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$19.5M Grant to Bridge Gaps Between Medical Research, Health Care in RI

With a new five-year federal grant, the Rhode Island Center for Clinical Translational Science will strengthen connections between scientific discovery and health around the state.

PROVIDENCE – Rhode Island’s scientists can deliver the benefits of discoveries more quickly to health care providers and those clinicians can pose more pertinent questions to scientists when they work together closely with broad, deep and cohesive services and support from their academic medical institutions. That’s the vision the Rhode Island Center for Clinical Translational Science (RI-CCTS) will implement with a new $19.5 million, five-year grant from the National Institute of General Medical Sciences.

The grant will allow RI-CCTS to create the educational and technical infrastructure needed to spur Rhode Island researchers to design, conduct and analyze more medical studies, including treatment trials, that build on basic research. The center — based at Brown University in full partnership with the University of Rhode Island and the Care New England, Lifespan and Veterans Affairs hospitals – will also expand the access that medical and public health researchers have to population health data by working with the Rhode Island Quality Institute.

To achieve those aims, RI-CTTS will create a robust foundation of services and supports and fund dozens of pilot projects and training grants to catalyze new clinical research, said DR. JAMES PADBURY, principal investigator and program director of the new center.

“This is an infrastructure grant,” said Padbury, the William and Mary Oh-William and Elsa Zopfi Professor of Pediatrics for Perinatal Research at Brown’s Alpert Medical School and pediatrician-in-chief at Care New England’s Women & Infants Hospital. “We aren’t being awarded resources to target a specific disease but to build the infrastructure to target a wide range of opportunities.

“Nonetheless, with these resources we will be able to support the kinds of advances that have already been taking place in our own research community – for example, new therapies for asthma and muscular dystrophy; technology for cardiac regenerative medicine; methods for pain management; national trials on hormone therapy for menopause; the development of vaccines for malaria; the measurement of the effect of home-delivered meals on loneliness in the elderly; and the identification of the link between the mechanisms underlying preeclampsia and Alzheimer’s disease.”

The funding comes from the Institutional Development Award program at the National Institutes of Health, which has supported many local Center of Biomedical Research Excellence (COBRE) grants dedicated to conducting research in areas ranging from behavioral neuroscience to perinatal medicine, cancer and skeletal health. As those centers around the state have emerged over the last decade, local professors and physicians also began to lay the groundwork to earn a grant that would amplify the ability to pursue clinical research.
“There has been a group of faculty across our various institutions who have worked together on this for quite a while,” said RI-CTTS program coordinator ED HAWROT, Brown’s Alva O. Way University Professor of Medical Science and associate dean of biology. “This has been a great collaboration.”

The structure of RI-CTTS will be built upon seven cores and programs and will create at least 10 jobs, said HELEN LEFFERS, administrative director of the new center. For example, the administrative core will hire four new staff members for functions including communications and finance. As researchers earn funding for pilot projects, they may create additional jobs for the 1–2 year duration of their projects.

- **Administrative Core:** Led by Padbury, Hawrot and Leffers, the center’s administrative core will be housed at 233 Richmond Street and will manage, coordinate and supervise RI-CTTS operations.

- **Pilot Projects Program:** Led by medical professors and Providence VA Medical Center physicians DR. SHARON ROUNDS and DR. MICHELLE LALLY, the core will provide 20 seed grants to multidisciplinary teams of junior researchers and mentors to do new clinical research. At least one project each year will be a clinical trial.

- **Biomedical Informatics Core:** Led by Brown medical professors NEIL SARKAR and ELIZABETH CHEN, this core will provide expertise, training and technological resources to allow for “big data” analyses of medical and genomic data. Sarkar said the grant will accelerate the ability of the Brown Center for Biomedical Informatics to establish a multi-institutional framework for using electronic health data from Lifespan, Care New England and RIQI to enable novel biomedical research opportunities and to support enhanced patient care. This would be among the first such statewide integrations of biomedical, clinical and health data spanning research laboratory, healthcare system and state government sources in the U.S., Sarkar said.

