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IN THIS ISSUE

Medical Device Security Is Deeply Lacking, Says New Study

Two-thirds of medical devicemakers and about half of healthcare delivery organizations believe a cyber attack on a medical device built or in use by their organizations is likely to occur during the next year — and only 17 percent of those devicemakers and 15 percent of those healthcare organizations are taking significant steps to prevent such attacks.

That's according to a study conducted by the IT research organization Ponemon Institute for the security company Synopsys.

Focused on North America, the study included responses from about 550 individuals whose roles centered on the security of medical devices. The study's aim was to determine whether devicemakers and healthcare organizations are in alignment about the need to address cybersecurity risks. What it found was that both groups are unprepared for possible cyber attacks via medical devices.

In addition, only one third of those surveyed understood the potential for adverse effects to patients from insecure medical devices.

(See **Safety**, *Page 2)*

Australia Follows FDA and IMDRF Lead in Regulating Software

Australia's Therapeutic Goods Administration will likely follow the FDA's lead and the International Medical Device Regulators Forum's model for regulating software for medical devices.

The TGA is a founding member of the IMDRF, and the agency is participating in the working group tasked with developing and harmonizing approaches to the regulation of standalone medical device software including mobile medical apps. The FDA's draft guidance on SaMD was also prepared by IMDRF.

Just as the TGA first determines what a device's intended purpose is, the same would apply for software that will be regulated as a device, said David Hau, medical office for the TGA's Medical Devices

(See **Software**, *Page 4)*

Safety, *from Page 1*

"I thought we were further along than that," said Mike Ahmadi, global director of critical systems security for Synopsys' Software Integrity Group. "We have gone from zero to 50 percent in this arena, but 50 percent is still an F."

Fear of the FDA is not motivating action, according to Dr. Larry Ponemon, chairman and founder of the Ponemon Institute. The study showed that only 51 percent of devicemakers and 44 percent of healthcare organizations follow current FDA guidance to mitigate or reduce inherent security risks in medical devices.

"Companies told us guidance from the FDA has been around for a while without much enforcement," Ponemon said, "and they say they don't really have the budget to make all their devices safe from attack."

Most are not willing to accept responsibility for the security of medical devices, he said. Almost one-third of devicemakers and healthcare organizations say no one person or function in their organizations is primarily responsible for the security of medical devices.

"There's a lot of finger pointing," said Ponemon. "Manufacturers say, 'We build the product. It's the healthcare group's responsibility to make sure the product is safe.' And the user, the healthcare group, says, 'It's the manufacturer who should do it.' Who decides? Likely regulators, but my guess is that's probably not imminent."

What's it going to take? Something catastrophic, says Ahmadi.

"The FDA is not interested in any new regulations regarding security," he says. "I'm a little concerned that it won't just take a catastrophe, but rather a series of catastrophes or a black swan event — an event that's not merely catastrophic, but so bad that it affects the way we do things for the rest of our lives. Think 9/11, or Pearl Harbor."

Ponemon says his institute plans to dig deeper, researching specific technologies that are potentially poised to do real damage if hacked, including MRIs and robotic arms.

NICE Launches Online Tool to Help Devicemakers Get To Market

The UK's National Institute for Health and Care Excellence is launching a fee-based online tool to help devicemakers get their products to market faster.

The Medtech Early Technical Assessment (META) tool will help companies identify what evidence they already have and what gaps need to be filled to satisfy payers.

NICE says the new tool will help developers of medical devices and diagnostics generate evidence to show their products are clinically relevant and cost effective. The tool will enable companies to better articulate the benefits of their products, and will help companies prepare for a dialog with health technology assessment organizations and payers.

META is aimed primarily at small and medium sized companies, according to Leeza Osipenko, head of NICE Scientific Advice, the institute's fee-based consultancy service. The tool will also benefit larger companies, but the agency's goal is to look for ways to support smaller companies in generating evidence.

NICE recognizes that medical devices and diagnostics is a fast growing and highly competitive field, and healthcare systems are facing financial pressures and are keen to adopt transformative and cost saving technologies.

"We want to help healthcare systems get access to more products that meet such criteria and help companies develop these technologies and relevant evidence to demonstrate their value to patients and payers," Osipenko said.

The META tool can be licensed by partner organizations working with medtech companies, including academic networks, healthcare consortiums and consultancies, both in the UK and internationally.

The META tool will be launched July 3. Interested parties can register here: www.fdanews.com/05-31-17-NiceRegister.

TGA Pulls Philips' IntelliVue MX40 Patient Monitors

Australia's Therapeutic Goods Administration has suspended Philips' license for its IntelliVue MX40 wearable patient monitor after repeated speaker failures.

