg/L VH_2O_2 at 50°C for 360 seconds exposure. When exposed to these conditions the indicator must change color, indicating a pass. The manufacturer must declare the SVs in the instructions or print them on the CI.

The international standard EN ISO 11140-1[4] specifies the performance requirements for six different types of CI. These are shown in table 2 along with their uses. Types 4, 5 and 6 are for placement inside sterile packs, as required by some guidance documents.[5] They prove particularly useful for the end user who, as part of their practices, are required to check every pack to ensure external and internal indicators have given a correct response.[6] EN ISO 11140-1 does not provide requirements for types 5 and 6 VH_2O_2 CIs.

Chemical indicators for monitoring VH_2O_2 sterilization

The exposure conditions under which a type 1 CI should show a pass result (its endpoint) and a fail result are stated in EN ISO 11140-1. For a type 4 CI, the exposure conditions which give rise to a pass response (SVs) will be specified by the manufacturer ideally having some relationship to the sterilization process being

Self-Study Test Answers: 1. A, 2. C, 3. A, 4. B, 5. C, 6. B, 7. B, 8. A, 9. B, 10. B

Page 48

CI Type	Description	Use
1	Process Indicator	Used to show exposure to a process, no information provided about the quality of the process. Valuable for differentiating processed from unprocessed packs.
2	Specific Test Indicator	Used in specific tests described in equipment and process standards, e.g. Bowie and Dick Test.
3	Single Variable Indicator	Responds to one of the specified process variables e.g. temperature.
4	Multivariable Indicators	Respond to two or more of the specified process variables.
5	Integrating Indicators	Respond to all of the process variables for a given sterilization process in a manner which mimics the response expected from an equivalent biological indicator. Also provide a result which directly relates to the minimum conditions required to achieve sterilization in any given process standard (see table 1).
6	Emulating Indicators	Respond to all of the process variables for a given sterilization process providing a result equivalent to the minimum sterilization conditions specified in a process standard (see table 1).

Table 2: The types of chemical indicators specified in international standard EN ISO 11140-1.

monitored. The standard also specifies the test conditions under which a fail response should be observed and these are related to a specified reduction in each of the SVs. Table 3 shows the exposure conditions for a pass and fail response for types 1 and 4 VH_2O_2 CIs. In the example the SVs for the type 4 CI are the same as for the type 1, and the table then illustrates the test conditions required for the CI to show a fail response. It should be clear from the information shown that a type 4 CI will have greater sensitivity towards process failures.

Recent studies examining the performance of VH_2O_2 CIs

Two studies have recently been published examining the performance of some types 1 and 4 CIs. The first study[7] examined the performance of eight CIs for VH_2O_2 sterilization processes to give a pass or fail result when tested according to the methods in EN ISO 11140-1 and also to detect changes in the individual process variables time, temperature and VH_2O_2 concentration.

When tested according to the methods described in EN ISO 11140-1, it was found that two of the type 1 CIs showed appropriate pass and fail results. Another type 1 CI gave all passes and one all fails. Two of the type 4 CIs gave appropriate pass and fail results. Another type 4 showed slight differences in color in pass or fail tests and another type 4 gave the same pass color in all tests.

In the second study[8] the same CIs were tested in two sterile processing departments in US hospitals in order to examine their performance when placed in four different model loads, then processed in sterilization cycles which were recommended, and then when operated with unsuitable overweight loads or incorrectly selected sterilization processes. The ability to detect differences in sterilizing conditions within individual packs was also evaluated.

The results indicated that not all of the CIs were able to indicate if a VH_2O_2 sterilizer had not been used according to recommendations. Of the eight CIs tested, four were able to indicate the use of an incorrect loading configuration or use of an incorrect sterilization process. Two of these four were also capable of indicating non-uniformity of sterilizing conditions within individual model load packs. The results of these studies confirm the importance of using a range of monitoring systems, rather than relying on one, the information from which add to the overall assurance of process efficacy and load sterility.

Use of CIs during performance qualification

Unlike steam sterilization, which provides a high overkill, and wide utility, VH_2O_2 processes are designed for a specified range of instruments and loads. It is vital that manufacturers' recommendations are carefully followed. Failure to do so has potential implications for the sterility assurance associated with a load and indicates the importance of conducting PQ studies when introducing new devices, sterile barrier systems or accessories into the work flow in order to detect incompatibilities and potential processing problems, but also to establish the area of the pack that creates the greatest challenge to sterilant penetration, thereby informing the position of placement for routine monitoring. In hospitals it can be difficult for practitioners to carry out PQ using independent PIs since introducing sensors into the sterilizer chamber require specialist expertise. Free-standing temperature loggers, which are activated and then placed into the chamber, are available, however these can be expensive. However, PQ can still be performed using CIs and BIs. The use of CIs within instrument sets can potentially detect process problems when conducting PQ studies to ensure a new load is compatible with the intended sterilization cycle. PQ of VH_2O_2 is discussed in national guidance documents.[5]

Use of CIs during routine monitoring

Sterilizer manufacturers will specify the loads which can be sterilized in each cycle programmed into the equipment and medical device manufacturers and will specify which types of sterilization process can be used to sterilize their

products. It is important that these instructions are followed. However, despite best intentions, in a busy sterile processing department it is possible to inadvertently process a device or load in a sterilization cycle which is not recommended by the manufacturer. It is also possible to use inappropriate accessory items and sterile barrier systems, which can, individually or in combination compromise process efficacy.[9] The placement of type 4 VH_2O_2 CIs at locations within a pack identified during PQ will ensure that the end user can see that sterilizing conditions were met at the point(s) of placement and therefore aid in answering the question "is the sterility of the pack confirmed?", as discussed in the WHO surgical safety checklist.[6]

The value of reference colors – a warning

The interpretation of color change of CIs is subjective and depends on human factors such as the experience, health, visual acuity, or stress levels of the operator, and environmental factors such as the brightness of incident light.[10] The presence of a color reference, either printed on the CI or in instructions, might aid or confuse interpretation, if not a good match for the pass color. CIs placed inside sterile packs will be interpreted by practitioners who are under pressure to use the instruments and might be in subdued light, so many indicators exhibiting marginal fails might be interpreted as passes. CIs with a clear color change, which are easily interpretable under less than ideal conditions, are therefore more valuable than others which do not. It is essential that manufacturers provide comprehensive educational and training material not only for SPD staff but also for the practitioners (e.g. Operating Room staff) who will interpret the color change at the point of use.

Summary

CIs form part of an overall quality assurance system, which when taken as a whole, provides assurance that each and every pack is sterile. The use of chemical indicators of good quality in terms of performance and ease of interpretation is vital in order to make meaningful judgements. HPN

References:

1. Submission and Review of Sterility Information in Premarket Notification (510(k) Submissions for Devices Labelled as Sterile. Guidance for Industry and Food and Drug Administration Staff, January 21 2016, Food and Drug Administration, Washington, USA

2. Wallace, C, Breaking the Chain of Infection, Self-Study Series, Healthcare Purchasing News, October, 44-47, 2020.

3. EN ISO 11138 Sterilization of health care products - Biological indicators - Part 1: General requirements, 2017,

4. EN ISO 11140-1, Sterilization of health care products - Chemical indicators - Part 1: General requirements, 2014

5. ANSI/AAMI ST 58.:2013 Chemical sterilization and high-level disinfection in health care facilities , 2013, Association for the Advancement of Medical Instrumentation.

6. World Health Organization, WHO surgical safety checklist, 2009.

7. Kirk, B. Evaluation of a number of chemical indicators for monitoring vaporized hydrogen peroxide (VH2O2) sterilization processes. Zentr Steril, 2020; 28(4), 208-217

8. Kirk, B. Detecting vaporized hydrogen peroxide sterilization (VH2O2) process failures in clinical settings using chemical indicators. Zentr Steril, 2020; 28(6): 334-343.

9. Talapa, L, Vaporised Hydrogen Peroxide VH2O2 Sterilization; riding atop a new wave, presentation at IAHCSMM 2019 annual conference April 27th to May 1st, Anaheim, CA2019.

10. Hurlbert A, Pearce B, Aston S. All illuminations are not created equal: The limits of color constancy. *In: 38th European Conference on Visual Perception (ECVP).* 2015, Liverpool, UK: Sage Publications Ltd.

Dr. Brian Kirk is Director of Brian Kirk Sterilization Consultancy Group Ltd, specializing in Standards Development, Education and Sterilization Consultancy. Kirk is qualified as a pharmacist. He holds a Master's degree in Pharmaceutical Analysis and a PhD in Pharmaceutical Sterilization Technology. He received the 1985 annual award for best submitted paper to the Parenteral Drug Associations Journal. Kirk joined 3M Health Care in 1989 as a development scientist for sterilization monitoring products, where he was responsible for developing and supporting a number of new products. He has had special responsibilities for monitoring the development of national, European and international standards relating to sterilization. He has participated in a number of BSI, CEN and ISO committees responsible for developing standards for chemical and biological sterilization indicators and steam, ethylene oxide and vaporized hydrogen peroxide sterilizers and sterilization processes.