- **Clinical Research Design, Epidemiology and Biostatistics Core:** Led by Brown School of Public Health biostatistics professor CHRIS SCHMID and Lifespan Biostatistics Core Director JASON MACHAN, this core will create a central “storefront” of statewide resources and services, mentoring and training, and tools and methods development for conducting well-designed clinical research.

- **Professional Development Core:** Led by IRA WILSON, chair of health services, policy and practices in the Brown University School of Public Health, the core will provide Mentored Research Awards to three scholars each year. It will also create training programs and develop a statewide mentoring network for clinical and translational research.

- **Clinical Research Resources and Facilities:** Led by Rhode Island Hospital Clinical Research Center Medical Director DR. BHARAT RAMRATNAM, this core will unify the many successful clinical research enterprises among partner institutions (encompassing 700 researchers) into a general Clinical Research Center to share best project management and other practices and to gain cost efficiency in setting up and conducting clinical research.

- **Tracking and Evaluation Core:** Led by University of Rhode Island pharmacy professor CYNTHIA WILLEY and Hasbro Children’s Hospital pediatric immunologist DR. ANTHONY HAYWARD, this core will ensure that the center’s work is aligned with program goals and community needs and uses resources wisely. The core will also track the center’s output and monitor progress and practices to achieve continuous process improvement in the center’s work.

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Alpert Medical School, Hope Hospice & Palliative Care Expand Affiliation

PROVIDENCE – The Warren Alpert Medical School of Brown University and Hope Hospice & Palliative Care Rhode Island have renewed and expanded their affiliation for five more years, the institutions announced Tuesday, July 12. DR. JACK A. ELIAS, dean of medicine and biological sciences at Brown, said the renewal between Rhode Island’s medical school and its largest not-for-profit hospice and palliative care organization emphasizes the importance of training new and future physicians in compassionate care for those who are seriously ill. Brown and Hope Hospice first affiliated in 2012, formalizing a longstanding collaboration under which scores of students and residents receive training every year.

“Comforting and guiding patients and their loved ones at the end of life is an essential responsibility of medical practice,” Elias said.

“We are honored this renewal allows us to continue to train the next generation of physicians to understand the role and importance of caring for those who are seriously ill,” said EDWARD W. MARTIN, MD, MPH, FAAHPM, Chief Medical Officer, Hope Hospice & Palliative Care Rhode Island and clinical associate professor, Warren Alpert Medical School of Brown University.

Hope Hospice President and CEO DIANA FRANCHITTO praised the new accord and the partnership it represents. “We are honored this renewal allows us to continue to train the next generation of physicians to understand the role and importance of caring for those who are seriously ill.”

Among the specific terms of the agreement, Hope Hospice & Palliative Care can now begin using Brown’s logo. The medical school will approve clerkship directors, elective directors and key faculty.
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Women & Infants Research: Women Trust Their Own Instincts When Choosing Breast Cancer Surgery

PROVIDENCE – A research team led by Breast Health Fellow REBECCA M. KWAIT, MD, at The Breast Health Center at Women & Infants Hospital of Rhode Island, recently presented research indicating that when faced with a decision on the type of surgery to have to remove breast cancer, more women trust their own judgment over the input of their surgeon and even their partner.

The manuscript – which is scheduled for publication this fall in the Annals of Surgical Oncology and was presented at the New England Association of Gynecologic Oncologists annual meeting – is entitled “Influential Forces in Breast Cancer Surgical Decision-Making and Impact on Body Image and Sexual Function.” In addition to Dr. Kwait, the research team included: SARAH PESEK, MD; MICHAELA ONSTAD, MD; DAVID EDMONSON, MD; MELISSA A. CLARK, PhD; CHRISTINA RAKER, ScD; ASHLEY STUCKEY, MD; and JENNIFER GASS, MD, co-director of The Breast Health Center and surgeon-in-chief at Women & Infants.

“With the great advances in screening and treatment for breast cancer, leading to prolonged survival rates as high as 98 percent, survivorship outcomes have become an increasingly important consideration among patients. Women must consider quality of life and intimacy after surgery; these become influencing factors when they make decisions about their care,” Dr. Kwait explains.

