RI delegation delivers $81.7M for new state-of-the-art public health lab

New federal Epidemiology and Laboratory Capacity grant will upgrade RI's public health infrastructure and improve coordination and integration of laboratory with epidemiology and health information systems

WASHINGTON, DC – U.S. Senators **JACK REED** and **SHELDON WHITEHOUSE** and Congressmen **JIM LANGEVIN** and **DAVID CICILLINE** recently announced a new $81.7 million federal grant to enable the Rhode Island Department of Health (RIDOH) to build a new public health laboratory facility.

From its current facility on Orms Street in Providence, the RIDOH State Health Laboratories (RISHL) play a critical role in the State's efforts to investigate and mitigate life-threatening diseases, including COVID-19, as well as other public health threats like Eastern equine encephalitis (EEE), Ebola, H1N1, and Zika. RISHL also provides important services for State and municipal agencies to ensure the safety of drinking water and food products; monitor pollution of air and water; and aid public safety and criminal investigations through police officer training, DNA testing, and illegal drug identification.

The Orms Street facility was commissioned in 1978 and has become outdated, with insufficient laboratory space, inadequate building systems, and equipment in need of repair. According to RIDOH, over $500,000 annually is spent in capital expenditures to keep the facility working efficiently.

Last year, when commercial testing services weren't yet widely available, insufficient laboratory space limited the number of COVID-19 samples that could be tested at the State Health Laboratories. In fact, the State's pandemic response required limited renovation/construction of the facility in order to accommodate processing of thousands of samples for testing.

In the wake of the COVID-19 pandemic, Senators Reed and Whitehouse and Congressmen Langevin and Cicilline voted to include nearly $50 billion for COVID-19-mitigation and public health infrastructure, such as testing, contact tracing, enhanced genomic sequencing and Epidemiology and Laboratory Capacity grants. This federal funding may be used to "prevent, prepare for, and respond to coronavirus."

"COVID-19 revealed a serious gap in our health care infrastructure. This new federal funding will help Rhode Island bridge that gap and create a new state-of-the-art lab facility for the 21st century. This is a wise investment in upgrading our public health infrastructure and ensuring that advanced diagnostics tests and other clinical capabilities are readily available here in Rhode Island," said Senators Reed and Whitehouse and Congressmen Langevin and Cicilline in a joint statement.

The state will receive $81,716,590 to construct a new laboratory building that is expected to be LEED Silver certifiable and contain state-of-the-art equipment. The new facility will enable RISHL to continue to provide high-quality scientific test results more efficiently through improved workflows, while avoiding the expensive recurring maintenance and allow for spatial flexibility in the event of another pandemic or as new public health initiatives unfold.

Plans for the facility also call for a newly created section of the RISHL Center for Biological Sciences that will function as a dedicated Genomics Sequencing Core Laboratory.

Like the State Health Lab on Orms Street that it will replace, the new lab would be categorized as a Level 3 biosafety facility that is equipped to handle dangerous materials, microbes, and pathogens.

Federal support for the project will be allocated to the state through the Epidemiology and Laboratory Capacity grant funds administered by the U.S. Centers for Disease Control and Prevention (CDC). ❖

Westerly Hospital introduces micro-ultrasound device for enhanced prostate biopsies

WESTERLY – Westerly Hospital is the first hospital in New England to use a state-of-the-art micro-ultrasound device that more precisely visualizes prostate tumors for patients undergoing prostate-specific antigen (PSA) screening and prostate biopsies.

The new system allows for real-time, high-resolution imaging that guides the surgeon during the biopsy and produces images that allow the urologist to better distinguish cancerous tissue from normal tissue, which can enhance the quality of the biopsy.

Because of its superior resolution, an accompanying MRI of the prostate may not always be necessary. Current practice suggests that to get optimal biopsy results, men with high PSA levels or suspected prostate cancer should get an MRI in addition to ultrasound.

Patients undergoing the procedure remain awake and receive only a local anesthetic. The images appear in real time on a console monitor to help guide the urologist to perform the biopsy. The procedure takes no more than 15 minutes.

"This is an outstanding addition to the tools that we can use in the office to better detect prostate cancer," said **JOSEPH F. RENZULLI, MD**, regional medical director and chief of urology for both L+M Hospital and Westerly Hospital. "With this new device we can better detect smaller abnormalities within the prostate gland and more accurately direct our biopsies to enhance the pathologic evaluation of the grade and stage of the cancer." ❖

AG, RIDOH deem Lifespan/CNE merger application complete under Hospital Conversions Act

The Attorney General and Director of RIDOH will have 120 days to determine whether to approve, approve with conditions, or deny the application

PROVIDENCE – Attorney General **PETER F. NERONHA** and Director of Health **NICOLE ALEXANDER-SCOTT, MD, MPH** announced November 16 that the Lifespan/Care New England Hospital Conversions Act (HCA) application has been deemed complete and accepted for review. The review period under the HCA will commence November 17, 2021.