Page 50

Test Condition	Type 1 CIs		Type 4 CIs	
	Pass	Fail	Pass	Fail
H_2O_2 vapor conc mg/L (tolerance)	2.3 (+/- 0.4)	2.3 (+/-0.4)	SV eg 2.3	SV -20% 1.84
Temperature ºC (tolerance)	50 (+/- 0.5)	50(+/-0.5)	SV eg 50	SV-3 47
Time seconds (tolerance)	360 (+/-1)	7 (+/-1)	SV eg 360	SV-25% 270

Table 3: The exposure conditions for a pass and fail response for a type 1 and 4 VH_2O_2 CI according to EN ISO 11140-1.

CONTINUING EDUCATION TEST • FEBRUARY 2021

Current evidence

Monitoring vaporized hydrogen peroxide sterilization processes using chemical indicators

Circle the one correct answer:

1 Steam Sterilization is the most popular method used in hospitals.
A. True
B. False

2 Which is the most recently introduced low temperature sterilization process now popular in hospitals?
A. EO
B. Irradiation
C. Vaporized hydrogen peroxide sterilization

3 Validation of a sterilizer involves three steps.
A. True
B. False

4 Which type of indicator provides microbiological assurance of process efficacy?
A. Physical indicators
B. Biological indicators
C. Chemical indicators

5 How many types of chemical indicators are there?
A. 4
B. 5
C. 6

6 Type 1 chemical indicators are internal pack indicators for placement inside instrument sets.
A. True
B. False

7 For a vaporized hydrogen peroxide sterilization process to be effective, the correct time and concentration of hydrogen peroxide are the only two considerations.
A. True
B. False

8 A type 1 chemical indicator must show a pass when exposed to:
A. 2.3mg/L VH_2O_2 at 50oC for 360 seconds
B. 3.2mg/L VH_2O_2 at 50oC for 360 seconds
C. 2.3mg/L VH_2O_2 at 50oC for 7 seconds

9 EN ISO 11140-1 specifies requirements for types 4, 5 and 6 VH_2O_2 chemical indicators.
A. True
B. False

10 The stated values for a chemical indicator specify the conditions under which it will show a fail result.
A. True
B. False

IAHCSMM
Instrumental to Patient Care®

The approval number for this lesson is **3M-HPN 211501**.

CBSPD

Request for Scoring

❑ *I have enclosed the scoring fee of $10 for EACH test taken — **Payable to Healthcare Purchasing News.** We regret that no refunds can be given. (It is not neccessary to submit multiple tests separately.)*

Detach exam and return to:
Continuing Education Division
Healthcare Purchasing News
2477 Stickney Point Road, Suite 315B
Sarasota, FL 34231
PH: 941-927-9345 Fax: 941-927-9588

Presented by
HEALTHCARE PURCHASING NEWS

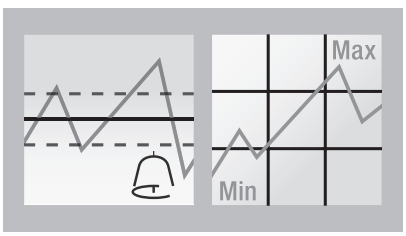
Please print or type. Return this page only.	
Name	
Title	
Hospital Name	
Mailing Address	
Apt/Suite	
City, State, Zip	
Daytime Phone	
Email	

Ultra-Low Temperature Freezers: Reliability when you need it most.

Trust the experts when it comes to safely storing sensitive samples. With innovative ultra-low temperature freezers (ULTs) that reach extreme temperatures spanning from –40 to –86°C, Liebherr is setting a new standard in the scientific and health care sector. Liebherr ULTs are capable of holding up to 700 liters and were released during the second half of 2020. We invite you to learn more about our new range of appliances.

Secured access to samples

Fast-acting alarm systems in case of emergencies, to keep valuable materials safe



Minimal temperature fluctuations to preserve the quality of samples

Reliable and safe long-term storage of valuable and sensitive samples.

Depending on their size, our new ULTs have storage capacities of almost 30,000 to over 40,000 samples. Assuming an average value of $10 per sample, this results in a storage value of over $300,000, and even more for longer research projects and rare materials. Consequently, this makes safety of the utmost importance. Several integrated safety features ensure the highest level of reliability and make it easy to choose and trust the new Liebherr ULTs.

A Wide Range of Applications:

-40°C to -60°C: Low Temperature Tests of Materials, Mid-term storage Reagents/ Vaccines

-60°C to -86°C: Long-Term Storage of Biological Products, Chemical Reagents, Vaccines, Bacteria

The safest long-term storage with the lowest energy consumption.

High energy input is required to reach low temperatures that go down to -86°C. Liebherr's ULTs differ significantly from standard commercial freezers in regards to both insulation and energy consumption because we use highly-efficient systems with cascade cooling and KW refrigerant, in combination with a vacuum/foam sandwich construction.

home.liebherr.com/lab

LIEBHERR

Cleaning hinged instruments effectively, anticipating ANSI/AAMI ST 79 updates

by Stephen Kovach

Q We are having a hard time cleaning our double-action bone rongeur. What advice do you have for us?

A That is an excellent question. The double-action type bone rongeur does offer a significant challenge for cleaning. Stille first developed the double-action bone rongeur around 1872; the "double-action" provides a second hinge point. (See Figure 1) This increases the pressure and force applied to the cutting edges of the rongeur through the lever-action provided by the second pivot point and results in better cutting for the surgeon. The double-action bone rongeur can be found in orthopedic, neurosurgery and plastic surgery instrument trays. While this is an excellent feature for the surgeon, the "double-action" creates a cleaning concern for the medical device reprocessing staff because it can harbor tissue or bone from the surgery, as seen in the picture. (See Figure 2)

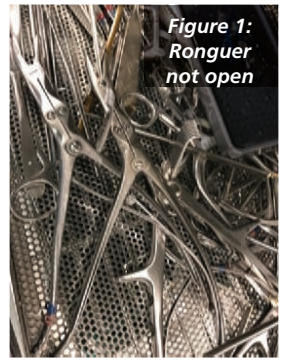


Figure 1: Ronguer not open

Figure2: Dirty ronguer, not open

Our mantra in Sterile Processing is to refer to the original equipment manufacturer's (OEM's) instructions for use (IFU). However, in reviewing many IFUs for this type of surgical instrument, I cannot find specific details on how to keep the rongeur open during the cleaning process or how the open position, place the instrument in a mesh bottom instrument basket. Visually inspect the instrument for cleanliness and clean off any remaining debris. Visually inspect the instrument for damage. Open and close the jaws to ensure proper operation of the instrument."

The question is how to keep the jaws open during the cleaning process. It is difficult. And we know that if not given the proper tools for our job, the CPD (creative people downstairs) staff, as they are sometimes referred to, will come up with solutions to help solve concerns. (See Figure 3) I have seen inventive measures such as using tongue blades, picks, or anything else to keep the jaws open to allow for the cleaning action to work properly. The cleaning action works to get into the hard-to-reach spots that must stay open during this critical step. One must not forget that pre-cleaning is important, and this area is sometimes overlooked when it comes to proper brushing technique or is never brushed, and this sets up failure.

Many companies provide solutions to keep all types of instruments open during the cleaning process (i.e., adjustable stringer). Exposure to the cleaning process is vital to having clean and functional instruments. You need the proper brushes; that is a given. My other suggestion is to find companies that sell these types of products and provide solutions to help resolve your quest for cleaner double-action bone rongeurs or any other type of hinged instrument that must be kept open during the cleaning process . (See Figure 4)

Q I have heard that ANSI/AAMI ST 79 has been updated. Is that true?

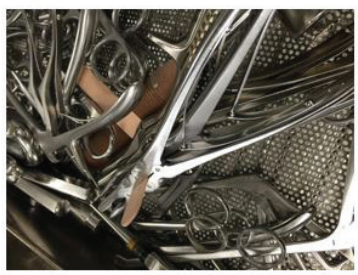
A ANSI/AAMI ST 79 was last approved in 2017. Officially, it is on a five-year review process, so it will be around until 2022 when there is another complete document review. Yet, the committee felt there were four significant concerns that needed to be addressed before 2022. (See list below) To my understanding, the results of the changes are to be shared and updated in early 2021, which had not happened yet at press time in early January.

A.1: Amendment for Environmental Services/Fans/Food and Drink.
A.2: Amendment for Inspection of Insulated Instruments.
A.3: Amendment for Modification of Content Pertaining to Frequency of Cleaning for Routine Care of Sterilizers for Sterile Processing Areas in Health Care Facilities.
A.4: Amendment for Content Addressing Recording BI Lot Numbers in Sterilizer Records for Sterile Processing in Health Care Facilities. HPN

Reference

(Rongeurs – Recommended Cleaning, Sterilization, and Instructions for Use) https://www.medline.com/media/mkt/pdf/Rongeurs-IFU.pdf

Stephen M. Kovach, BS, CFER, started in the medical field in 1975 as a sterilization orderly and has worked in many positions within the healthcare industry. He presently is Clinical Educator Emeritus at Healthmark Industries.



