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News We're Watching: New Cybersecurity Standard; CMS Prodded On TCET; Olympus Scopes Recalled

by Brian Bossetta

This week, NIST published a new version of its international cybersecurity standard; SeaStar Medical's kidney device got an HDE; and the FDA announced safety issues for DT MedTech LLC, operating room tables, and GE incubators.

NIST Cybersecurity 2.0 Final Published

The National Institute of Standards and Technology's (NIST) *final version* of its internationally recognized Cybersecurity Framework (CSF) 2.0 has been published, providing advice for shoring up cybersecurity across industries,

The draft, released in August 2023, added the Govern function to NIST's existing Identify, Protect, Detect, Respond and Recover functions. The Govern function introduces ideas about how to implement risk management strategies and properly arm an organization against cybersecurity threats. (Also see "*NIST Cybersecurity Framework 2.0 Expands Guidance's Scope, Introduces 'Govern' Function*" - Medtech Insight, 17 Aug, 2023.)

It also expanded the scope of the guidance beyond critical infrastructures like healthcare organizations, encouraging proactive cybersecurity for all industries.

In response to comments on its draft, NIST also added resources for a variety of audiences to expand understanding of the principles.

"CSF 2.0… is not just about one document. It is about a suite of resources that can be customized and used individually or in combination over time as an organization's cybersecurity needs change and its capabilities evolve," NIST Director Laurie Locascio said in a *release*.

AdvaMed Tells CMS Enough Delay On TCET

In a *letter* to Centers for Medicaid and Medicare Services Administrator Chiquita Brooks-LaSure, medical device advocacy group AdvaMed urged the agency to get a move on Transitional Coverage for Emerging Technologies (TCET).

TCET is a proposed policy to cover breakthrough devices after their designation. It was introduced in June 2023 to replace the repealed Medicare Coverage of Innovative Technology (MCIT) policy.

In November 2023, CMS told industry that a final notice would be published soon. However, as AdvaMed points out, it's been months since that promise, and patients are suffering because of it.

"CMS's delay in finalizing TCET is puzzling. The ability to establish a workable policy to ensure Medicare coverage of safe, effective, FDA-designated and market authorized breakthrough devices should be easily within the agency's grasp," AdvaMed CEO Scott Whitaker said.

He urged the agency to release a final TCET notice "as soon as possible."

SeaStar Medical Wins Humanitarian Device Exemption for Pediatric Acute Kidney Injury

The US FDA has granted a Humanitarian Device Exemption (HDE) Approval Order to *SeaStar Medical* for its device to treat acute kidney injury in pediatric patients.

The Denver-based company's Selective Cytopheretic Device Pediatric (SCD-PED) is intended for use in children weighing 10 kilograms or more with acute kidney injury (AKI) due to sepsis or a septic condition requiring kidney replacement therapy (KRT).

The company said the device, which is the first product in its newly branded Quelimmune portfolio, can now be marketed commercially as a Humanitarian Use Device (HUD).

Eric Schlorff, SeaStar Medical CEO, said the approval provides critically ill children with AKI access to a "much-needed" new therapy, adding only about a half of children in ICUs with AKI requiring continuous kidney replacement therapy, or CKRT, survive.

The Quelimmune pediatric device, according to Schlorff, has been shown to reduce mortality

rates and dialysis dependency in clinical studies, which were the basis for the HDE approval.

The initial commercial launch of Quelimmune for pediatric AKI is expected in the coming weeks, the company said, with a full commercial program to follow.

Canadian Diagnostics Company Completes Successful Phase I Of Breast Cancer Trial

Toronto-based RNA Diagnostics recently announced the results from phase 1 of the BREVITY (Breast Cancer Response Evaluation for Individualized Therapy) clinical trial, which aims to validate the utility of the RNA Disruption Assay (RDA) to predict outcome from pre-operative chemotherapy.

RDA is a molecular diagnostics test that evaluates tumor response to anti-cancer drug therapy with the potential utility to enable timely optimization of cancer treatments.

The phase 1 results demonstrate a strong capability to accurately predict therapy outcomes during treatment, the company said, allowing oncologists to personalize patient care. The trial findings have recently been published in *JNCI Cancer Spectrum*, a peer-reviewed oncology journal.