The monitors are worn by patients in hospitals to record and generate alarms for heart rate, oxygen saturation and other functions. The agency determined that the device could fail in certain situations, particularly when the patient is being moved and the monitor is not connected to the fixed display unit.

The company will not be able to market the product in Australia until the problem is fixed. But the agency recommended not removing monitors that have not been problematic.

The device is manufactured by Philips Medical Systems in the United States and is supplied to Philips Australia and New Zealand.

Philips initiated a Class II recall of the device in May 2014, citing a software design problem. The company reported the issue to be a global problem, affecting more than 42,000 devices.

Philips spokesman Steve Klink told *IDDM* the TGA suspension is unrelated to the software issue and the speaker failure "does not impact any other features or functionalities of the device."

Philips is working closely with the TGA to resolve the issue, he said. The company has already improved the design of the device and the changes "have resulted in very low or non-existent speaker failure reports for newer devices," he said.

More than 2,000 IntelliVue MX40 devices are currently used in Australian hospitals.

Read the TGA notice here: www.tga.gov.au/alert/philips-intellivue-mx40-wearable-patient-monitor.

Software, *from Page 1*

and Product Quality Division. The intended purpose will be determined from statements made by the manufacturer in labeling, instructions, advertising material or other documentation provided with the software, Hau said, during a recent Digital Health Show by the agency.

Hau said the agency will define software as a medical device (SaMD) when the legal manufacturer intends for the software to be used in:

- Diagnosis;
- Prevention;
- Monitoring;
- Treatment, or
- Alleviation of a disease.

Software that is currently regulated by the TGA includes software used in manufacturing, software for maintaining quality management systems, software systems and toolsets, software with a therapeutic purpose such as is used with monitors, defibrillators, pumps and pacemakers. Mobile apps would be considered within this framework.

Medical device software that is intended to control a device, or influence the functions of a device will generally fall into the same classification as that device. However, medical device software intended as an accessory to a medical device is classified separately from the device with which it is used.

Manufacturers of medical device software products will be required to obtain a conformity assessment certificate.

Some industry stakeholders complained that the FDA's draft guidance used some terms that have particular meanings in the EU or that are specific to FDA regulations, and which do not necessarily translate across jurisdictions.

For example, the term "clinical evaluation" is usually associated in the EU with a clinical evaluation report prepared to support marketing of a product — but not in the U.S. Use of the term would cause confusion and could lead other regulatory authorities to implement documentation requirements that are not intended, the group said (*IDDM*, Oct. 16, 2016).

The 21st Century Cures Act exempts five categories of software from regulation as a medical device, including software used for administrative support, maintaining or encouraging a healthy lifestyle, electronic patient records, processing or displaying clinical data or related findings by a healthcare professional, and supporting or providing treatment recommendations.

But it remains unclear how the FDA will apply a provision in the act on clinical decision support software (*IDDM*, Jan. 19).

PEOPLE ON THE MOVE

Gecko Biomedical has appointed **Youssef Biadillah** as chief development officer. Biadillah has 13 years of experience at various product development roles. He was part of the core R&D teams at Baylis Medical in Toronto, Canada (now Kimberly-Clark) and Sadra Medical in Silicon Valley, USA (now Boston Scientific). He then joined Symetis in Switzerland.

Stimwave has hired **Pat Tompkins** as executive vice president of sales. Tompkins was most recently vice president of sales at Interrad Medical for three years. Prior to that role, he was vice president of sales for St. Jude Medical for eight years and at Entero Medics as executive director for a year and a half.

Illumina has named **Mark Van Oene** as chief commercial officer. Van Oene was previously Illumina's senior vice president of the Americas region and was named interim chief commercial officer in late 2016. He joined the company in 2006 as regional account manager for Canada.

DJO Global has appointed **Jeffery McCaulley** as global president of its subsidiary, **DJO Surgical**. McCaulley was most recently president and CEO of Smiths Medical. Prior to that role, he served as president of the global reconstructive division at Zimmer. Previously, he was president and CEO of the health division at Wolters Kluwer and vice president and general manager of the global diabetes business unit at Medtronic. He began his career at GE Healthcare.

How to Detect Trends In Medical Device Complaints

Some devicemakers can be slow to recognize trends in medical device complaints. It's not enough to have a solid complaint handling system when regulators expect you to learn something from the feedback you receive.

Quality systems expert Dan O'Leary, president of Ombu Enterprises, reviewed the FDA, EU and ISO standard requirements for analyzing trends in medical device complaints, in an FDAnews webinar.

Under FDA's Quality System regulation, devicemakers need to maintain a system to collect information about their devices in production and postproduction, and to evaluate complaints to detect hazardous situations.