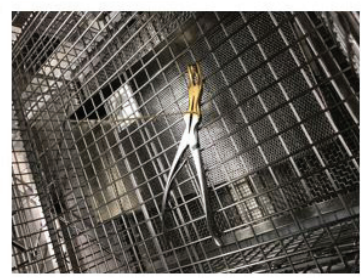
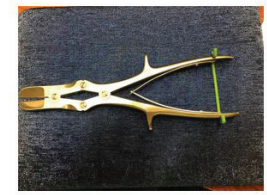


Figure 3: Open ronguer tactics



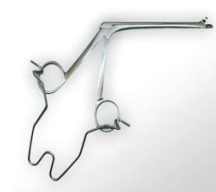


Figure 4: Better open ronguer solutions

OR buying new reusable instruments or equipment? Have SPD weigh in first.

by Julie E. Williamson

It's an all-too-common conundrum: Sterile Processing (SP) professionals discover too late in the acquisition cycle that new surgical instruments or equipment have been purchased – without those in the Operating Room (OR) or other user departments first ensuring SP technicians have the knowledge, training, instructions for use (IFU) (and, sometimes, even the required processing equipment) to ensure it can be cleaned and sterilized safely and effectively.

Numerous factors can contribute to this glaring oversight (one that, by the way, can jeopardize patient safety and place the healthcare organization at significant liability risk). For starters, it's not uncommon for physicians/surgeons to demand certain devices or equipment based on their experience with them at previous facilities, and for their current facility to then cater to their wishes without first considering all implications of the purchase.

Lack of SP visibility and presence within the facility can also play a key role. In some cases, SP professionals aren't actively involved in multidisciplinary committees, so they may be either simply unaware of product evaluation or purchasing discussions, or don't want to rock the proverbial boat by interjecting their opinions, objections or concerns. What's more, not all facilities have effective, enduring partnerships between SP, the OR and Infection Prevention (IP), an unfortunate reality that can perpetuate an "us and them" perception that erodes effective, proactive communication across all sides of business.

Over the years, the International Association of Healthcare Central Service Materiel Management (IAHCSMM) has heard numerous examples of near-disastrous consequences stemming from new purchases being made without first consulting with those in the SP department (SPD). Some shared how new reusable devices or equipment made their way into the department for initial processing, only to discover the SPD lacked the required equipment to clean, high-level disinfect or sterilize the item according to the manufacturer's IFU. One SP professional shared how a surgeon became infuriated when told the SPD didn't have the proper equipment to process the new device safely and properly. The surgeon sternly suggested the SPD process it with the equipment they had (a request that was promptly and prudently denied by the SP manager who reiterated the need to follow IFU, standards and best practices to the letter).

Stakeholders must step up

SP professionals who don't currently participate in detailed discussions on new product selection, evaluation and, ultimately, purchase need to take steps now to ensure they have a regular seat at the table (if any efforts to participate are met with resistance, it can be helpful to seek support from IP).

Every instrument or piece of equipment that would require reprocessing by SP professionals must be carefully assessed prior to purchase and acquisition to ensure the technicians have the resources (e.g., supplies, equipment, training, IFU, etc.) to manage the new item(s) safely and consistently. ANSI/AAMI ST79:2017, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, recommends healthcare organizations establish a multidisciplinary product evaluation committee that has representation from those who will be affected by the new product.[1] For a product that would undergo steam sterilization, for example, the committee could consist of someone from the SPD, the OR, IP, Risk Management, Materials Management, Staff Development, and potentially others.

During the evaluation process, it is recommended to ensure all stakeholders have access to critical data that includes clearance documentation from the US Food and Drug Administration; the manufacturer's literature and written IFU for the product being evaluated; expert opinions and relevant research published in peer-reviewed journals; and reports from peers who are currently using the product or have trialed it.[1]

The following factors should also be considered before a facility procures a new product[1]:

- How the new product will contribute to patient care and safety;
- Legal concerns or safety implications that could arise from the product's use;
- Product's expected return on investment;
- Education/training needed to ensure all staff members can safely and effectively use the product;
- Product's ease of use and compatibility with the facility's existing equipment and products;
- Product's environmental impact;
- Availability of ongoing vendor support (e.g., for training or maintenance); and
- The new product's impact on inventory standardization.

Conclusion

New product and equipment purchases are ongoing and necessary to keep healthcare organizations competitive and current with the latest medical/surgical procedures and industry trends that impact the delivery of patient care. It is essential, however, that new product evaluations and purchasing decisions never occur in a vacuum but rather with multidisciplinary involvement that includes representation from all disciplines that would be impacted by the purchasing decision. Only then can facilities help ensure that the purchasing decision is one that meets the broader needs and priorities of the organization and the patients it serves. HPN

References

1. ANSI/AAMI ST79:2017, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. Section 15, New product evaluation.

Julie E. Williamson serves as Senior Editor and Director of Communications for the International Association of Healthcare Central Service Materiel Management.

Analyzing value during a global pandemic

COVID-19 response need not thwart progress but enhance it

by Rick Dana Barlow

Photo credit: tadamichi | stock.adobe.com

Just as the definition and parameters of value vary from person to person, organization to organization, so goes the definition and parameters of value analysis.

Short of universal acceptance and implementation, value analysis seems to slide along a scale of convenience. Some consider value analysis to be a synonym for "product evaluation," even though the former tends to be more strategic, less tactical and transactional than the latter. Further, value analysis concentrates more on people – patients, staff, etc. – through personal and professional relationships as key to process improvement, whereas product evaluation focuses on technology and device use connected to costs and outcomes.

Unfortunately, delineation between the two can be murky.

But not everyone thinks so. For example, Lumere subscribes to product evaluation as a function of the larger and more encompassing value analysis process.

"Product evaluation is a single component of Value Analysis," observed Suzanne Smith, RN, Senior Solution Advisor – Value Analysis, Lumere, a GHX company. "There were 'Product Evaluation' committees a long time ago that have since evolved into Value Analysis committees, which are much broader and more strategic in scope. Organizations that narrowly define Value Analysis as only product evaluation are typically very nascent in their maturity."

Suzanne Smith

Smith encourages Value Analysis teams "to create a charter that defines product evaluation as a component – not the sole purpose of the function. This charter must then be broadly socialized within the organization to ensure uptake. If you want something to stick, you must preach it to anyone who will listen!"

Smith contends it's critical that the Value Analysis charter connects to an organization's strategic goals – particularly now during the pandemic.

"What many failed to recognize – until COVID-19 brought perspective – is that the Supply Chain department is a strategic partner in helping organizations realize these goals," she noted. "They have the data and insight to help connect the dots."

Smith's colleague Dan Hermes, Senior Solution Advisor at Lumere, views the connection and integration between the two functions as evolutionary. In healthcare, product evaluation began as an independent process that migrated to becoming a "single input" within Value Analysis, he indicates.

Dan Hermes

"The profession may have started out by evaluating products, but it's evolved into informing evidence-based decision making that's integrated with clinical practice," Hermes said. "It's about clearly communicating that Value Analysis goes above and beyond evaluating a product's cost or efficacy. To do this, you must have a champion that's willing and able to build a coalition of Value Analysis supporters across departments and service lines. This doesn't happen by osmosis. You need to change the culture."

Ron Denton & Associates LLC COO Angie Haggard advocates a holistic approach with value analysis that incorporates a broad framework with strategic direction reaching into the C-suite. *(See Figure 1, page 52.)*

Angie Haggard

"Value Analysis is the collaborative structure and

Page 56

66% lower bed costs.[1]

That's **more** than a surface improvement.

Each year, an estimated 2.5 million patients are affected by pressure injuries,[2] impacting both quality of care and risk exposure. Specialty beds may offer relief — but at a very high cost.

As a unique support surface overlay*, Tortoise gives you an alternative to specialty beds that is as affordable as it is effective.

In studies and daily use, **it has been shown to provide an 84% reduction in pressure injuries** when used as a part of prevention protocols.[3]

Tortoise. The cost control you need without sacrificing patient care. **That's definitely more than a surface improvement.**

For more information or to arrange a demo, visit us today at **www2.molnlycke.us/tortoise**

1. C. Trevellini, Connecting the dots: Pressure Ulcer Prevention and Safe Patient Handling. Poster presentation at National Pressure Ulcer Advisory Panel Biennial Conference, Orlando, Florida, United States of America, 2015
2. AHRQ – Preventing Pressure Ulcers in Hospitals. https://www.ahrq.gov/professionals/systems/hospital/pressureulcertoolkit/putool1.html
3. Cooper, M., et.al., Bundling for Change: Implementing Pressure Injury Prevention, Poster WOCN 2017 Conference

* Non-powered reactive support surface

Mölnlycke® Tortoise® Turning and Positioning System

Mölnlycke®

The Mölnlycke, Tortoise, names and respective logos are registered trademarks of one or more members of the Mölnlycke Health Care Group of Companies. Distributed by Mölnlycke Health Care US, LLC, Peachtree Corners, Georgia 30092. © 2020 Mölnlycke Health Care AB. All rights reserved. 1-800-843-8497 MHC-2020-78891

Figure 1 – The Value Proposition

Ron Denton & Associates delineates between a product evaluation committee and a true Value Analysis structure in four key areas: Scope, people, process and progress.