The proportion of early stage breast cancer patients choosing mastectomy with reconstruction surgery over lumpectomy has been steadily increasing, prompting the team to wonder what factors are driving the decisions. In addition, while there is substantial research available showing the relationship between surgery and a woman’s self-confidence and sexual pleasure, there was nothing identifying who or what influences her surgery-related decisions.

“We know that women feel especially vulnerable when they receive a breast cancer diagnosis and turn to their support system, including their partner,” Dr. Kwait says. “We also know that the greater the support she receives from her partner leads to greater relationship satisfaction and less sexual difficulty in the long run.

“However, the partner’s role in treatment decision-making remained nuanced. No studies to date, that we were aware of, had evaluated the influence of a partner in surgical decision-making.”

Close to 400 women returned surveys as part of the study. Of those, 67.9 percent had lumpectomy; 8.6 percent had a mastectomy; and 23.5 percent had a mastectomy with breast reconstruction. More than 77 percent of participants were in a relationship, and almost 75 percent of those women reported that their partner attended their surgical consultation.

To the researchers’ surprise, the majority of women having a mastectomy identified themselves as the most important influence on their surgical decision (56.6 percent of those having mastectomy with reconstruction, 46.3 percent having a mastectomy, and 42.7 percent having a lumpectomy). Those women who chose a lumpectomy identified their surgeon as the most influential (44.2 percent having lumpectomy versus 39 percent having a mastectomy and 23.2 percent having a mastectomy with reconstruction).

“Only 7.5 percent of patients identified their partner as the greatest influence on their surgical choice,” Dr. Kwait notes. “Yet, within this subgroup, patients who chose a mastectomy with reconstruction valued their partner’s opinion more than those who chose a mastectomy alone or a lumpectomy.”

Post-surgical satisfaction
The researchers also asked about the patients’ satisfaction with their breast appearance and the breast’s role in intimacy both before and after cancer surgery. All levels of satisfaction dropped dramatically after surgery, with a significantly greater decrease in breast intimacy for women having a mastectomy with reconstruction.

“Nearly half of the patients – or 48.6 percent – who chose a mastectomy with reconstruction devalued the breast in intimacy post-operatively,” Dr. Kwait says. “Comparatively, only 20.4 percent of patients who chose lumpectomy experienced this change.

The reason, she says, is simple. “The breast relates to attraction, intimacy and sexuality. A woman must define a new normal for herself and her breasts in survivorship.”

This correlates with their finding that despite most patients making their own surgical choices, the type of surgery they have significantly impacts their romantic relationships. The majority of women surveyed reported that after surgery they were less comfortable undressed in front of their partner and experiencing less pleasure from caresses during intimacy. This was particularly true for patients who were eligible for a lumpectomy but instead opted for a mastectomy with reconstruction.

“Our findings highlighted a need for clinicians to mention specific things as part of the informed surgical consent discussions they have with their patients,” Dr. Kwait notes.
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Legislation Aimed at Preventing Overdose Deaths Signed into Law

New requirements for health care providers, hospitals, insurers

PROVIDENCE – On July 12, Gov. Gina M. Raimondo, joined by Senate President M. Teresa Paiva Weed, Senate Health and Human Services Committee Chairman Joshua Miller, Representative David A. Bennett, legislators, advocates and individuals in recovery, signed a broad, aggressive suite of legislation aimed at preventing drug overdose deaths.

Among other measures, the bills will set opioid prescribing parameters for health care providers, require hospitals to connect overdose victims with treatment and recovery resources, and require insurers to cover life-saving overdose medication.

The bill signing, which took place at a recovery house administered by Bridgemark Addiction Recovery Services, follows the passage of several bills, summarized here:

• Require comprehensive discharge planning for patients with substance use disorders and requires insurers to cover expanded medication-assisted treatment.
• Sets out guidelines for opioid prescribing practices by limiting the length of most first-time opioid prescriptions for acute pain. Requires pharmacies to upload dispensing data to the Prescription Drug Monitoring Program (PDMP) within 24 hours.
• Requires all insurers to cover naloxone and related devices, including in cases where the medication is intended for patients other than the insured.
• Allows the PDMP to be electronically connected to electronic medical records systems.
• Adds Schedule V prescriptions to the PDMP.
• Requires DOH to look for federal funding opportunities to improve the PDMP, such as by adding additional analytical functions and incorporating data from similar programs in other states.
• Authorizes BHDDH to develop a process to certify recovery housing facilities for residential substance use disorder treatment.
• Allows patients to synchronize certain drug refills for chronic conditions by requesting a limited supply (less than 30 days), with pro-rata cost sharing applied by the insurer.
• Allows licensed chemical dependency professionals with the proper training to use treatment known as auricular acu-detox.