The primary source of feedback is through complaints, so companies need to use complaints to update their risk management files, O'Leary explained.

MEDDEV

The EU has similar requirements under its MEDDEV guidance.

O'Leary said it is critical that companies keep records of complaints and have procedures in place that trigger when they must conduct investigations.

Devicemakers are supposed to use an appropriate statistical methodology to help detect recurring quality problems, but many companies run into trouble when it comes to using and documenting statistical techniques.

The new EU Medical Device Regulation, published May 5, includes a requirement for conformity assessment. Applications for a CE mark must include "a description of how you're going to conduct postmarket surveillance, which means building a whole postmarket surveillance system and a postmarket clinical follow-up plan," O'Leary said.

The first step is to establish a baseline by looking at historical data and at risk analysis.

"This is particularly important when we have complaints that may involve patient harm. Not every complaint involves patient harm, but over in risk analysis what you've done is analyze the frequency and severity.

Whatever you said in the risk management file is probably a good place to establish the baseline, particularly if you think your historical data might be higher than what you originally estimated."

One way to use historical data is look at the five previous periods, add up the complaints, divide by five, and find the average over that five-month interval, which provides the baseline.

Detecting Signals

Once the company has a baseline, it can put together a risk management file and decide what the threshold is for detecting a signal, which indicates that something might have changed.

"Then I'm going to have to decide whether I'm going to operate on that signal or not. So, I'm going to have to set some rules," O'Leary said.

"You probably want to be able to analyze complaints using the same hazardous situations and harms that you used in setting up the risk management."

If there is a potential failure to meet a specification for a device, for labeling or for packaging, then that needs to be investigated, and complaints should be classified.

O'Leary recommends using a matrix to trace design inputs to outputs, verification and validation.

"If you know the list of essential design outputs, one of the things that you might want to do is classify complaints by that list, because what that's saying is that the things you've determined are really important, you're getting complaints about them."

(See **Complaints***, Page 6)*

CFDA to Exempt 130 In-Vitro Tests From Clinical Trials

China's Food and Drug Administration is proposing to exempt 130 kinds of in-vitro diagnostic tests from clinical trial requirements.

The CFDA included the proposal as part of a draft rule for clinical development of IVD tests that are not eligible for exemption. The preliminary list of exempt tests includes reagents used to detect biomarkers such as hemoglobin, troponin and C-reactive protein, which are used to detect heart attacks, inflammation and anemia.

China has historically granted few exemptions for such devices, creating a heavy burden for companies forced to generate the trial data.

The CFDA also issued a document establishing the process for IVD testing, including selecting reference methods and sample sizes and the preparation of evaluation reports. The CFDA will accept comments on both drafts through the end of June.

Read the draft proposal here: www.fdanews.com/05-31-17-CFDA.pdf. — Zack Budryk

Complaints, *from Page 5*

Complaint investigation records also require that companies include the unique device identification, which provides a lot of useful data. Companies need to update these UDIs whenever they make a version or model change.

When companies see a statistically significant increase in any signal, they should categorize them by frequency and severity.

O'Leary said the expectation is that in the future manufacturers will report incidents to regulators, and the regulators will be able to exchange information to determine whether they're seeing different rates for similar devices in other countries.

The FDA has a set of problem codes and patient codes, and companies might want to use the same codes for their complaint classification system, he said.

Access the webinar materials here: www.fdanews.com/products/51171.

483 Roundup: Firms Cited Over Complaints, CAPAs, Quality Issues

The FDA cited device manufacturer Medtronic for lack of corrective action procedures and inadequate handling of complaints.

The agency issued a Form 483 following a late January-early February inspection of Medtronic's Juncos, Puerto Rico, facility. According to officials, the facility did not consistently escalate CAPA quality data sources for investigation to include non-conforming events.

The facility also did not adequately document CAPA investigations, according to the Form 483. One such investigation, opened in May 2015, did not clearly document the results of the proposed corrective actions and the final disposition of the units involved in the investigation. The investigation involved re-testing to correct for an incorrect initial equipment set-up, but the investigation records did not contain the data from the re-testing.

The facility also lacked procedures for receiving, reviewing and evaluating complaints, according to the Form 483. Inspectors found numerous complaints logged in 2016 with no accompanying formal investigation. Medtronic did not respond to a request for comment.

Backjoy Orthotics: The FDA cited device manufacturer Backjoy Orthotics for lacking written procedures and failure to properly handle complaints.

Following a March inspection of Backjoy's Boulder, Colo., facility, the FDA issued a Form 483. The firm did not have procedures in place for investigating, assessing and documenting adverse event reports, the agency said.

