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Health dept., Kent sign consent agreement after patient medical errors

Kent has committed $1.7M to improvement plans

The Rhode Island Dept. of Health and Kent Hospital entered into a consent agreement on June 22, 2018. [http://health.ri.gov/di...](http://health.ri.gov/di...)

The agreement was the result of an investigation into “deficiencies relating to the verification of procedure site/side” incidents involving four patients. These incidents, according to the agreement:

“1. On 12/6/2017, Patient #1 underwent a re-excision of the right breast which was performed on the wrong area of the breast.

“2. On 3/14/18, Patient #2 underwent an incision on the left abdomen for a nephrectomy which was intended to be done on the right abdomen.

“3. On 4/10/18, Patient #3 underwent insertion of a catheter with use of a guidewire that was subsequently found to be retained in the patient following the procedure.

“4. On 5/20/18, Patient #4 underwent insertion of a catheter with use of a guidewire that was subsequently found to be retained in the patient following the procedure.”

JAMES E. FANALE, MD, president and CEO, Care New England, and RAYMOND O. POWRIE, MD, FRCP(C), FACP, interim president, Kent Hospital, issued a joint statement regarding the RIDOH agreement:

“Kent Hospital and Care New England (CNE) are firmly committed to addressing the issues put forward by the Rhode Island Department of Health today. There is no greater issue on which we focus than patient safety and quality of care.

“We take the matters raised in these findings very seriously and, from the very beginning, self-reported all of these events to the RI Department of Health. We are grateful to the RI Department of Health and the Centers for Medicare and Medicaid Services (CMS) for their careful review, assessment, and guidance to enhance our own internal reviews.

“Specific to the findings highlighted in today’s agreement, Kent Hospital and Care New England have begun an active and aggressive improvement plan that is resulting in a complete and thorough review of our safety culture and practices, hospital-wide education, retraining, and recommitment to a level of excellence that will be unsurpassed. Much of this work and financial investment already began prior to the findings issued today and includes disciplinary action, policy and procedure review, competency assessment, auditing of compliance with policies and protocols, and prospectively maintaining a constant state of renewed diligence towards adherence and compliance.”

Kent has implemented a 100-day turnaround plan that Kent voluntarily initiated in March after the second incident and which was, according to the agreement, “subsequently expanded to address URFOs [unintended retained foreign objects] and overall hospital procedures to ensure patient safety and compliance…”

As part of the agreement, Kent has committed at least $1.7 million to implement its year-long plan. The hospital also has agreed to hire an independent monitor by August 1st to oversee compliance with the agreement.

RIDOH announces consent agreement with Rhode Island Hospital over patient medical errors

RIH to invest a minimum of $1M in improvement efforts

The Rhode Island Department of Health (RIDOH) and Rhode Island Hospital have entered into a consent agreement, in lieu of regulatory action, that will result in the healthcare facility implementing a series of system improvement measures over the coming year.

The agreement follows a review by RIDOH of four reported incidents involving Rhode Island Hospital patients during February and March 2018. The incidents involved patient identification and procedure verification.

According to the consent agreement, the incidents included:

“1. On 2/21/18, Patient ID#2 underwent a computed tomography angiography of the brain and neck intended for another patient.

“2. On 2/26/18, Patient ID#1 was not correctly identified and as a result underwent an angiogram intended for another patient.

“3. On 3/12/18, Patient ID#3 underwent a surgical vertebroplasty on Patient ID#3’s C-6 which was intended to be done on C-7.

“4. On 3/16/18, Patient ID#8 underwent a mammogram of the right breast intended for another patient.”

“Whenever preventable errors occur in hospital settings, it is essential that we scrutinize those errors carefully and that facilities make the systems changes needed to ensure that they do not occur again,” said Director of Health NICOLE ALEXANDER-SCOTT, MD, MPH.

The steps to be taken by Rhode Island Hospital outlined in the consent agreement include:

• Requesting and implementing the recommendations of the national hospital accrediting body, known as the Joint Commission, and putting in place process improvement methodologies developed by the Joint Commission.

• Conducting facility-wide training on patient identification and procedure verification.

• Scheduling a series of meetings with community emergency medical service (EMS) leadership and emergency department staff [among other staff] to identify opportunities for improvement related to patient identification.

• Submitting to RIDOH policies and procedures related to access to electronic medical records, with a focus on policies related to the number of patients records a user can access simultaneously.

• Hiring an external compliance organization to provide monitoring and oversight for at least one year.