Area	Product Evaluation	Value Analysis
Scope	Supplies	Supplies, Purchased Services, Pharmacy, Equipment
People	Includes supply chain and physicians (Physicians are not effectively engaged) Executives are not engaged	Includes executives, physicians, stakeholders, supply chain – with clearly defined roles and meeting consistency with executive leadership
Process	Price-focused Never say "no" Supply chain dictates priorities Unclear process	CQO analysis and review prior to sourcing decision Physician engagement plan and communication Escalation path in place to resolve conflicts Proactive meeting and initiative planning
Progress	No savings goal Complete 1-25 initiatives per year	Specific financial goals (savings, quality, outcomes) Complete 50-100 initiatives per year

Source: Ron Denton & Associates, December 2020

process to make decisions for products, services, capital and pharma that are used across multiple departments," she said. "More importantly, it is a decision structure and process that incorporates CQO [Cost, Quality and Outcomes] – not just price. Value Analysis can be used for product evaluation but Value Analysis is much more. Value Analysis evaluates process, services, equipment and their impact on clinical outcomes. It is a structure that is driven by clinicians, facilitated by Supply Chain and led by a CXO."

Value Analysis represents a transforming methodology to help providers select products and services on the value they bring to the organization and its patients – and not on price, according to Jenny Sydnor, RN, Director, Healthcare Consulting, Advisory Services, Premier Inc.

Jenny Sydnor

"Looking beyond product evaluation and selection, today's value analysis enables enterprise-wide decision making on high-quality supplies, services and equipment by first considering care delivery, safety and outcomes as well as total cost," she noted. "It strives to balance issues related to quality, patient and staff safety, revenue enhancement and reimbursement optimization across the continuum of care."

Keith Lohkamp

Fusing the two makes sense from an operational evolutionary perspective, muses Keith Lohkamp, Senior Director, Industry Strategy, Workday.

"The confusion or equating of the two terms is certainly understandable, particularly as organizations continue to mature their value analysis processes," Lohkamp said. "For many organizations, the initial driver for setting up value analysis is to expand on the product evaluation process by coordinating more inputs from more teams and including evaluation of the impacts on how care is delivered. We're starting to see organizations look to tools like Workday Strategic Sourcing to formalize intake processes to prioritize value analysis projects and keep stakeholders involved. This allows a direct connection to subsequent sourcing and contracting activities needed to execute on committee recommendations and track results."

Power among people

Sydnor insists that successful value analysis programs require strong relationships and ongoing collaboration among multidisciplinary teams that incorporate the engagement and support of executive leadership as well as collaboration with suppliers.

"Robust and contemporary value analysis programs focus on the intersection of cost, quality, safety, outcomes and patient experience," she continued. "Alongside these goals, the scope of value analysis moves far beyond that of product evaluation — requiring a strong people element and coordinated effort across provider departments, service lines and vendor partners."

Value analysis is all about relationships across providers, clinicians and supporting departments all aligned with the strategic vision of the organization and its providers, according to Deborah Roy, Principal, Vizient.

Deborah Roy

"A solid clinically integrated value analysis process empowers providers to work on initiatives that are most important to their patient care," Roy indicated. "That effort includes a review of variation in practice, which gives providers a burning platform for change. This results in measuring the total cost of care across departments and into the post-acute space. Organizations need to structure what works best for their culture, establish executive guidance, communication methods and an alignment strategy. They must also share success stories and develop a widespread education plan that becomes a standard part of daily work activities for all staff."

Marc Phillips, Senior Vice President, Corporate Sales, Medline Industries, embraces Clinical Value Analysis as multiple teams promoting systematic change based on areas of care or service line.

Marc Phillips

"This allows subject matter experts within particular areas to have a refined approach and build strong relationships with critical physicians and clinicians," Phillips said. "This approach engages clinical stakeholders and leads to conversion and changes that sustain value over time. As a result, it can also develop greater trust in Supply Chain leadership to make the tactical decisions that are in the best interest of the health system."

Depth and maturity

Fred Crans, a veteran healthcare supply chain executive with extensive experience in hospitals, healthcare systems, group purchasing organizations and consulting/service firms, delineates the terms with surgical aplomb, dissecting title from function.

Fred Crans

"Value Analysis is process-driven. Product Evaluation is acceptance and price-driven," summarized Crans, Business Development Executive – Healthcare, St. Onge Co. "One focuses on the best way to approach a situation while the other focuses on the best way to do things the same way we are doing them now.

"The challenge is to define and enact the process in a real-time manner so that it

becomes what the title implies, i.e., analyzing the 'value' of doing something – and 'value' includes more measurements than simple price. The Association of Healthcare Value Analysis Professionals (AHVAP) has extremely clear-cut definitions and guidelines as to what constitutes a legitimate Value Analysis operation. The key is to have a title mean something. You can't just take down the Standardization Committee sign and replace it with one that says, 'Value Analysis Committee' and have a legitimate VA function any more than you can take down the 'Materials Management' sign, replace it with one that says 'Supply Chain' and have a functional supply chain operation."

Supply Chain executives, leaders and professionals should look at the five-year-old Value Analysis Maturity Curve, which was published in 2015 through a collaboration between the AHVAP and the Strategic Market Initiative (SMI), insists value management expert Barbara Strain, CVAHP, Managing Principal, Barbara Strain Consulting LLC. *(See Figure, below.)*

Barbara Strain

"For so long the notion of basic patient care products evaluation was synonymous with value analysis with a focus on price, along with the vestiges of product standardization to eliminate variation," Strain added.

During several live and virtual workshops and panel discussions the past 18 months, Strain recalls sharing the maturity curve and asking participants to place themselves along the curve. She found that roughly 75 percent of provider value analysis participants ranked themselves between Levels 3 and 4, while five percent selected Level 1 and seven percent Level 5. Suppliers, who based their positioning on their perceived readiness to address customers, posted similar results within a few percentage points, according to Strain.

Enter COVID-19.

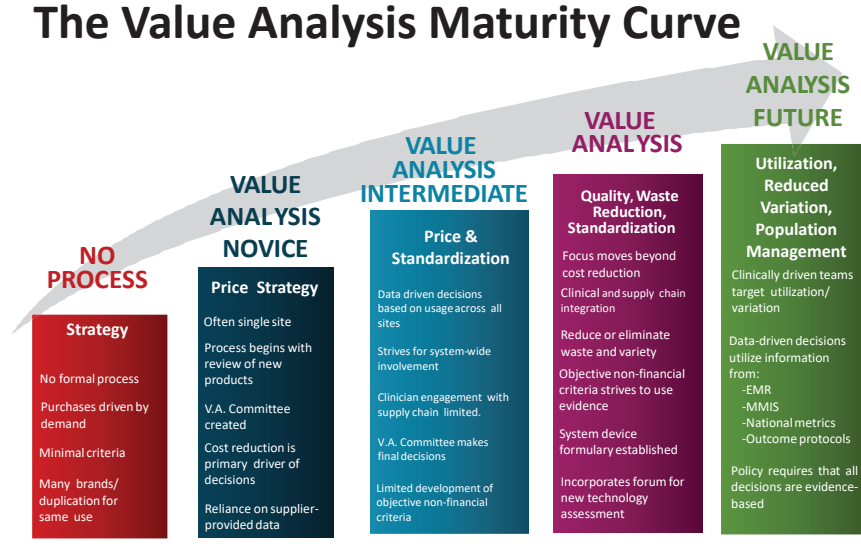
Prior to 2020, healthcare value analysis was evolving to the point that providers recognized and understood it was not a person, a team or a program, Strain cites. "Value Analysis is a profession based on proven processes that move organizations from one level of maturity to the other all the while improving quality of care at reasonable costs," she added.

"In 2020, however, healthcare leaders, physicians and clinicians quickly became aware of the value [that] value analysis professionals play," Strain continued.

AHVAP hosted a podcast series from mid-April through mid-July 2020. The content ranged from vetting supplies and suppliers to lab tests, communication, collaboration and community outreach. The subject matter experts in the last few podcasts were value analysis professionals from various sized provider organizations that were asked, "What is value analysis like today?" Strain recalls the participants expressing a contextual understanding of the process against the backdrop of the pandemic.

Strain also envisions a "new value analysis" emerging from 2020 that will spend time differently on the medical/surgical supply process and more time on "need-to-have" initiatives that will move organizations to population health and quadruple aim maturity levels.

The Value Analysis Maturity Curve



Created by AHVAP & SMI task force published in 2015

Alternate states

The Resource Group, which provides a variety of supply chain and support services to the members of Ascension Health, developed their own alternative to what they term the "traditional" Value Analysis process, stripping out the "emotional" attachments, according to Scott Caldwell, TRG President and CEO.