What does "complete" mean?

An HCA application is deemed complete when enough information has been provided by the transacting parties to begin the review. It is a procedural milestone in the review process of this transaction.

"Completeness' does not mean that regulators have resolved all of their questions or that new questions will not arise as the review moves forward. During the review period, the Attorney General and the Rhode Island Department of Health (RIDOH) will gather the information necessary to evaluate the transaction described in the application, as required under the HCA, which includes taking testimony, requesting and reviewing more documents, and conducting public meetings

"As a regulator with the immense responsibility of evaluating hospital transactions in our state, our goal is clear. We need to determine whether the transaction is legal and understand how, if approved, it will impact cost, quality and access to care for the people of Rhode Island," said Attorney General Neronha. "While the goal is clear, the path toward accomplishing that goal is complex and requires a thorough and careful vetting of an enormous amount of information. We need to sift through all that information, with the help of our experts, to ensure compliance with the law. A determination of completeness is the first step toward conducting a thorough review that will, importantly, include input from the public."

"RIDOH will conduct a thorough review of this application to ensure that quality, access, and affordability of healthcare is maintained throughout Rhode Island, with a focus on communities that have historically experienced health disparities," said Director of Health Nicole Alexander-Scott, MD, MPH. "This review process will be rigorous and thorough and will involve the gathering of feedback from people throughout Rhode Island in public comment sessions."

Next Steps

- Now that the application has been deemed complete, consistent with the standard process set forth in the HCA, the Attorney General's Office will perform confidentiality determinations, which will be complete on or before December 30, 2021.
- At that point, the application will be made public, and public meetings will be scheduled within two months of that date.
- Under the HCA, the deadline for a decision approving, approving with conditions, or denying the transaction falls 120 days from the date of completeness. In this case, the deadline falls on March 16, 2022. ❖

RIDOH approves Kent for Hospital-at-Home Pilot Program

PROVIDENCE – Kent Hospital's request to offer the state's first-ever Hospital-at-Home program was approved on Nov. 16th by the Rhode Island Department of Health (RIDOH). The Program, also approved by the Centers for Medicare & Medicaid Services (CMS), is designed to provide patients with acute hospital-level care in a patient's home.

Hospital-at-Home programs provide more direct contact and clinical oversight of patients than what is available through typical home care services. Patients are only admitted to the Program from Emergency Departments and inpatient hospital beds, and an in-person physician evaluation is required before starting services at home. Other requirements of the program include:

- Clinical care must include a visit from a registered nurse at least once a day, at least two in-person daily visits by a registered nurse or mobile integrated health paramedic, and once-daily check-in with a physician.
- The patient must have immediate, remote audio technology that can connect the patient with the Hospital-at-Home care team.
- If a patient's condition declines and they need care at the hospital, emergency response must be able to get to the patient's home within 30 minutes.
- The hospital must report monthly to CMS on establish quality metrics.

Kent Hospital will be only the third hospital in New England that has been approved to have a Hospital-at-Home Program. The other two hospitals are Brigham & Women's Hospital and Massachusetts General Hospital, both in Boston.

"As a geriatrician, to be able to offer acute hospital level care at home for our older adults who prefer it, after years of seeing the adverse outcomes of multiple transitions of care for older adults, is amazing. I'm so proud of the work Kent Hospital has done to become an Age Friendly Health system, and now the first hospital in RI to be able to offer Acute Hospital Care at Home. Care at home is the future, and the Kent team looks forward to building this option and sharing lessons learned with other systems of care both local and national," said **ANA TUYA FULTON, MD, MBA**, Executive Chief of Geriatrics & Palliative Care, Care New England; Health System Chief Medical Officer, Integra Community Care Network)

For information on CMS' Acute Hospital Care at home, visit https://qualitynet.cms.gov/acute-hospital-care-at-home. ❖

Lung Association report: RI ranks as #2 state for 5-year survival

PROVIDENCE – The American Lung Association's 4th annual "State of Lung Cancer" report, released Nov. 16th, highlights how the toll of lung cancer varies by state and examines key indicators throughout the U.S. including: new cases, survival, early diagnosis, surgical treatment, lack of treatment and screening rates. The report showed positive results in Rhode Island, with the state landing top 5 rankings for 5-year survival, early diagnosis, surgical treatment rate and people receiving treatment.