Rhode Island Hospital has agreed to invest a minimum of $1 million in these and other improvement efforts that RIDOH required through this consent agreement.
Newport Hospital kicks off emergency department expansion campaign

NEWPORT – Newport Hospital recently launched its public campaign to expand its emergency department by announcing a $3-million gift from the van Beuren Charitable Foundation and a $1.5-million challenge grant from the Alletta Morris McBean Charitable Trust. Both foundations are longtime supporters of the hospital and Aquidneck Island charities.

The hospital’s $12.5 million construction project is needed to better meet Aquidneck Island residents’ needs as well as the demands put on the hospital by the growing summer tourism industry.

The construction will nearly double the number of treatment and exam rooms, critical to keeping wait times low, improving patient privacy and advancing the ED’s best practice models. Treatment rooms will increase from 17 to 29 and include a new behavioral health section and a four-bed observation unit.

“It’s time that the expertise and compassion our caregivers provide are complemented by a healing environment that is spacious, modern and comfortable for patients and families,” said CRISTA DURAND, president of Newport Hospital. “We are thrilled that the van Beuren Charitable Foundation and The Alletta Morris McBean Charitable Trust are so committed to helping Newport Hospital provide the very best in care when our patients need us the most.”

HOPE H. VAN BEUREN, founder and chair emerita of her family foundation, said, “Our mission is to invest in the quality of life and quality of place of Aquidneck Island and surrounding communities. The hospital is most important for the betterment of the community and the Foundation recognizes that the Emergency Department must be expanded to address Aquidneck Island’s growing health care needs.”

“Strain on health care access – seasonal or not – is not sustainable. Newport Hospital is committed to providing exceptional care in a timely manner year-round,” said Durand. She added that the renovated emergency department will factor in future growth, and could accommodate as many as 40,000-plus visits annually.

The physical transformation will include a four-bed behavioral health unit, providing patients more privacy and dignity. Visits by patients with addiction and/or mental health issues have increased by 17 percent during the last three years and now represent eight percent of all emergency room visits.

A “clinical decision unit” will also be added, and is considered a national best practice. These four rooms will be for patients who need extended emergency department treatment and observation but may not require admission as an inpatient, lowering the total cost of care.

Other highlights of the project include:

- Three triage spaces for arriving patients, compared to one.
- A lounge and waiting area for patients waiting for tests and their family members.
- Dedicated workstations in each treatment space to facilitate bedside registration and documentation, and ultimately reduce wait time.
- Space that is geriatric and pediatric friendly

The existing emergency department will remain operational throughout the construction, which is expected to begin in July and be completed by September 2019.
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Rhode Island recognized nationally for top immunization rates

The Centers for Disease Control and Prevention (CDC) celebrated Rhode Island for having immunization rates that are among the highest in the country for several vaccines in different age groups at their most recent National Immunization Conference.

“Our tremendous immunization success is directly attributable to the dedication of Rhode Island’s healthcare provider community, including doctors, school nurses, pharmacists, and community partners, as well as to KIDSNET, a statewide health information system that helps children be as well vaccinated as possible,” said Nicole Alexander-Scott, MD, MPH, Director of the Rhode Island Department of Health (RIDOH).

The CDC’s annual National Immunization Conference brought together more than 1,500 local, state, and federal officials to explore science, policy, education, and planning issues related to immunization and vaccine-preventable diseases. Rhode Island received four individual awards:

- The highest flu vaccination coverage rate in the nation among children six months to 17 years of age during the 2016–2017 flu season (74%);
- The second highest flu vaccination coverage rate in the nation for adults during the 2016–2017 flu season (51%);
- Outstanding immunization rates for the vaccines routinely administered to adolescents. For example, among adolescents, Rhode Island had the highest HPV (Human papillomavirus) vaccination rate for males and females, the highest meningococcal vaccination rate, and the second highest Tdap vaccination rate. Tdap protects people against tetanus, diphtheria, and pertussis;
- Outstanding immunization rates for each of the nine vaccines routinely administered to children 19 to 35 months of age, such as measles, mumps, and rubella (MMR) vaccine, rotavirus vaccine, and Hepatitis A vaccine.

In addition to preventing the health effects of many vaccine-preventable diseases, vaccines substantially reduce disease-associated healthcare expenses. According to a CDC study published in 2014, childhood vaccines prevented 21 million hospitalizations nationally and resulted in savings of $295 billion in direct medical costs nationally between 1994 and 2013.