Scott Caldwell

"The organizations that we serve asked us to innovate a means by which products and services could be evaluated objectively, without the emotional attachment, to brands and brand representatives oftentimes present throughout the process," Caldwell stated. "Our User-Directed Strategic Sourcing process begins with Decision Teams and Affinity Groups comprising clinicians and end users who evaluate products and services based on attributes. By defining the attributes required, we identify a wider range of clinically acceptable products that are well established in the market but may not be top of mind for clinicians who may be considering a singular brand with which they may be comfortable and familiar. While this may seem similar to Value Analysis, evaluation of attributes of a product rather than the evaluation of a product as a whole has proven highly effective. The process has resulted in the establishment of a comprehensive and highly accepted contract portfolio that has delivered $1.2 billion in annual savings to our participants."

Robert T. Yokl, Veteran supply chain executive-turned- value-analysis-consultant, and Founder, CEO and Chief Value Strategist, SVAH Solutions, embraces more of a purist philosophy of value analysis, hearkening back to the late 1940s and what emerged at General Electric Co.

Robert T. Yokl

"When asked about this topic, I always like to say that value analysis is one of the most misunderstood terms in supply chain management," Yokl noted. "By definition, value analysis is the study of function and the search for lower cost alternatives as described by Larry Miles, 'the Father of Value Analysis.' Unfortunately, this definition has been lost in translation in healthcare. Instead, in healthcare value analysis is just another name for 'product evaluation,' thereby misinterpreting the true purpose of value analysis, which is to reinvent the way we specify, analyze, and classify our products, services and technologies. I suggest that VA practitioners read Larry Miles' book, 'Techniques of Value Analysis and Engineering' if they want to gain the full benefits of this powerful cost and quality management technique." HPN

Page 58

Value Analysis: Deserving a seat at the table?

Looking back on the healthcare industry's response in 2020 to the global pandemic, should providers carve out Value Analysis for its own place on the organizational chart – particularly to address COVID-19 during 2021? If so, where? And to whom would such a newly designated department report? Clinical? Financial? Operational? Reviews remain mixed among supply chain and value analysis experts, but themes emerge.

Dan Hermes, Senior Solution Advisor, Lumere, a GHX company

"I would have Value Analysis report into both Clinical and Finance leadership. If it reports into one or the other, there is a misconception that supply chain decision making is colored by the priorities of that given department's leadership.

"Value Analysis must retain its neutrality and act as a bipartisan player within a hospital or healthcare system as it's responsible for looking after both clinical and financial outcomes. The benefit of Value Analysis sitting in between these departments is quicker consensus building and greater engagement from Clinical and Financial departments in the Value Analysis process, which is critical for achieving optimal patient outcomes.

"COVID-19 made it abundantly clear that these departments cannot function in siloes. To achieve greater resiliency requires an integrated supply chain where evidence-based data is used to make clinical and financial decisions. This collaboration will help improve the stewardship of available resources and enable greater agility and flexibility. This is especially critical during a crisis."

Marc Phillips, Senior Vice President, Corporate Sales, Medline Industries

"I would ideally see this group reporting to Operations with a dotted line to Clinical Affairs. There needs to be a focus on total cost and impact to the organization, not just the transactional cost. Operations provides greater visibility into considerations such as total cost of ownership, utilization, SKU impact/rationalization, contingency planning and finally, resiliency. If this approach is coupled with clinical outcomes, you begin impacting the overall budget through reduced acquisition costs, labor and staffing improvements, and patient outcomes."

Jenny Sydnor, RN, Director, Healthcare Consulting, Advisory Services, Premier Inc.

"Value Analysis should be housed under Operations, and specifically, Supply Chain to support a strong understanding of contract penetration and process, total cost of ownership and supplier/GPO partnerships. But again, [Value Analysis Teams] should be multidisciplinary with stakeholders from a variety of departments and service lines.

"For example, strong clinical leadership is needed for each VAT as clinical integration promises advancement toward highly reliable care and cohesive operations, and accounts for the vital perspectives of staff who are directly caring for patients. Providers should also look to include product end users from various disciplines including Surgical Services, Pharmacy, Nursing and Facilities/Environmental Services as well as subject matter experts from Infection Control, Sterile Reprocessing, Risk Management, Finance, Legal and Regulatory/ Compliance.

"A unified structure – in which the goals of supply chain, clinical and finance leaders are inextricably linked via targeted clinical initiatives and tied to the budget – is the best way to achieve meaningful results and ensure long-term success."

Doug Heywood, Managing Partner, Ron Denton & Associates LLC

"Historically, Value Analysis started in Supply Chain as a replacement to the 'product evaluation' process. However, Value Analysis's scope has evolved from a scope of 10 percent of an operating expense budget to cover more than 45 percent of a hospital's overall operating expense budget. In addition, it has expanded from just measuring savings to measuring savings, quality and outcomes. It encompasses supplies, purchased services, pharmacy and capital expenses and spans multiple departments, facilities and physicians/stakeholders. There are Value Analysis initiatives that are clinically focused, others that are operationally focused and others that span multiple functions and departments (e.g., clinical, financial, IT, etc.). Value Analysis requires collaboration and executive leadership across multiple departments and executive levels – including the Board."

Angie Haggard, COO, Ron Denton & Associates LLC

"Since Value Analysis crosses multiple departments and engages service-line leads, executive stakeholders, etc., it should be part of administration and led by a CXO level (e.g., Chief Supply Chain Officer or CFO). A CXO has the recognition with the Board and other CXOs to transform and execute the needed strategy for Value Analysis success. An organization's strategy and goals may or may not impact Value Analysis. Value Analysis effectiveness will determine an organization's timeliness to achieve its financial and clinical goals."

Fred Crans, Business Development Executive – Healthcare, St. Onge Co.

"The Value Analysis approach applies to virtually every aspect of an organization's operations and templates and methodologies should be devised and implemented that provide a consistent rigor and methodology in the decision-making process. I [recently] participated in an Executive Forum led by Brent Petty. He highlighted an approach titled, 'SBAR (Situation, Background, Assessment, Recommendation),' which he had used at several places where he worked. The idea is to bring structure to the decision-making process. SBAR can be used everywhere, including the clinical Value Analysis process.

"As to where that clinical VA process should be housed, I would pick Clinical Affairs, and would include input from Finance, Operations, Supply Chain and other departments as needed. One of the impacts of the post-COVID world will be the need to create alternative strategies for the acquisition of mission-critical items such as PPE. Contingency plans will need to be developed – what is known in the auto industry as 'A plan for every part.' There won't be a need for a plan for EVERY part, but there will need to be plans developed for key critical ones, and since most of these items will be clinical in nature, Clinical Affairs seems to be the appropriate place from which the process should be managed."

Barbara Strain, CVAHP, Managing Principal, Barbara Strain Consulting LLC

"'Difficult roads often lead to beautiful destinations...' – Zig Ziglar

"Besides being used by Davey Martinez when the Washington Nationals won the 2019 World Series, this quote has been cited many times in 2020. Of the many learnings in these unprecedented times has been the need, or should I say the obvious conclusion, that the closer value analysis and supply chain are to a seat at the table with key organizational leaders the more well-informed and bespoke the outcomes will be.

"Value Analysis should be no further than three levels from their organization's chief executive. Reporting within a department who reports through two to three other departments may filter out and dilute key messages, adding delayed time to execute decisions that may mean the difference between saving lives, understanding what is available to change the course of action and advising on processes or practices that might be able to be performed now while waiting for more ideal conditions.

"The notion of where value analysis should sit in the line of reporting really can be addressed by looking back to the value analysis maturity curve. (See Figure 2.) Organizations that have embraced value analysis processes do best through an executive steering or leadership advisor committee-level 4-5. Value analysis has specific processes, timelines and means to deliver the clinical-based evidence, quality outcomes and financial impact reports to drive organizational decision making to reach their full value potential.

"Based on personal experience, about five-to-seven times additional value was derived through a leadership-driven structure than through a middle management organic process. That same experience was enhanced through the establishment of a separate value analysis department that reported to the Chief Financial Officer. People often see these approaches as the difficult roads and take the directions of their cultural GPS too literally and stray from their goal. Others know that the rest of the quote is, 'the best is yet to come.'"

Robert T. Yokl, Founder & CEO, SVAH Solutions

"Based on the classic value analysis model developed at General Electric in the 1940s, value analysis is an extension of procurement; thereby, [it] falls under the responsibility of Supply Chain Management. Interesting enough, it is observation that 97 percent of healthcare organizations have followed the same trend."

Deborah Roy, Principal, Vizient

"Creating balance across all clinical areas involves a high degree of input from the physician population. As value analysis grows in organizations, it should migrate to a more strategic clinically integrated department with a focus that includes quality along with associated pricing. Having value analysis sit under the Chief Medical Officer allows that visibility. Under the leadership of a CMO, opportunities arise to consider value-based purchasing and key performance indicators (KPIs) — strategic imperatives in organizations focusing on HCAHPS [CMS' Hospital Consumer Assessment of Healthcare Providers and Systems], HACs [CMS' Hospital-Acquired Conditions], safety, etc. — and to provide a more valuable view of total cost of care. As we work through the pandemic, organizations are challenged to find a more robust and efficient method of clinical decision making and are better able to do so with guidance at the CMO level. Under this direction, investment strategies for providers can be optimized as focus moves towards the delivery of services at home and other ambulatory opportunities."

