Put It on the Board, 10/17

Houston labs learn: know the back roads

The disaster plan of the laboratories at Memorial Hermann Health System in Houston held up well in Hurricane Harvey, thanks to lessons learned in years past, but the labs have something new to add: Know in advance the back-road access routes to the various hospitals.

Dr. Brown

Unlike previous storms, Harvey caused unforeseen and extended road and highway closures, forcing laboratory leaders to improvise courier routes and adjust staffing plans while some hospitals remained inaccessible for up to a week.

"We really depend on our highways here in Houston," says Richard Brown, MD, medical director for laboratory services. "Our couriers did an amazing job, and we did not have any specimens lost due to loss of integrity. Our blood supply remained in date and maintained the appropriate refrigeration. Everything worked, but it was difficult, as we had to rely on the staff of each hospital to find and communicate to us the accessible routes on a daily basis. Now we know the back roads that do not flood, and next time we'll know in advance the alternate routes we need to use."

The road closures also prevented team B staff from getting to the laboratories to relieve team A staff for the first two to three days post-hurricane. Team A staff at the core laboratory bunked in with sleeping bags in the laboratory office suite and worked 12-hour shifts until reinforcements arrived. "The laboratory staff were just incredible," Dr. Brown says. "They spelled each other so that somebody would be ready to go at all times."

Lessons learned from Tropical Storm Allison in 2001 and Hurricane Ike in 2008 helped Memorial Hermann's laboratory professionals prepare for expected disruptions this year, Dr. Brown says.

Sandra Ratliff, system vice president for laboratory services, began holding conference calls 24 to 48 hours before Harvey was predicted to make landfall. On the twice daily calls, at 8 AM and 2 PM, were Dr. Brown, all Memorial Hermann Health System laboratory directors, its courier service supervisor, and representatives from the health system's reference laboratory and regional blood supplier. The calls were especially effective in helping Memorial

Hermann prepare for potential areas of shortfall in staff and supplies.

“That was the great success story,” Dr. Brown says. “We were able to lay in enough supplies of blood in advance, particularly red cells. We also overstocked on our major chemistry, hematology, and coagulation reagents.” In retrospect, the labs should have increased the level of supplies from the smaller vendors, such as for microbiology and immunology, because airport closures made it impossible to receive deliveries from outside the region for an extended period.

“The most unanticipated thing with this storm was the length of time that the major highways into Houston and both airports were shut down,” Dr. Brown says. Although Allison and Ike dumped significant amounts of rain over Houston, “it was over a relatively short period of time, so the flooding came and went on the highways. Here, we got continuous rain for four days and that ended up being 51 inches—a whole year’s worth of rainfall. There’s just no way to recover from that.”

Preparing to keep laboratory staff fed, hydrated, and rested was a lesson learned years ago.

“We learned that from Ike,” Dr. Brown says. “There was a lot of power loss and the cafeterias shut down, so there was no food. We anticipated that this time and made sure all the employees had snacks, plenty of bottled water, and a good place to sleep.”

Dr. Brown shares another lesson, one that preserved supplies when Memorial Hermann was forced to evacuate an acute-care hospital near the rapidly cresting Brazos River.

“When you close a facility and you’re closing down a lab, take everything perishable out. Take all the blood, take all the supplies, and move them to where the patients are going,” he says.

Memorial Hermann learned that lesson after a hospital evacuation during Hurricane Ike. “We just left everything in place thinking it was only going to be a short period of time,” he recalls. When the power and the backup generators failed, “we lost the blood and the supplies.”

A new lesson learned in the Harvey evacuation: Include phlebotomists in the move to the receiving hospital. “It was not a nurse-drawn facility, so even though all of the nursing staff accompanied the patients, we had to have somebody come over to draw those patients’ blood,” he says. “We moved everything needed to maintain laboratory services with the patients, and that’s a valuable lesson learned.” *—Amy Carpenter Aquino*

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FDA clears Idylla respiratory panel

The FDA has granted 510(k) clearance for the Idylla Respiratory (IFV-RSV) Panel, a fully automated molecular diagnostic test, developed by Janssen Diagnostics, LLC. The Idylla respiratory panel runs on the Biocartis Idylla platform.
Janssen led the submission process of this premarket notification and developed the test intended for the detection of various strains of influenza virus and respiratory syncytial virus, using Biocartis’ Idylla platform. Biocartis says the panel can be performed in about 50 minutes, requires less than two minutes hands-on time, and operates from nasopharyngeal swab samples in viral transport media.
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Dako PD-L1 IHC 28-8 PharmDx approved for new indications

The FDA has approved the PD-L1 IHC 28-8 PharmDx for use in cases of urothelial carcinoma and of squamous cell carcinoma of the head and neck.

The test had previously been approved for melanoma and for non-squamous, non-small cell lung cancer. PD-L1 IHC 28-8 PharmDx was developed in collaboration with Bristol-Myers Squibb.

Opdivo (nivolumab) is an immunotherapy developed by BMS and approved in these indications regardless of PD-L1 status. While the test is not required for treatment, with these latest indications, pathologists now have access to a clinically validated complementary test to determine tumor PD-L1 status.

Data from a pre-specified exploratory analysis of the CHECKMATE-141 clinical trial showed that tumor PD-L1 expression, as detected by PD-L1 IHC 28-8 PharmDx in SCC of the head and neck, may be associated with an enhanced survival benefit for the patient from the use of Opdivo. Data from CHECKMATE-275 showed that tumor PD-L1 expression assessed by PD-L1 IHC 28-8 PharmDx may help inform which urothelial carcinoma patients are more likely to respond to Opdivo.

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A positive coverage decision for NanoString's Prosigna

NanoString Technologies announced that Anthem issued a positive coverage decision for the Prosigna Breast Cancer Gene Signature Assay. NanoString says the decision is in line with ASCO guidelines released in 2016, which recommend the use of the Prosigna assay to guide decisions on adjuvant systemic therapy for women with early-stage invasive breast cancer with known hormone receptor and HER2 status.

The assay provides a risk category and numerical score for assessing the risk of distant recurrence of disease at 10 years in postmenopausal women with node-negative or node-positive hormone receptor-positive breast cancer.
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Genomic Health, Biocartis to develop IVD Oncotype DX

Genomic Health and Biocartis have agreed to develop an in vitro diagnostic version of the Oncotype DX Breast Recurrence Score test on Biocartis' Idylla platform.

"We are excited to augment our successful U.S. centralized laboratory business model with an IVD system that can be implemented by local laboratories to increase global patient access to standard of care testing with the Oncotype DX Breast Recurrence Score test planned for launch in Europe, beginning with France and Germany, in 2019," Frederic Pla, PhD, Genomic Health's chief business and product development officer, said in a statement.

Development is expected to begin late this year.
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Horizon launches CRISPRi, CRISPRa screening

Horizon Discovery has expanded its functional genomic screening portfolio to include first-to-market CRISPRi (interference) and CRISPRa (activation) screening services.

Although functional genomic screening using CRISPR gene knockout technology has provided a way to identify and validate novel drug targets, and to elucidate unknown drug mechanisms, there are biological studies for which CRISPR knockout screens are not appropriate. Horizon's CRISPRi/CRISPRa screening platform substantially broadens the range of possible studies through the capacity to reduce or increase, rather than eliminate, gene expression. This enables customers to address critical gaps in target ID and validation as they work to develop novel and more effective drug therapies. [hr]