The data were collected using the National Immunization Survey, which is a CDC program that generates vaccination estimates through calling randomly selected phone lines and following up with people’s healthcare providers (if permission is granted). The rankings above are best estimates. Data are not collected on every individual, so the true vaccination rates (and therefore rankings) could be slightly higher or lower. Vaccination rates in Rhode Island and other states are evaluated against Healthy People 2020 goals, which are national health targets set by various federal health agencies, including CDC.

An additional factor in Rhode Island’s immunization success is its Universal Vaccine Policy. This Universal Vaccine Policy allows healthcare providers to order all vaccines from the state for children from birth through 18 years of age, and most recommended vaccines for adults, at no cost. Complete immunization data are available online.
Survey reveals a mix of health behavior trends in RI youth

Survey shows data trends in the areas of sexual activity, drug use, smoking, and mental health

Results from a comprehensive youth health survey released recently suggest that middle and high school students in Rhode Island have made improvements in health behaviors over the past 10 years in many areas, including seat belt use, sexual activity, and alcohol and illegal prescription drug use. However, through the survey, the voices of Rhode Island youth revealed some concerning trends, including trends related to mental health, e-cigarette use, and marijuana use.

The Youth Risk Behavior Survey is a collaboration between the Centers for Disease Control and Prevention (CDC), the Rhode Island Department of Health (RIDOH), the Rhode Island Department of Education (RIDE), and the Rhode Island Department of Behavioral Healthcare, Developmental Disabilities, and Hospitals (BHDDH). The survey, which is administered every two years, is implemented through anonymous questionnaires in Rhode Island public schools. These most recent data were collected from January 2017 to May 2017. The data are used to help policy makers, school administrators, social service workers, and public health professionals understand trends in the health behaviors of young people across the state and to create health-related policies that will impact those behaviors. By participating, schools make sure their students’ voices are heard and can get resources with the support needed to help solve pressing challenges, like student stress, substance abuse, and bullying.

Rhode Island YRBS data overview
Examples of health behavior improvements

- Tobacco, illegal prescription drug, and alcohol use: 5% of middle school students have ever tried cigarette smoking, down from 16% in 2007. In 2017, 6.1% of high school students currently smoke, a decline from 15% in 2007. 7% of high school students reported having ever misused a prescription drug, a decrease from 14% in 2011. The percentage of high school students who currently drink alcohol was almost cut in half in 10 years (43% in 2007 to 23% in 2017).
- Driving: High school students who reported that they rode with a driver who had been drinking decreased from 28% in 2007 to 14% in 2017. In 2007, 14% of students reported rarely or never wearing a seat belt when riding in the car driven by someone else. This decreased to 7% in 2017.
- Sex: The percentage of middle school students who have ever had sex decreased from 15% in 2009 to 8% in 2017. The percentage of high school students who have ever had sex decreased from 46% in 2007 to 36% in 2017.

Some concerning trends

- Mental health: 23% of middle school and 29% of high school students were so sad or hopeless almost every day for two weeks or more that they stopped usual activities. 12% of Rhode Island high school students considered suicide in the past year in 2007, compared to 16% in 2017. In 2017, 14% of high schoolers said they had made a suicide plan in the past year. The percent of high school students who reported attempting suicide in their lifetime increased from 9% in 2007 to 11% in 2017.
- Smoking electronic cigarettes: 16% of middle school students have ever tried e-cigarettes and 6% currently use e-cigarettes. 40% of high school students have tried an electronic vapor product, and 20% have done so in the past 30 days.
- Marijuana use: Rates of marijuana use have not decreased in the last 10 years. In 2017, 23% of Rhode Island high school student smoked marijuana in the past 30 days, the same percentage from 2007. 9% of middle school and 37% of high school students report having ever used marijuana.

Examples of health disparities

- Mental health: The prevalence of sadness and suicide risk behaviors are two to four times higher among students who identify as lesbian, gay, or bisexual, compared to their heterosexual peers. Mental health issues were more common among female and Hispanic high school and middle school students. In addition, students with disabilities had a significantly higher rate of sadness and four times the prevalence of suicide ideation and suicide attempts compared to students without disabilities.
- Bullying: 17% of students were bullied on school property, and 14% were cyber-bullied in the past year. Students who identify as lesbian, gay, or bisexual [31% for both types of bullying] and students with a disability [30% at school, 25% cyber] experienced bullying at higher rates than their peers. Hispanic and Caucasian high school students were more likely to be bullied at school and online, compared to African American students. Female high school students experienced higher rates of cyber-bullying than males.
- Smoking: 34% of students who identify as lesbian, gay, or bisexual have ever smoked cigarettes, compared to 18% of students who identify as heterosexual. 52% of students who identify as lesbian, gay, or bisexual have ever used e-cigarettes, compared to 39% of students who identify as heterosexual. The rate of current...
cigarette smoking and e-cigarette use is higher among Caucasian high school students, compared to African American students. Current e-cigarette use is higher among male high school students than females.