The report reveals that the lung cancer five-year survival rate increased 14.5% nationally to 23.7% yet remains significantly lower among communities of color. In fact, while the national lung cancer survival rate increased, it remains at only 20% for communities of color and 18% for Black Americans. This is the second year that the "State of Lung Cancer" report explores the lung cancer burden among racial and ethnic minority groups at the national and state levels.

"While we celebrate that more Americans are surviving lung cancer, too many people are being left behind, and the disease remains the leading cause of cancer deaths," said **DANIEL FITZGERALD**, director of advocacy for the American Lung Association in Rhode Island. "Much more can and must be done in Rhode Island to prevent the disease and support those facing the disease, such as ensuring everyone who is at high risk is screened for lung cancer, funding tobacco prevention and cessation programs, and promoting testing of homes for radon."

The report found that Rhode Island ranked:

- **2nd in the nation for survival at 28.4%.** The national average of people alive five years after a lung cancer diagnosis is 23.7%.
- **5th in the nation for early diagnosis at 27.4%**. Nationally, only 24.5% of cases are diagnosed at an early stage when the five-year survival rate is much higher.
- **2nd in the nation for surgery at 28.5%.** Lung cancer can often be treated with surgery if it is diagnosed at an early stage and has not spread. Nationally, 20.7% of cases underwent surgery.
- **2nd in the nation for lack of treatment at 14.8%.** Nationally, 21.1% of cases receive no treatment.
- **26th in the nation for lung cancer screening at 6.3%.** Lung cancer screening with annual low-dose CT scans for those at high risk can reduce the lung cancer death rate by up to 20%. Nationally, only 5.7% of those at high risk were screened.
- **43rd in the nation for lung cancer incidence at 69.3 per 100,000.** Incidence refers to the number of new cases of lung cancer in each state. The national lung cancer incidence is 57.7 per 100,000.

While the "State of Lung Cancer" report findings show significant work to be done, there is hope. In March of 2021, the United States Preventive Services Task Force expanded its recommendation for screening to include a larger age range and more current or former smokers. This dramatically increased the number of women and Black Americans who are eligible for lung cancer screening. ❖

U.S. multi-society task force on colorectal cancer releases updated screening recommendations

The United States Multi-Society Task Force (MSTF) on Colorectal Cancer (CRC) represents the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy.

The MSTF updated the CRC screening recommendations that were last published in 2017, focusing on the specific questions of when to start and when to stop CRC screening in average-risk individuals (those without family history of colorectal neoplasia and those without gastrointestinal symptoms).

New guidance:

- The MSTF suggests CRC screening in average-risk individuals ages 45–49.

Unchanged from 2017:

- The MSTF strongly recommends CRC screening in all individuals aged 50 to 75 who have not already initiated screening.
- For individuals ages 76 to 85, the decision to start or continue screening should be individualized and based on prior screening history, comorbidity, life expectancy, CRC risk, and personal preference.
- Screening is not recommended after age 85.

The MSTF made these determinations based upon evidence demonstrating an increasing incidence and mortality from CRC in individuals under age 50, with data suggesting that the yield of screening in 45–49-year-olds is similar to the yield of screening 50–59-year-olds, and that the benefits of screening in younger individuals outweigh the harms and costs based on modeling studies. In addition, the MSTF summarized new data since 2017 regarding the risks and benefits of screening beyond age 75 and the appropriate age to stop screening.

This updated guidance from the MSTF is aligned with multiple other professional societies, including the United States Preventative Services Task Force, the National Comprehensive Cancer Network and the American Cancer Society.

The full recommendations have been published jointly online via Gastrointestinal Endoscopy, Gastroenterology, and The American Journal of Gastroenterology, and will be available in the January 2022 print issues. ❖

Alzheimer's Association announces national registry to collect 'real world' data on newly-approved treatments

BOSTON AND CHICAGO – The Alzheimer›s Association, the American College of Radiology, the American Society of Neuroradiology and the Department of Biostatistics, Brown University School of Public Health, along with other clinical research experts, announced on Nov. 9th a national registry, The National Treatment and Diagnostic Alzheimer's Registry. This new national registry will be an FDA-approved-agent agnostic approach to gathering routine clinical practice data and outcomes for sharing quickly and transparently with all stakeholders.

Earlier this year, the FDA gave accelerated approval for Aduhelm (Biogen/Eisai). This is the first treatment approved to treat patients in the Alzheimer's disease stage studied in the clinical trials – people with mild cognitive impairment (MCI) or mild dementia stage of disease. The sponsors of at least two other disease-modifying drugs for Alzheimer's are on record that they are applying to the FDA for accelerated approval. These, along with other experimental treatments in the pipeline, make a national registry essential for researchers, clinicians and people living with the disease.