Legislation Regulating Freestanding Emergency Rooms Signed into Law

PROVIDENCE – Governor Gina Raimondo has signed legislation that makes freestanding emergency care facilities subject to the same regulatory requirements as other health care facilities.

The law (2016-H 7500A, 2016-S 2696aa) defines freestanding emergency care facilities within state law, and makes them subject to the certificate of need process as well as emergency medical transportation regulations, just like all other medical facilities.

Under existing state law, proposals to build or expand other types of health care facilities are required to undergo a public process to get a certificate of need, which involves assessing the need for the proposal and ensuring that it wouldn’t be harmful to existing hospitals and medical facilities by offering unnecessarily duplicative services. But since freestanding emergency rooms are not currently addressed in the law, an emergency room is able to apply for a license from the Department of Health without a certificate of need, and has only to demonstrate that it is financially sound and capable of providing the services it proposes.
Staying competitive in today’s changing healthcare environment can be a challenge. It may require investing in new technologies, expanding services, even merging with another practice.

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**State Approves PTSD to List of Conditions Approved for Treatment with Medical Marijuana**

**PROVIDENCE** – Recently passed legislation and signed into law adds post-traumatic stress disorder to the list of conditions that may be treated with medical marijuana.


According to a report from the Veterans Administration, nearly 30 percent of veterans who served in the Iraq and Afghanistan wars suffer from PTSD. Some scientists have suggested that marijuana may help PTSD symptoms, which can include anxiety, flashbacks and depression. In a recent study, patients who smoked cannabis saw an average 75 percent reduction in PTSD symptoms.

The law also accelerates the issuance of an approved medical marijuana use application if the patient is eligible for hospice care. It requires the Department of Health to issue a registry identification card to the qualifying patient and primary caregivers named in the patient’s application within 72 hours of receipt of the completed application.

According to the Department of Health, more than 10,000 people in Rhode Island carry medical marijuana cards to treat an approved list of conditions, including cancer, glaucoma, AIDS, hepatitis C, Crohn’s disease and Alzheimer’s, among others.

**First Patient at Kent Receives Subcutaneous Defibrillator System (S-ICD)**

**WARWICK** – Kent Hospital announced recently the successful implantation of its first subcutaneous defibrillator (S-ICD) system for the treatment of patients at risk for sudden cardiac arrest (SCA).

The procedure was performed by **BRUCE A. KOPLAN, MD, MPH**, director of the Cardiac Arrhythmia Service for Care New England. Dr. Koplan, part of Brigham and Women’s Cardiovascular Associates at Care New England, is also the first physician in New England to implant the same device in a patient previously at Brigham and Women’s Hospital in Boston.

Said Dr. Koplan, “As clinical technology continues to advance it allows us to provide our patients with excellent options that are best suited to their specific needs while also improving upon safety and long-term results. The first implant of this lifesaving device here continues to show Kent and Care New England’s ongoing commitment to providing the best possible cardiac care closer to home.”

The U.S. Food and Drug Administration (FDA) granted regulatory approval for the latest S-ICD system in March 2015.

A groundbreaking for a new intensive care unit at the Providence VA Medical Center was held July 22. In attendance were U.S. Sen. Jack Reed; U.S. Sen. Sheldon Whitehouse; U.S. Rep. James Langevin; Providence VA Medical Center Director Dr. Susan A. MacKenzie; and Retired Gen. Rick Baccus, Rhode Island Office of Veterans Affairs.

The new 10,000 square foot ICU, which is expected to be completed July 2017, will provide state-of-the-art equipment, a location adjacent to the surgical suite, and additional space for patients and staff. The facility will incorporate nine inpatient care units, modern nurse stations, modern consultation rooms and adequate family space.