- Marijuana use: Hispanic middle school students had a higher prevalence of use than Caucasian students. Males were more likely than female middle school students to try marijuana before age 11.
- Physical activity: 32% of students with disabilities were physically active for at least 60 minutes five days a week, compared to 44% of students without a disability.

Additional Youth Risk Behavior Survey data on other health trends are available online. Only statewide data are available. [Data are not available by city and town.] However, comparisons between Rhode Island and other states are available online.

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**Lifespan makes $400,000 payment in lieu of taxes to Providence, increasing health system’s PILOT payments to $3.6 million**

**Providence** – Lifespan made a $400,000 payment in lieu of taxes last week to the City of Providence. The PILOT payments from the state’s largest health system to the city now total $3.6 million over the last seven years.

Lifespan also annually contributes more than $1.2 million in taxes to Providence on property either owned or leased by the health system. Its workforce is an economic engine for the city and state and has grown by nearly 25 percent from 2009 to nearly 15,000.

Providence Mayor **JORGE O. ELORZA** said Lifespan’s collaborative efforts and investments in Providence are essential to the continued growth and success of Providence.

“We continue to look for ways to work collaboratively with our anchor institutions, including our health care partners. I thank Lifespan for their continued support of the City of Providence and look forward to working with them as we move our city forward together,” said Mayor Elorza.

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**IN THE NEWS**

Lifespan makes $400,000 payment in lieu of taxes to Providence, increasing health system’s PILOT payments to $3.6 million

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**Aetna is proud to support the members of the Rhode Island Medical Society.**
PROVIDENCE – The Miriam Hospital has been awarded a $9.1 million grant from the National Institutes of Health to fund new and continuing initiatives at its Providence/Boston Center for AIDS Research (CFAR), a collaboration between the Lifespan health system, Brown University and Boston University/Boston Medical Center.

The five-year grant supports a major new relationship between two prominent universities: Brown University in Rhode Island and Boston University in Massachusetts, along with their affiliated medical centers, Lifespan and Boston Medical Center. The relationship significantly enhances the substantial resources and expertise of the Providence/Boston CFAR.

The grant also reflects a timely new emphasis of CFAR to address the relationship between HIV and substance use disorder – just as public health officials are seeking to curb the nation’s deadly and costly opioid epidemic. Each of the participating academic institutions operate NIH-funded HIV and alcohol research centers.

Based at The Miriam Hospital, the Providence/Boston CFAR has secured continuous NIH funding since its founding in 1998 by former infectious disease chief Charles C. J. Carpenter, MD, and this year it’s celebrating its 20th anniversary. The new funding is an acknowledgment that HIV/AIDS continues to pose a serious threat around the world and that the center produces valuable multidisciplinary research to help battle the disease.

Along with the new emphasis on substance use disorders, the Providence/Boston CFAR maintains a special focus on women, MSM [men who have sex with men], at-risk youth, and individuals in the criminal justice system. Its research is aimed at preventing and treating the disease here in the United States and in highly pandemic regions around the world including, sub-Saharan Africa, South Asia and Central Europe.

“This is very exciting,” said SUSAN CU-UVIN, MD, director of the Providence/Boston CFAR and an HIV physician at The Miriam as well as a faculty member at Brown’s Warren Alpert Medical School and the School of Public Health. “CFAR is devoted to translational research. Its primary goal is to improve the lives of people with HIV/AIDS. There is no reason to do this if it doesn’t reach the people who need it – in Rhode Island, Massachusetts and all around the world. “

She continued, “It’s not a science grant. It’s a service grant to support investigators to become researchers in the HIV/AIDS field. If you’re tied to a clinic, there’s no way you can do research. The grant allows us to attract young people who are promising investigators. We have the resources and mentorship they need.”

Currently, CFAR investigators have secured over $30 million in NIH-funded research in addition to $18.6 million from non-NIH sources, and $3.8 million in institutional support from the collaborating institutions for the next five-year cycle. The center provides services to over 250 faculty members from participating sites including international collaborators and those in Providence and Boston.