"Creation of a national provider registry for disease-modifying Alzheimer's treatments, and for the associated diagnostic tests and biomarkers, is meant to swiftly advance the science," said **MARIA C. CARRILLO, PhD**, Alzheimer's Association chief science officer. "The pipeline is growing and more exciting advances are around the corner, including several more disease-modifying therapies that may be approved in the next two to three years."

Similar successful registries in heart disease and cancer have enabled stakeholders to track the long-term performance of therapies using a large, real-world evidence dataset.

"There is an urgent unmet need to provide effective treatments for all who need them, and a transparent approach that allows for immediate sharing of data will not only accelerate advances, but identify gaps in effectiveness and safety, and highlight opportunities to improve care and treatment for all affected by Alzheimer's," said Carrillo.

The registry will be designed to continuously collect routine clinical practice data over time from healthcare providers caring for patients diagnosed with Alzheimer's who are taking an FDA-approved disease-modifying treatment. The registry will be designed to grow with scientific and medical advancements. As new drugs are approved and implemented in care, these will also be captured by the registry.

"We need to assess the benefits that people from all backgrounds and communities derive from this and future treatments in the real world – in other words, outside of narrowly constrained clinical trials. We also need to push for additional, even more effective therapies. This initiative aims to achieve this goal," said Carrillo.

The announcement of the National Treatment and Diagnostic Alzheimer's Registry was made by Carrillo at the Clinical Trials on Alzheimer's Disease conference (CTAD) in Boston.

The Alzheimer's Association will provide the initial seed funding to launch the project. The Association will then seek additional funding from government and philanthropic sources.

"The Alzheimer's Association is perfectly positioned to lead this effort – and we have the experience, team and infrastructure already in place through registries we've built and operated for our IDEAS and New IDEAS studies," Carrillo said. ❖

FDA issues final orders reclassifying certain Hepatitis C diagnostic tests from Class III to Class II

WASHINGTON, DC – On Nov. 19th, The FDA issued two final orders, reclassifying certain HCV diagnostic tests from class III to II. These orders allow these HCV tests to use FDA's 510(k) pathway rather than the PMA pathway.

The two types of HCV diagnostic tests being reclassified are nucleic acid-based HCV ribonucleic acid (RNA) devices intended for the qualitative or quantitative detection or genotyping of HCV RNA and certain HCV antibody devices intended for the qualitative detection of HCV.

TIMOTHY STENZEL, MD, PhD, director of the Office of In Vitro Diagnostics and Radiological Health in FDA's Center for Devices and Radiological Health, said:

"Today's action allows manufacturers of certain types of Hepatitis C virus (HCV) tests to seek marketing clearance through the less burdensome premarket notification (510(k)) pathway rather than submitting a premarket approval application (PMA), the most stringent type of FDA medical device review.

"We are confident that following reclassification, with adherence to the special controls, these devices will continue to provide a reasonable assurance of safety and effectiveness. Additionally, the reclassification may support the potential for more manufacturers to develop these tests, which can increase competition and increase access to these important tests.

"These reclassifications will also benefit the Department of Health and Human Services' National Viral Hepatitis Action Plan, as increased access to tests will likely aid patients in seeking the appropriate treatment and likely reduce transmission." ❖

Association of Migraine Disorders funds two innovative research projects

PROVIDENCE – The Association of Migraine Disorders (AMD) recently announced it has approved and funded two migraine research projects in 2021. With a mission to expand the understanding of migraine disease, the organization has a goal to fund three additional projects by year's end.

Research to help personalize migraine treatment

The first research project includes developing a program to help identify the various forms of migraine and how patients respond to treatments. This will help physicians personalize migraine treatment.

"We aim to build a tool that will allow rapid extraction of migraine patients from electronic medical records and their associated symptoms and treatment response, allowing us to study these more homogenous cohorts," said **DR. WILLIAM RENTHAL**, Director of Headache Research, Brigham and Women's Hospital and Harvard Medical School. "We aim to understand genetic differences that may drive treatment response to CGRP monoclonal antibodies."

The second project focuses on understanding the association between sleep apnea and migraine.

"The project will foster a more detailed understanding of the causal nature between sleep disorders – especially sleep-disordered breathing, such as obstructive sleep apnea – and migraine, and address the question of whether proven therapies for sleep-disordered breathing also improve migraine outcomes, such as migraine frequency and intensity," said Dr. Eric Gruenthal, Sleep Medicine Fellow at the Cleveland Clinic Foundation and Cleveland Clinic Lerner College of Medicine. ❖