HPN Virtual Forum

First of four:

Disinfecting Your Facility - Tools of the Trade

March 16, 2021

Join *HPN* Editor Rick Dana Barlow as he discusses the ins and outs of Surface Decontamination and the latest Disinfection tools.

Industry leaders will be invited to weigh in on all aspects of this important topic.

Coming soon!

Watch your inbox for registration instructions.

Registered participants will be able to watch live and/or on demand.

WORTH REPEATING

"Supply Chain executives, leaders and professionals should look at the five-year-old Value Analysis Maturity Curve, which was published in 2015 through a collaboration between the AHVAP and the Strategic Market Initiative (SMI). For so long the notion of basic patient care products evaluation was synonymous with value analysis with a focus on price, along with the vestiges of product standardization to eliminate variation."

Barbara Strain, CVAHP, Managing Principal, Barbara Strain Consulting LLC

"Given the pandemic-driven strain many facilities faced in 2020, EVS and IP staff continue to play a critical role in maintaining a high hygiene standard, so care providers can work effectively and know that stringent cleaning and disinfecting efforts are taking place to help prevent the spread of infection or cross contamination. In addition to hand hygiene, cleaning and disinfecting environmental surfaces, such as bedrails and door handles, is a fundamental part of hygiene protocols."

Deborah Chung, Regional Marketing Manager, Essity Professional Hygiene, North America, part of Tork

"Although most people understand the impact of the pandemic regarding the reuse of supplies, in the future the Infection Preventionists and other regulatory experts will now be faced with changing back to the practices before the pandemic. This definitely will be challenging, and perhaps research should be performed to evaluate if the change in practices related to certain products should remain even after the pandemic."

Janet Pate, JD, MHA, RN, Nurse Consultant and Educator, Ruhof Corp

"Scheduling cases is more difficult now because so many contingencies are subject to a quick change, whether from government guidelines, hospital capacity, testing requirements, or patient issues. COVID-induced constraints and an increased emphasis on sterility and cleanliness are all causing breakdowns in scheduling, flow, and turnover, increasing the hurdles for the OR desk."

Shawn Sefton, MBA, BSN, RN, VP of Client Operations and CNO, Hospital IQ

PEOPLE & OPINIONS

Supply Chain rotation critical for hospital administrative fellowships

by Zach Tudor

There are hundreds of administrative fellowship programs across the country, spanning healthcare organizations of all sizes. These programs allow fellows to rotate through administrative departments to gain a comprehensive understanding of organizational, operational, and financial strategies. Spending time with the various departments demonstrates the holistic approach that is needed to successfully run a healthcare organization.

Historically, these fellowships have not included formal exposure to the organization's supply chain. However, COVID-19 has illustrated the value and complexity of the healthcare supply chain. The pandemic has further demonstrated the significant impact of the Supply Chain department within hospital and healthcare systems, making it a great rotation opportunity for an administrative fellow.

Supply Chain's strategic importance

The functions of a supply chain department play a critical role in the day-to-day operations of a healthcare organization. At its core, Supply Chain is responsible for delivering products and services on time and at a competitive cost. The processes and systems impact clinical workflow, the supplies procured influence patient care and the associated costs affect the financial position of the organization. All of these operational considerations help an administrative fellow understand the many inputs that derive from the supply chain department.

There are many intricate responsibilities of the Supply Chain department worth exploring during a fellowship rotation. These activities are important in a healthcare organization's strategic scheme. These distinct functions – sourcing, informatics, and operations – illustrate the interconnected nature of the entire department.

Integrated structure and cross-functional collaboration

Organizational structure and staffing model: The labor required to manage the inputs and outputs of a healthcare system's supply chain is considerable. An effective organizational structure and staffing model is critical to the success of the department.

Depicting the organizational design at the onset of the rotation allows an administrative fellow to visualize and understand how the various supply chain functions interoperate. At HonorHealth, the Supply Chain department is performed as a shared service by the network of facilities. This means that staff and resources are used flexibly to meet the anticipated and unanticipated needs of daily operations. The HonorHealth Supply Chain Shared Services model is unique in that it incorporates HTM Biomedical Engineering and Facilities Management within its organizational structure. This strategic alignment empowers greater business intelligence and evidence-based value creation. Another benefit of this model is the standardization of best practices from one facility to the next. Ultimately, this model develops employees who are cross-functional and collaborative, a seemingly necessary attribute in today's unpredictable healthcare market. In an era of the COVID-19 pandemic, this model proves extremely valuable.

From my experience, the most integral aspect of the supply chain department is the collaborative relationship with clinical staff. Whether it's commodities, clinical preference or physician preference items, the appropriate clinical resources need to be engaged during the sourcing, procuring, and distributing processes. The value analysis team represents the cross-functional committee that compares the clinical value of a product and validates end user acceptance of the vendor and product offering. Pairing the clinical insight with evidence-

based value develops a decision-making formulary and implementation framework for supplies, services and equipment.

Contracting and sourcing: Getting exposure to an organization's contracting and sourcing strategy is a foundational component of a supply chain rotation. Supply expenses can be as high as 30 percent of an organization's operating budget. With this procurement volume comes hundreds of vendors and thousands of contracts. Executing this effort internally is incredibly involved and expensive. Because of this, many healthcare systems nationwide use group purchasing organizations (GPOs) for some aspect of their purchasing strategy.

For an administrative fellow, understanding the purpose of a GPO and how your organization leverages their services is essential, especially given the financial implications of the relationship. A GPO has the luxury of negotiating vendor terms on behalf of multiple buyers. Leveraging the collective demand results in contract negotiations that have more favorable pricing, length of term and utilization commitments. After the vendor contracts are established and the products have been sourced, the next steps are to define the item attributes and input the product information.

Informatics: The informatics pillar is another fundamental element of the supply chain rotation. At a macro level, controlling the functionality of the enterprise resource planning software and the integration with the other systems is necessary for clinical workflow. Having a team dedicated to analyzing and implementing system updates will help end users utilize the information strategically. At a more granular level, this pillar is responsible for maintaining a robust and accurate item master. Storing relevant product information enables products to be tracked throughout the product life cycle. All of these activities lead to data integrity in the form of an accurate, complete and consistent enterprise resource planning system, which can be leveraged by other supply chain associates.

Operations and logistics: The final pillar of a supply chain rotation is the operations branch. The primary functions of this group are distribution, inventory management and clinical support services. Takeaways for a fellow in this part of the rotation are internal and external logistics strategies, inventory optimization techniques and the defined aspects of the ordering process. In the clinical logistics setting, the operations' functions close the loop on the purchasing process by defining who does the reordering, at what frequency, what they need to order and how much. Whereas the external logistics of the operations' activities are an opportunity for healthcare networks to partner with vendors to execute aspects of this function.

Photo credit: md3d | stock.adobe.com

Programs reflect critical pillars of performance improvement

There are many benefits of outsourcing the distribution from manufacturers to the hospital, such as quicker delivery times, consolidated shipments, lower space utilization and lower employee utilization to manage manufacturer relationships. Meeting with the primary distributor account manager helps an administrative fellow to further understand the role and requirements of the hospital-distributor relationship.

There are significant costs associated with this department in the form of labor and supplies; these expenses come with cost savings opportunities. HonorHealth has an Operations Excellence and Solutions team that is dedicated to addressing these cost savings opportunities. This team implements initiatives using design thinking, lean six sigma and project management techniques to create value for the clinical and non-clinical staff. A primary example is inventory optimization analysis, which helps departments manage and procure supplies based on historical data, as well as forecasted volume. This careful analysis saves time and money for clinical and administrative staff. Once again, collaborating with the clinical team to create buy-in and sustain comfortability is a key lesson for the fellow.

COVID-19 — a clarion call

As the COVID-19 pandemic has highlighted, the healthcare supply chain is complex and interdependent. For healthcare organizations, a clinically integrated model and strategy is critical when sourcing and distributing supplies. As an administrative fellow, getting exposure to the roles and responsibilities of the various supply chain functions will help build a comprehensive understanding of operations. I want to thank the HonorHealth Supply Chain Shared Services' associates for accommodating my rotation and teaching me so many valuable lessons. This education is a testament to the culture and leadership of the HonorHealth supply chain organization. HPN

Zachary Tudor is an administrative fellow at Phoenix-based HonorHealth, a finalist for the 2020 Supply Chain Department of the Year by Healthcare Purchasing News. Tudor's professional experience spans medical device marketing to industrial engineering and software consulting. He holds a Bachelor's in Supply Chain Management from Purdue University and a Master's in Business Administration from the University of Arizona. His professional mission is to use his cross-functional experience to become an organizational leader that creates value and a culture of collective fulfillment for an organization and its employees

Supply Chain visibility alert: Unseen roadblocks ahead

by Karen Conway, Vice President, Healthcare Value, GHX

When the U.S. Food and Drug Administration (FDA) was promoting the importance of the still unpublished UDI rule, the underlying value proposition was visibility. The rule requires manufacturers to assign unique device identifiers (UDIs) to the label of their products and to mark those products at each packaging level with the UDIs in both human and machine-readable formats. The FDA cautioned that the UDI on labels alone would not do the trick. It is a building block necessary to unambiguously identify products across organizations – both public and private sector – and in technology systems from electronic health records to claims databases. The FDA was also clear that the UDI rule was not a track and trace requirement; rather the UDIs would be a necessary element to make such a system possible for medical devices. While the FDA was focused on its regulatory responsibilities, supply chain professionals were quick to see additional benefits, including improved transactional efficiency, order fulfillment and inventory management.