“The funding allows Brown faculty and trainees to continue to interact with our colleagues in Boston on cutting-edge HIV/AIDS research,” said JACK A. ELIAS, MD, senior vice president for health affairs and dean of medicine and biological sciences at Brown University. “CFAR is central to the HIV/AIDS research at The Warren Alpert Medical School because it provides critical funding for basic science, clinical, translational, and behavioral studies and for the training of new investigators.”

“Collaboration is the hallmark of HIV research and education, and this support reinforces the successful partnerships between our institutions,” said BESS MARCUS, dean of the School of Public Health at Brown University. “Because of the expertise of researchers in biology, medicine and public health, HIV has gone from a deadly infectious disease to a chronic illness that affords those afflicted with the chance to live a longer life. Continued work alongside our talented partners will lead to further advances in testing and treatment, and most importantly, improvements in the outcomes for people living with HIV/AIDS.”

Dr. Cu-Uvin praised Boston University/Boston Medical Center for their participation and said the Boston institutions bring invaluable expertise and resources to CFAR. The new collaboration could potentially leverage even greater funding from NIH in future grant cycles, she said.

SANDRO GALEA, MD, DrPH, the Robert A. Knox Professor and dean of the School of Public Health at Brown University, said, “I am delighted to partner with Brown in this award. This is consistent with our strategic direction as a school and I am much looking forward to seeing how this award will create more opportunities for science and scholarship by our faculty, bridging the two schools.”

KAREN ANTMAN, MD, dean of the Boston University School of Medicine and provost of the medical campus, said, “We are looking forward to substantial progress in HIV research with this important new NIH funded regional collaboration.”

“The expertise of HIV/AIDS and substance use disorders among CFAR partners will allow for the advancement of treatment and research at the intersection of these critical public health issues,” said Boston Medical Center President and CEO KATE WALSH.
Legislative Round-up

Hospitals now required to offer flu vaccines to patients 65 and over
Legislation that requires hospitals to offer influenza vaccinations to their inpatients who are 65 and over has been signed into law.

The new law requires the policy to be in effect during flu season, between Oct. 1 and March 1 of each year. The vaccine will be offered unless contraindicated, and contingent upon the availability of the vaccine, in accordance with the latest recommendations of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention.

Medical consent to minors for prenatal, delivery and postnatal care
A new law now allows minors to consent to medical care involving pregnancy. The law provides that any person, including, but not limited to, a minor who is pregnant, may give effective consent for medical, dental, health and hospital services relating to prenatal, delivery, and post-delivery care.

Dr. Emily White, a Rhode Island obstetrician, gave committee testimony, saying, “Teenage pregnancy is never an ideal situation, but it does happen. And when it does, we want to make sure these young women receive the best medical care. Because of the current law, there can be many barriers to these young women receiving timely and appropriate care.”

Dr. White proceeded to give examples, such as pregnant teens in labor who cannot be given appropriate anesthetic because they have to wait sometimes hours for their parents to be reached to give consent.

With the passage of this legislation, Rhode Island joins 37 other states that already allow the consent of a minor in prenatal and delivery care.

New laws empower patients to curb possibility of opioid addiction
Gov. Gina Raimondo has signed two pieces of legislation that empowers patients to curb the possibility of opiate addiction.

The first law gives patients the option of only partially filling their prescription for painkillers. It allows a pharmacist to dispense a partial fill of a Schedule II controlled substance at the request of either the patient or the prescriber.

Under the provisions of the legislation, subsequent fills would have to be dispensed at the same pharmacy where the original prescription was partially filled, and the total quantity dispensed could not exceed the total quantity prescribed. After 30 days, the prescription expires.

The second law establishes a procedure for individuals to file a revocable voluntary non-opiate directive form with the patient’s licensed health care practitioner. The form indicates to all practitioners that the patient would not be administered or offered a prescription or medication order for an opiate.

The Centers for Disease Control published guidelines for the prescribing of opioids for chronic pain. Among the agency’s recommendations are limiting the dosage and coming up with a plan to mitigate the risk of addiction. While the CDC’s guidelines are a set of voluntary recommendations aimed at health providers, some states have begun to explore how to combat the crisis through legislation. Last year, Massachusetts passed comprehensive legislation based on the guidelines, including the creation of a non-opiate directive form.

Bill requiring insurers to cover mastectomies signed
Legislation to ensure that mastectomies are covered by insurance in Rhode Island has been signed into law. Rhode Island law has set some requirements about what insurance coverage for mastectomies must cover since 2005, but stopped short of actually requiring that insurers cover the procedure.

The new law eliminates provisions that allow insurers not to cover mastectomies, and also eliminates provisions that say they are allowed to require deductibles and copayments.