The FDA also found Backjoy's procedures for reviewing and evaluating complaints were inadequate. The company's protocols failed to address: uniform and timely processing of complaints; documentation of oral complaints upon receipt; records documenting determinations that no investigation of a complaint was necessary; and evaluation of complaints to determine whether it should be reported to the FDA.

The company did not respond to a request for comment.

Frye Electronics: The FDA faulted Frye Electronics for inadequate design validation and verification as well as incomplete complaint records.

Following an April inspection of the firm's Tigard, Ore., facility, the FDA issued a Form 483, citing the company's failure to establish procedures for design validation. Specifically, the company could not document that it conducted the required design validation for every major step of the design process.

The FDA also faulted Frye's design verification process, noting that its design verification documentation did not demonstrate testing was completed and passed. Its verification checklist for the B-Phase of design also failed to include results in the pass-fail column for several requirements.

Inspectors also found several complaint investigation records were missing required information. One complaint dated August 2014 remained open.

Frye did not respond to a request for comment.

Stryker: The FDA issued a Form 483 to Stryker's medical division, citing problems with its quality system, design verification and device-servicing procedures.

The FDA issued the form following a February-March inspection of the company's Portage, Mich., facility. Inspectors found the facility lacked established quality system procedures. In addition, the facility lacked the design verification to support the cleaning and disinfection process outlined in the service manuals for its thermal regulators.

The agency also faulted Stryker on its servicing procedures for equipment. According to inspectors, the firm did not require documentation of test and inspection data for the device-servicing process.

Read the Form 483s here: www.fdanews.com/06-02-17-FourForm483s.pdf. — Zack Budryk

APPROVALS

Soterix Medical Gains FDA Clearance for IontoDC System

Soterix Medical has received FDA marketing clearance for its IontoDC electrotherapy device.

The device uses direct current to introduce ions of soluble salts or other drugs into the body andincludes controls to adjust the duration and intensity of the treatment.

Stimwave Receives CE Mark Approval for Percutaneous Stimulator Anchoring System

Stimwave Technologies has gained a CE Mark for the Sandshark percutaneous injectable anchor system, used in conjunction with the company's wireless neurostimulator devices to provide relief of chronic pain. Once the anchor is in the desired location, it secures the stimulator to the surrounding tissue to prevent migration throughout the life of the implant.

Ra Medical Systems Achieves FDA Clearance For Peripheral Artery Disease Treatment

The FDA has granted marketing clearance to Ra Medical Systems for its DABRA System for peripheral artery disease treatment. The single-use catheter produces a lumen while minimizing trauma to the vasculature. The DABRA laser ablates arterial blockages, reducing calcium, thrombus and atheroma, minimizing downstream debris. The portable laser weighs about 100 pounds.

Masimo Wins FDA Clearance of O3 Regional Oximetry for Pediatric Patients

The FDA has granted marketing clearance for Masimo's pediatric indication for O3 regional oximetry with the O3 pediatric sensor. O3 regional oximetry monitoring, which was already available for adult patients in the United States, is now also available for pediatric patients weighing more than 11 pounds and less than 88 pounds. O3 regional oximetry uses near-infrared spectroscopy to continuously monitor absolute and trended regional tissue oxygen saturation (rSO2) in the cerebral region.

Intuitive Surgical Gets FDA Clearance For Robotic-Assisted Surgical System

Intuitive Surgical has received FDA clearance for its da Vinci X surgical system.

The device features 3D digital optics and flexible port placement. The system enables quadrant surgery including procedures like prostatectomy, partial nephrectomy, benign hysterectomy and sacrocolpopexy.

The device received a CE mark in April. The system will be available for sale in the U.S. later this year.

Atonomics Gains CE Mark For Trace Lipids Test Panel

Atonomics has gained a CE Mark for a lipids test panel on its proprietary Trace platform.

The lipids panel determines total cholesterol, HDL, LDL and triglycerides levels from a blood sample with results generated within minutes.

The cartridge test can be used to monitor the effectiveness of diet, lifestyle changes and medication to lower cholesterol.

The device is linked to an app that provides a read-out and tracking.

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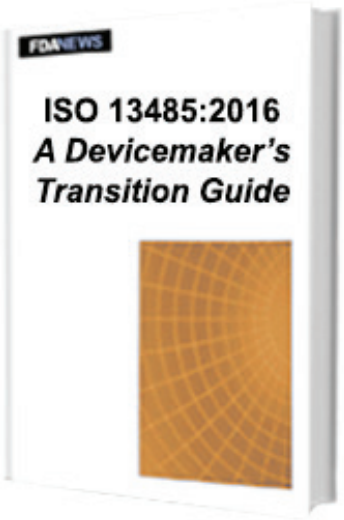

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