When the UDI rule was published in 2013, it noted the potential to more effectively 1) identify adverse events and 2) target and manage medical device recalls. That same year, the FDA published an updated version of "Strengthening Our National System for Medical Device Postmarket Surveillance,"[1] which clearly depicted the vision for UDI in electronic health records, claims data, registries and medical device reports, among others. Nearly eight years later, achieving the vision of UDI has been stifled in part due to regulatory delays and the reluctance of both providers and suppliers to do more with UDI than required by regulators. Even more disconcerting, some of those roadblocks exist within the FDA and other government agencies, as outlined in a recent perspective piece[2] in the *Journal of the American Medical Association Internal Medicine*.

UDI in adverse event reporting and recalls

Perhaps most surprising is the lack of consistent use of UDIs for adverse events and recall management, given that both were noted in the Regulatory Impact Analysis published with the final rule. Less than 2 percent of the more than one million adverse event reports made in 2019 contained UDIs, while only one-tenth of medical device recalls include UDIs. The problem, in part, is that the UDI is just one of many identifiers the FDA will accept for recalls. With adverse events, the story is even stranger. The JAMA viewpoint piece says the Freedom of Information Act office at the FDA often redacts the UDI if it believes it could jeopardize protected patient information. Unfortunately, that risk could be addressed by redacting only the production identifier portion of the UDI, e.g., when it contains a serial number, as opposed to the full UDI, which includes the more generic device identifier.

UDI in claims

For years, the FDA has relied on national drug codes (NDC) in claims forms to identify and conduct post market surveillance on specific drugs used in patient care. The FDA had envisioned the UDI would serve that purpose for medical devices; without it, claims data only says a patient received a type of device, e.g., a coronary stent, but not the specific brand, model or serial number of the device. In 2017, after considerable debate, the standards organization that administers claims forms agreed to add a field for UDIs for implantable devices; three years later, the field is not yet in place, and the Centers for Medicare and Medicaid Services (CMS) would still have to mandate its consistent use.

UDI in electronic health records

Both CMS and the Office of the National Coordinator for Health IT require that EHRs be able to capture and store UDIs for devices implanted in patients in electronic patient records and be able to share that data. Many health systems still struggle with data management, point of use capture, and interoperability that would provide for greater visibility into device performance.

As mentioned earlier, UDI is a building block, but it takes a village (including hospitals, suppliers, payers, technology companies, and regulators, among others) to adopt and use the UDIs to achieve the value intended by the regulation.

UDI in COVID-19 response

The supply shortages experienced during COVID-19 may be the impetus to get UDI back on track. While UDIs could not have prevented the shortages resulting from the simultaneous unprecedented and extended global increase in demand and the constraint on global supply production and movement, the identifiers could have made it easier to optimize availability of supplies where they are needed most.

- UDI could be used by hospitals for better visibility into current inventory levels, utilization (burn) rates and anticipated needs based on patient volumes.
- Hospitals could use UDIs to share demand data with suppliers to help with more need driven allocation.
- The Strategic National Stockpile and other organizations managing safety stock could use UDIs, which include expiry dates, to rotate stock before it becomes unusable.
- Suppliers could let hospitals know about backorders or partial or delayed shipments using UDIs in electronic purchase order acknowledgements and advanced ship notices, allowing hospitals more time to take alternative action.
- Use of UDIs in conjunction with classification schemas and/or clinically relevant attributes for products can help hospitals identify alternative vendors or supplies.
- Global adoption of UDI could help manage products being used under emergency use authorizations to help minimize counterfeiting and to track potential adverse events or recalls.

For those of us who have been on the UDI journey, the road can seem impassable. On the other hand, if we think about why we headed in this direction in the first place, the investments we

have made to date, and the benefits for a wide range of stakeholders, this is not the time to stop in our tracks or turn back now. HPN

Refrences

1. https://www.fda.gov/files/about%20fda/published/Strengthening-Our-National-System-for-Medical-Device-Postmarket-Surveillance.pdf

2. Kinard M, McGiffert L. Medical Device Tracking—How It Is and How It Should Be. JAMA Intern Med. Published online December 16, 2020. doi:10.1001/jamainternmed.2020.7797

ADVERTISER INDEX

This index is provided as a service. The publisher does not assume liability for errors or omissions.

If you are not getting the *HPN*

Daily Update Newsletter

you are not getting all of the news!

Subscribe here:
www.hpnonline.com/subscribe

Next time you see a wheelchair, think about how many hands have touched its surfaces.

HUBSCRUB
A great Infection Prevention system.

Watch it Work
HUBSCRUB.COM

HEALTHCARE PURCHASING NEWS
CLINICAL INTELLIGENCE FOR SUPPLY CHAIN LEADERSHIP

How to contact us

Kristine S. Russell, Publisher, Executive Editor
Healthcare Purchasing News
2477 Stickney Point Road, Suite 315B
Sarasota, FL 34231
Phone: (941) 259-0854
Fax: (941) 927-9588
Email: *krussell@hpnonline.com*

SEND EDITORIAL INQUIRIES & MATERIALS TO

Ebony Smith, Managing Editor
Healthcare Purchasing News
2477 Stickney Point Road, Suite 315B
Sarasota, FL 34231
Phone: (941) 259-0839
Fax: (941) 927-9588
Email: *esmith@hpnonline.com*

SEND ADVERTISING MATERIALS TO

Tiffany Coffman
Healthcare Purchasing News
2477 Stickney Point Road, Suite 315B
Sarasota, FL 34231
Phone: (941) 259-0842
Fax: (941) 927-9588
Email: *tcoffman@hpnonline.com*

EAST COAST SALES

Blake Holton
Email: *bholton@hpnonline.com*
Michelle Holton
Email: *mholton@hpnonline.com*
724 Long Lake Drive
Oviedo, FL 32765
Phone: (407) 971-6286
Fax: (407) 971-8598

MIDWEST SALES

Randy Knotts
8084 E Michelle Dr
Scottsdale, AZ 85255
Phone: (312) 933-4700
Fax: (941) 927-9588
Email: *rknotts@hpnonline.com*

WEST COAST SALES

Blake Holton
Email: *bholton@hpnonline.com*
Michelle Holton
Email: *mholton@hpnonline.com*
724 Long Lake Drive
Oviedo, FL 32765
Phone: (407) 971-6286
Fax: (407) 971-8598

WEB/CLASSIFIED/RECRUITMENT ADS

Tiffany Coffman
Healthcare Purchasing News
2477 Stickney Point Road, Suite 315B
Sarasota, FL 34231
Phone: (941) 259-0842
Fax: (941) 927-9588
Email: *tcoffman@hpnonline.com*

SUBSCRIPTIONS

Please visit our website or send all subscription requests to:
Healthcare Purchasing News
2477 Stickney Point Road, Suite 315B
Sarasota, FL 34231
Phone: (941) 927-9345 Fax: (941) 927-9588
Email: *hpn-subscriptions@endeavorb2b.com*
Visit *www.hpnonline.com/subscribe*

Surveying post-pandemic landscape for Supply Chain leaders

by Fred W. Crans

Sometime in the spring or early summer of 2021, the dust will begin to clear as the mass vaccination of Americans starts to take effect and the number of new cases and deaths ebb and wane. As with the conclusion of every other war, there will be a momentary pause where the participants celebrate the end of hostilities and mourn their losses before taking a long, hard look at the landscape with which they have been left.

That's what will be happening to all American businesses, and most especially to healthcare organizations (HCOs). While many small businesses, such as restaurants and bars, may have faced, survived or succumbed to the ravages of the pandemic, HCOs will find themselves having to deal with the realities that were uncovered during the crisis.

And what were those realities? Here are some thoughts:

HCOs will face daunting financial challenges. By the time it finally abates, the pandemic will have gutted the finances of most HCOs. COVID-19 caused most HCOs to suspend their bread-and-butter money-makers – the 10 percent of the procedures that often produce 60 to 70 percent of revenues. Add to that the increased demand for personal protective equipment (PPE) – often 20 times the normal demand, and the accompanying rapacious prices paid for these items (also as much as 10 to 20 times) – and you have a situation where your costs on key items have gone up as much as 400 percent. Finally, the reimbursement rate for COVID-related cases is not as lucrative as those of the elective procedures the crisis caused to be cancelled. Once the dust settles, HCOs will have to rebuild their financial base. Some won't make it.