New law establishes additional home-based care option
Legislation to create a new long-term care option for seniors and people with disabilities has been signed into law by Gov. Gina M. Raimondo.

The legislation establishes in Rhode Island the “independent provider” model of at-home care, which allows consumers to hire and manage caregivers of their choice while the state takes on certain responsibilities, such as setting caregivers’ wages, qualification standards and hours.

By increasing both availability and quality of at-home care options, the new law’s ultimate goal is to move Rhode Island toward greater use of care in the community rather than in nursing facilities, since at-home care is both more comfortable and satisfying for consumers and less expensive than nursing facilities.

Currently around 77 percent of Medicaid funding for long-term services and supports goes to nursing facility care rather than community-based care. Those who use community-based care generally go through agencies or find, hire and manage a caregiver on their own. This bill would create a third option.

Two new laws will increase Narcan availability
Two bills passed by the General Assembly to help prevent opioid overdose deaths through increased access to Narcan have been signed into law.

The first bill requires the Department of Health to develop and distribute best practices guidelines for “co-prescribing” naloxone when also prescribing an opioid to patients who are at an elevated risk of overdosing. It requires the development of strategies for practitioners in non-pharmacy settings to prescribe and dispense naloxone while ensuring health insurance reimbursement.

The second bill amends the state’s Good Samaritan law to allow police and medical personnel to provide naloxone with instructions for its use to individuals who are at substantial risk for an overdose, or a family member or friend.
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VA Mindfulness Study underway for veterans with chronic pain

Researchers at the Providence VA Medical Center are investigating how mindfulness-based care benefits veterans who suffer from chronic lower back pain.

“This work is an important step towards improving outcomes of this and other related mind-body interventions, by helping to understand how they work in the brain,” said Dr. Benjamin Greenberg, associate director of the VA Center for Neurorestoration and Neurotechnology, which is located on the Providence VAMC campus.

Use of the therapy continues to grow as VA and other health care organizations seek alternatives to opiates and other medications for managing chronic pain.

The purpose of the study is to learn how the brain changes in response to mindfulness training by enrolling 30 veteran participants who will receive eight weeks of mindfulness training in weekly two-hour sessions.

“We will look at the EEG and MRI data alongside disability rating scales,” said Dr. Greenberg. “We think the data will change in predictable ways that can help providers refine their use of mind-body therapies to treat not only chronic back pain, but a wide range of issues.”

One cohort of veterans has run through the eight-week mindfulness course and the study is currently running a second cohort.

Dr. Benjamin Greenberg, associate director of the VA Center for Neurorestoration and Neurotechnology, left, and Dr. Armin Zand Vakili, a psychiatry resident, demonstrate using an electroencephalogram to record brain activity with Hannah Swearingen, a health science specialist, at the Providence VA Medical Center recently.

[PROVIDENCE VA MEDICAL CENTER PHOTO BY WINFIELD DANIELSON]

Women & Infants in trial to evaluate performance characteristics for high-volume, non-invasive prenatal testing platform

PerkinElmer, Inc., and Women & Infants Hospital are collaborating to evaluate an innovative test method using the Vanadis® NIPT system, which is under development and not available for clinical use in the United States.

Non-invasive prenatal testing (NIPT) using cell-free DNA (cfDNA) has become the standard follow-up procedure for women classified as high risk following traditional prenatal screening and other national guidelines indicating risk for aneuploidy. Unlike existing NIPT technologies which require more complex platforms such as sequencing or microarrays, the Vanadis NIPT platform is the first of its kind designed to simplify screening for trisomies 21 (Down syndrome), 18 (Edwards syndrome) and 13 (Patau syndrome). This cost-effective, high-throughput scalable platform measures fetal chromosomal trisomies in maternal plasma by labeling and counting specific cfDNA fragments using imaging – removing the costly and data-intensive steps required for sequencing or microarray solutions.

The VALUE (Validation of a Lower Cost Aneuploidy Screen) study is funded through a contract with Women & Infants Hospital, but the design, implementation, analyses and reporting is the sole responsibility of the study staff at Women & Infants. The research study aims to test samples from approximately 2,650 women, most from an average risk pregnancy population, with additional high-risk cases added to determine performance characteristics such as detection rates and false positive rates. Turnaround time, associated costs, fetal sex determination, and quality metrics will also be examined. Women & Infants will serve as the primary study center and laboratory site.

Fourteen enrollment sites across North America are currently participating in the VALUE study.