BREVITY is an International two-phase clinical trial conducted in 55 cancer centers in the US, Canada, Italy, Germany, France, Spain, and Poland. Phase 1 of the trial enrolled 80 patients with stage I, II or III breast cancer who received pre-operative drug treatment followed by surgical removal of the tumor.

Rna Diagnostics said the primary objective of phase 1 was to determine the levels of tumor RNA disruption required to effectively predict patient outcomes of the RDA test.

The phase 1 results demonstrate a strong capability to predict therapy efficacy during treatment, the company said, adding the results are undergoing validation in phase 2, which is currently recruiting 452 patients.

FDA Warns Of Heightened Risk For Ankle Replacement System

In a recent *safety communication*, the US FDA is alerting patients, caregivers, and health care providers about a “higher than expected” risk of device failure with the Hintermann Series H3 Total Ankle Replacement system manufactured by *DT MedTech, LLC*.

The FDA further says is evaluating interim post-approval study (PAS) results for the Hintermann Series H3 TAR system as well as other real-world data.

As of now, the FDA reports that for patients with the ankle replacement system, the results suggest a higher rate of failure; specifically, additional surgery associated with the implanted device compared with the rate in the premarket clinical studies.

For patients considering the system, the FDA advises discussing all available treatment options for painful arthritic ankle joints with their providers and know there are benefits and risks associated with all joint replacement medical devices and procedures.

For patients with the system, the FDA is not recommending surgery for removal so long as there are no new or worsening symptoms. However, patients should contact their providers if they experience any new or worsening pain or swelling, inability to use their ankle or bear weight, grinding or other noise, or weakness around the implanted device.

Class I Recall For Olympus Scopes Due To Burn And Fire Risk

Olympus Corporation has recalled more than 17,000 of its *bronchofiberscopes and bronchovideoscopes* because use of certain accessories involving use of high-frequency therapy while supplying oxygen may lead to fires and burns.

The FDA has labelled the recall class I.

The affected scopes are tubular devices that work with various accessories, such as cameras, lights, and instruments to examine or treat a patient’s airways. These devices are intended to be used for endoscopy and endoscopic surgeries.

Using the affected bronchoscopes, the FDA warned, may cause serious adverse health consequences, including critical burns in a person's airways or lungs, airway bleeding, trouble breathing, apnea, loss of consciousness, or death.

Further, injuries from the devices may lead to prolonged procedures, additional medical care, extended hospitalization, ICU care, and death. Combustion can damage or break parts of the device that may injure or unintentionally remain in the patient and may require endoscopic retrieval or surgical removal.

The FDA said it is aware of seven medical device reports specifically reporting thermal-related injuries associated with these devices, citing injuries from thermal events such as melting and fire.

US FDA Raises Awareness Electrical OR Table Safety

In a recent *letter* to health care providers, the US FDA warns of adverse events associated with electrical operating room tables and provides recommendations for providers to help protect patients. Following the instructions provided in the manufacturer's product manual and user training, the agency says, can reduce potential risks associated with electrical operating room tables.

Along with following the instructions for use, the FDA recommends that providers and facilities ensure that training is provided for staff; check for obstructions before repositioning the electrical operating room table; ensure that manufacturer recommended maintenance intervals and safety checks are followed; do not exceed the maximum load limit indicated by the manufacturer; and report any problems with any operating room tables to the FDA.

Door Latch Glitch Prompts Class I Recall Of Some Wipro GE Healthcare Incubators

Wipro GE Healthcare Private is recalling its *Care Plus and Lullaby incubators* because the bedside panel or porthole may look closed but not be latched properly.

The FDA has identified this as a class I recall, its most serious.

The company initiated the recall, which includes more than 15,000 devices, because the bedside panel or porthole may look closed but may not be properly latched. In addition, if a canopy cover is in place, the bedside panel may look secure because the canopy will hold it in a closed position, without the panel latches being locked correctly.

This could result in the incubator falling due to improper door closure, and other injuries such as skin abrasions, bleeding, fractures, and head trauma.

The FDA reports one serious injury associated with the recall, but no deaths.

Peterson Health Technology Institute Launches Digital Health Collaborative

Digital health research group Peterson Health Technology Institute (PHTI) announced the creation of a Digital Health Collaborative including top health organizations such as the HLTH Foundation, the American Medial Association (AMA) and the Digital Therapeutics Alliance (DTA).

PHTI evaluates digital health technologies and provides impact and financial assessments for patients.