The "old ways" of doing business will have to be reviewed. Inevitably, wars bring with them operational and social change. Nothing is ever the same after a war. So too will it be with healthcare. The old ways of doing business will give way to new ones. The old challenges will be magnified. The organizations that act quickly and thoughtfully will seize the day. Strategies such as just-in-time (JIT) and low unit of measure (LUM) have proven incapable of answering the challenges associated with a pandemic. New ways of doing business will necessarily be instituted in order to survive.

There will be a continuing transition away from real estate-based healthcare delivery. Just as WWII introduced penicillin and sulfa drugs to the caregiving toolkit, the pandemic has introduced the rise of telemedicine. The pandemic has accelerated a trend that was already in motion – the trend away from the monolithic "hospital" as the central point of a healthcare system. Decentralization will place additional strain on inter- and intramural logistics – creating challenges the Supply Chain leaders will have to solve.

HCO closings, mergers and acquisitions will continue. The pandemic already has caused several hospitals to close. The move toward more and more acquisitions of small change to integrated delivery networks (IDNs) by giant ones will not only continue; it will accelerate. Just as the number of major group purchasing organizations (GPOs), which at one time numbered seven, by and large, has shrunk to three, the number of IDNs will continue to shrink. The mega-IDNs will destroy the smaller ones.

Every HCO will have to bear responsibility for the operation of its supply chain. Traditionally, HCOs have outsourced two of the major functions of the supply chain – contracting (at least for commodities) to the GPOs and distribution and logistics (as well as inventory management via LUM) to the distributors. If the pandemic has revealed nothing else, it is that every HCO must take responsibility for the entirety of the supply chain operation. That means that each IDN will have to up its game in areas where it has traditionally forfeited responsibility. It will have to put better players on the field.

There only will be a brief moment of opportunity for Supply Chain leaders. It goes without saying that the conflation of the number of IDNs will mean fewer and fewer top-end jobs for Supply Chain leaders. As soon as the dust clears, those same leaders who so recently were praised for their ingenuity and hard work will be on the clock. Their C-suites will immediately shift focus from trying to secure supplies and treat the victims of the pandemic to keeping their own heads above water. The world of activity above the pay grades of the Supply Chain will push the supply chain's influence back to where it was before the war (the pandemic). I write this (in December 2020) not to frighten Supply Chain leaders, but to give them a heads-up. For the moment, you have influence. How well you use it could well determine your future career.

If I were a current Supply Chain leader, I would pay attention to the following things, because by doing so, I might be able to salvage my job and build a successful future:

- Learn everything I can about how successful supply chains work, both within and outside of healthcare.
- Explore the possibilities of regional collaborations with like-sized IDNs.
- Give deep thought to the role of the GPOs and how I need to interact with them.
- Explore alternative approaches to distribution and inventory management.
- Become well-versed in the demands associated with telemedicine.
- Encourage the hiring of an objective cross-industry-versed third party to analyze my supply chain operation and advise me on developing an action plan. Finally, update my CV/résumé. HPN

Fred W. Crans currently serves as Healthcare Business Development Executive for St. Onge Co. He is a veteran industry observer and frequent HPN contributor with decades of experience as a hospital supply chain leader within hospitals, IDNs and GPOs. In 2020, Crans was inducted into Bellwether League Foundation's Hall of Fame for Healthcare Supply Chain Leadership. Crans can be reached at fcrans@stonge.com and at fcrans@wowway.com.

ADHERENCE HAS NEVER BEEN MORE IMPORTANT.

Reduce Pain & Fear

Reduce Fainting

Improve Satisfaction

Buzzy® Proven Effective For:

- *Vaccinations*
- *Flu Clinics*
- *Lab Draws*
- *IV Starts*

50+ Clinical Studies

"Buzzy reduced pain experienced by adults undergoing annual influenza vaccination...and is especially effective in those with high levels of anxiety."

Redfern et al Pain Manag Nurs 2019 Apr;20(2):164-169.

Each healthcare Buzzy® guaranteed for 400 uses.
Approved by Infection Control in 5000+ hospitals & clinics.

Buzzy®
« DRUG FREE PAIN RELIEF »

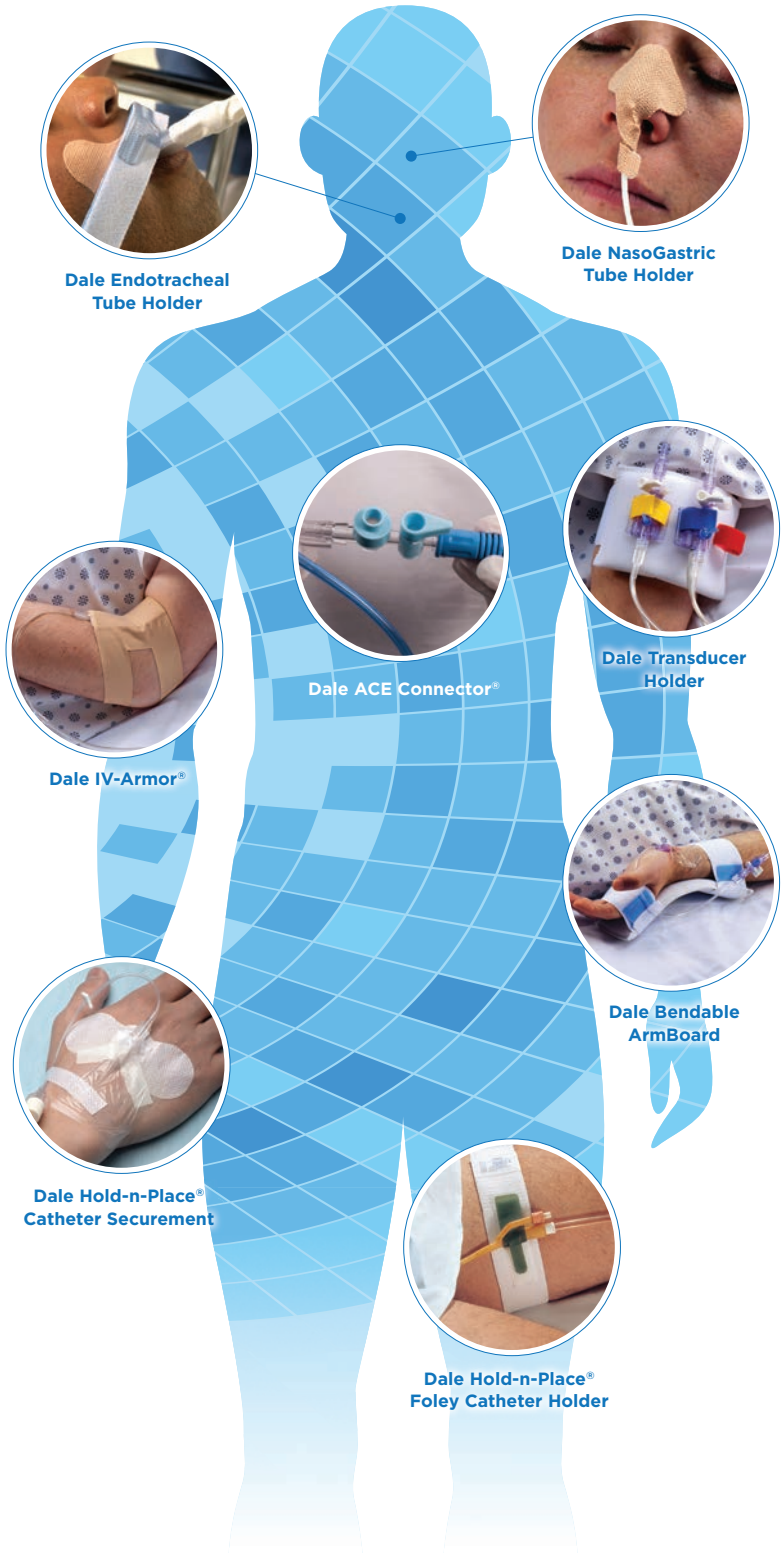
Learn about our pain solutions at
PainCareLabs.com
orders@paincarelabs.com
877-805-2899

PainCareLabs™
DRUG FREE PAIN SOLUTIONS

Security You Can Count on When Your Patients Need It Most

ALWAYS FROM DALE

COVID-19 Product Reminder



During these unprecedented times, you don't want to worry about whether the medical products you use will perform as expected. With Dale, you don't have to. Dale products have been providing security without compromise for more than 50 years.

Dale offers a range of products to help you provide the best care for your COVID-19 patients.

Our enteral products include the **Dale NasoGastric Tube Holder** and **Dale ACE Connector®** to keep a 100% closed system for feeding.

Our vascular products include **Dale Bendable ArmBoards, Dale Transducer Holder, Dale Hold-n-Place® IV Securements and IV-ARMOR®** — all for uncompromising protection and comfort.

Finally, our low-profile **Dale Endotracheal Tube Holders** secure the ETT in supine, prone and lateral positioning.

Visit www.dalemed.com for more information on each product and to request evaluation samples.

Dale®
Always Better

©2020, Dale Medical Products, Inc. All rights reserved. AD-100 Rev A