“We believe that it is important that prenatal screening be under local laboratory control rather than concentrated in a few large commercial laboratories. The Vanadis technology requires less upfront investment as well as non-specialized laboratory space and technicians. It has the potential to be as efficient as current next generation sequencing offerings, yet could be cost-competitive with current serum-based screening,” said Glenn Palomaki, PhD, associate director of the Division of Medical Screening and Special Testing at Women & Infants Hospital and professor in the Department of Pathology and Laboratory Medicine at The Warren Alpert Medical School of Brown University.
Rhode Island expands access to Hepatitis C treatment for Medicaid patients

CRANSTON — The Executive Office of Health & Human Services (EOHHS) and advocates for patients with Hepatitis C (HCV) announced a change to the state’s Medicaid policy that will increase access to life-saving treatment for people living with the virus.

EOHHS and the Rhode Island Department of Health (RIDOH) worked with attorneys from Jones Kelleher, LLP, in conjunction with the Rhode Island Center for Justice, and the Center for Health Law and Policy Innovation of Harvard Law School and with other community partners to make this voluntary policy change. This occurred after the law firms notified Rhode Island officials on behalf of a Rhode Island Medicaid recipient who had been denied treatment for HCV that they were challenging the policy on her behalf and on behalf of other Medicaid patients. The new policy brings Rhode Island in line with federal medical necessity requirements for Medicaid.

Rhode Island’s new HCV policy, now in effect, removes previous Medicaid coverage restrictions for HCV treatment that permitted only those people with severe liver damage or cirrhosis to be covered. Under the new policy, any Medicaid beneficiary living with HCV and requiring treatment will be covered.

This expansion of access to treatment complements RIDOH’s efforts to prevent hepatitis C transmission through the ENCORE needle exchange program, administered by AIDS Care Ocean State, which provides services annually to over 500 clients. In addition, RIDOH funds community-based agencies to conduct rapid hepatitis C testing and link people to care. RIDOH has recently established a relationship with the RI Health Center Association to facilitate improvements in hepatitis C screening, diagnosis, and treatment in Federally Qualified Health Centers that serve low-income patients.

South County Hospital introduces daVinci Xi robot

South County Hospital introduced the latest member of its surgical team recently, the daVinci Xi robot, giving staff and visitors an up close look at robotic-assisted technology.

With the actual model used at South County Hospital for surgical procedures kept in the sterile environment of the operating room, a working demonstration model was brought in by the manufacturer, Intuitive Surgical. Throughout the day, anyone who was curious could sit in the surgeon’s chair and maneuver the robotic arms and attachments as the surgeons do. For this demonstration, daVinci was used to perform functions such as fold and unfold a five-dollar bill, manipulate rubber rings on and off finger-like protrusions, and pick up a coin from a plexiglass surface.

Marking its official introduction to the public, the daVinci robot was used to cut its own ribbon.

The daVinci Xi robotic arm assisted system was installed at South County Hospital in March. After technicians and operating room staff completed a thorough set-up and trial period with the system, the first surgical procedure on a patient was successfully completed on Thursday, May 31.

It will be used in a variety of urologic and general surgeries performed by chief of urology, Joseph Renzulli, II, MD, and general surgeon, Joseph Brady, MD. Other members of the South County Health surgical team have already been selected to receive training to use the daVinci system.
Rhode Island Foundation awards $340K to 16 medical research projects

The Rhode Island Foundation is awarding nearly $340,000 in seed funding to 16 promising medical research projects. The grants are designed to help early-career researchers advance projects to the point where they can compete for national funding.

The Miriam Hospital received $16,000 for a project entitled “Defining Chronic Lyme Symptoms and Quality of Life to Develop Future Interventions.” The project will be led by research scientist SARA VARGAS, PhD. Rhode Island ranks fifth nationally in Lyme incidence, according to the Centers for Disease Control and Prevention.

The University of Rhode Island received $25,000 for “Correlations between Dietary Quality of Food Purchases and Diabetes Prevalence” led by MAYA VADIVELOO, assistant professor of nutrition and food sciences.

The remaining research grant recipients are:

- Bradley Hospital was awarded $25,000 for “tTMS (sic) and EF Training for Working Memory Deficits in Adolescent Psychopathology” led by BRIAN KAVANAUGH, PsyD.
- Brown University was awarded $25,000 for “NMR Structure and Function Studies on Constituents of Promyelocytic Leukemia Nuclear Bodies” led by MANDAR NAIK, PhD.
- The Miriam Hospital received $25,000 for “Counting Kids; Enhancing Detection of Pediatric Tuberculosis in Ukraine” led by NATASHA RYBAK, MD.
- The Miriam Hospital received $11,458 for “A Pilot Study Exploring Powassan Virus Prevalence in Rhode Island” led by REBECCA REECE, MD.
- Rhode Island College was awarded $11,246 for “Understanding the Effects of Metabolism on Protein Folding and Aggregation” led by WILLIAM HOLMES, PhD.
- Rhode Island Hospital received $25,000 for “Novel Diagnostic Approaches to Delirium Detection in Patients with Acute Stroke” led by MICHAEL REZNIK, MD.
- Rhode Island Hospital received $25,000 for “Role of PKD in Right Ventricular Dysfunction Under Pulmonary Arterial Hypertension” led by BONG SOOK JHUN, PhD.
- Rhode Island Hospital was awarded $25,000 for “Challenges in Adolescent Transition to Adult HIV Care” led by SABINA HOLLAND, MD.
- The University of Rhode Island received $21,743 for “Identification of Extemporaneously Prepared Oral Anticancer Therapy Stabilities” led by BRITNY ROGALA, PharmD.
- The University of Rhode Island was awarded $12,321 for “Utilization and Adverse Perinatal Outcomes of P2Y12 Agents in Pregnant Women” led by XUERONG WEN, PhD.
- The University of Rhode Island received $24,911 for “Digital Electrochemistry: Ion-Selective Nanoparticles for Biomedical Analysis” led by JYEOON KIM, PhD.
- The University of Rhode Island was awarded $24,914 for “Appropriate Care and Associated Outcomes in Women with Metastatic Breast Cancer” led by AMI VYAS, PhD.
- The University of Rhode Island received $25,000 for “Novel Biomimetic Inhalable Nanoparticles for Sustained Lung Cancer Drug Delivery” led by XYOTHI MENON, MD.
- Women & Infants Hospital was awarded $16,259 for “Improving Obstetric Care to Underserved Rhode Island Women: Expanding the Role of Prison Health” led by ERIN CHRISTINE BROUSSEAU, MD.

A review panel made up of scientists and physicians assisted the Foundation in reviewing the proposals.
Rhode Island’s updated pain management regulations now require healthcare providers who are writing opioid prescriptions:

1. to have a conversation with their patients on the risks of taking an opioid prescription,
2. indicate the diagnosis code(s) on the prescription,
3. to co-prescribe naloxone to patients at higher risk or overdose.

The regulations apply to anyone who can prescribe a controlled substance including physicians, dentists, physician assistants, and advanced practice registered nurses (APRNs).

In communications about the regulation changes, Rhode Island Department of Health (RIDOH) officials also firmly reiterated to healthcare providers that effective, non-opioid pain management treatments are available with much less risk to patients, and that these treatments should be considered before opioids. These alternatives include non-prescription ibuprofen (i.e., Advil, Motrin) and/or acetaminophen (i.e., Tylenol), physical therapy, chiropractic care, acupuncture, massage, exercise, and cognitive behavioral therapy, among other modalities.

1. The regulations allow for patient education to happen either through a conversation with the patient or in writing. The patient education must include a conversation that includes:
   - Risks of developing dependence and the potential of overdose or death.
   - Risks related to the concurrent use of opioids and alcohol or benzodiazepines. (Benzodiazepines are sedatives, such as Xanax and Valium.)
   - The effect of opioids on one’s ability to safely operate any motor vehicle.

   • Patient’s responsibility to safeguard all opioid medications in a secure location.
   • Alternative treatments for managing pain (non-opioid and/or non-pharmacologic options).
   • Risks of relapse for those who are in recovery from substance dependence.

RIDOH has provided material to healthcare providers in English and Spanish that they can use to guide conversations with patients about the risks of opioids.

2. The requirement that healthcare providers include the diagnosis code on the prescription allows the pharmacists to understand why the controlled substance is being dispensed to the patient. Pharmacists are then able to use this information to have follow-up conversations with prescribers or patients to ensure that patients are being treated with the appropriate medication.

3. Prescribers must co-prescribe naloxone in these three different clinical scenarios:
   - When prescribing an opioid individually or in combination with other medications that is more than or equal to 50 morphine milligram equivalents (MMEs) per day.
   - When prescribing any dose of an opioid when a benzodiazepine has been prescribed in the past 30 days or will be prescribed at the current visit.
   - When prescribing any dose of an opioid to a patient with a prior history of opioid use disorder or overdose. Prescribers must also document in the patient’s medical record the medical necessity of prescribing an opioid to this high-risk individual and explain why the benefit outweighs the risk, given the patient’s previous history.