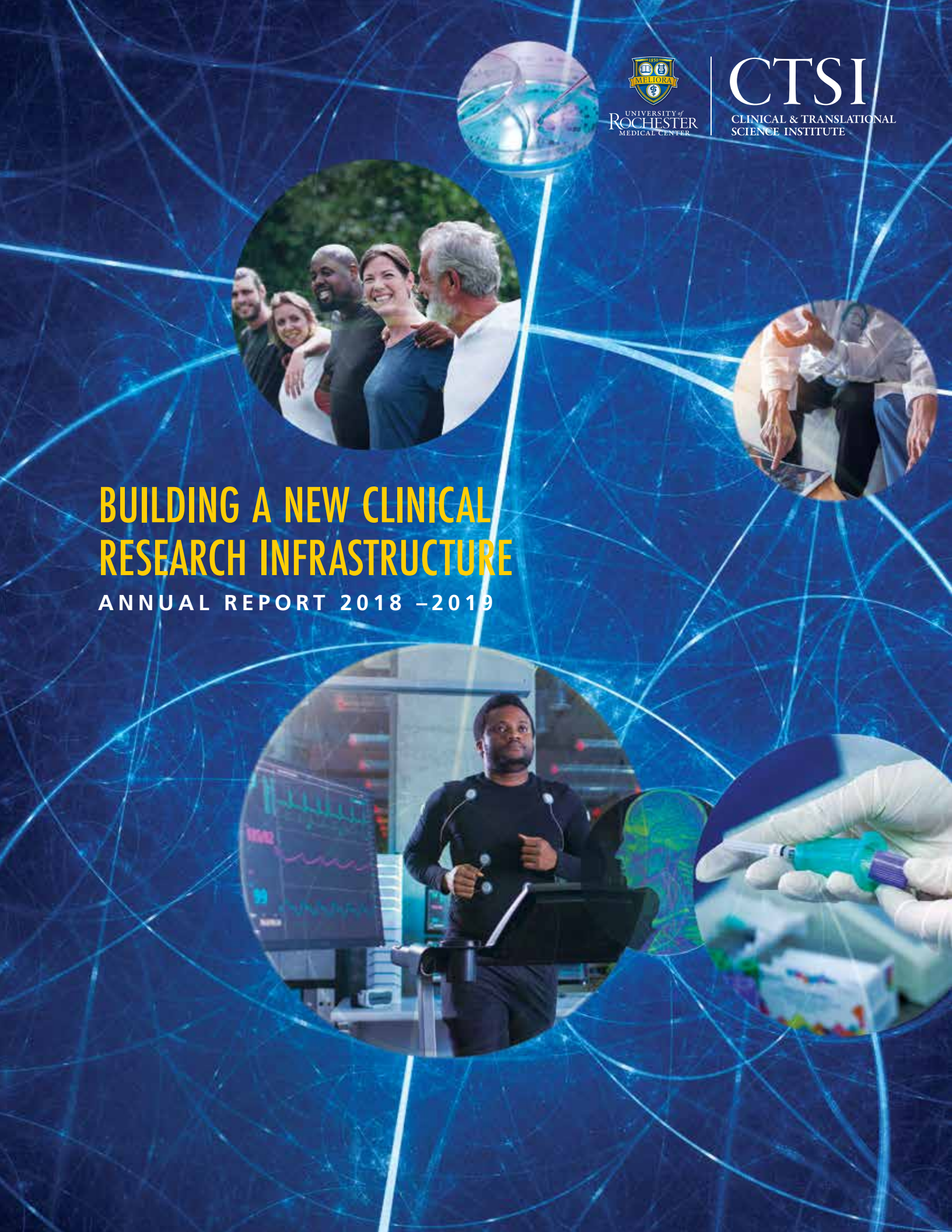


UNIVERSITY of ROCHESTER MEDICAL CENTER

CTSI
CLINICAL & TRANSLATIONAL SCIENCE INSTITUTE

BUILDING A NEW CLINICAL RESEARCH INFRASTRUCTURE

ANNUAL REPORT 2018 –2019

Table of Contents

About the UR CTSI

The UR CTSI helps research teams produce results better, faster and cheaper, with the ultimate goal of improving the health of communities and populations. We link researchers with the connections, resources and education they need for success.

Mission

The University of Rochester Clinical and Translational Science Institute (UR CTSI) develops, demonstrates and disseminates methods and approaches to advance translational research by providing education and training, supporting transdisciplinary teams, improving quality and efficiency, and engaging community and national stakeholders.

Vision

The UR CTSI will be a replicable model environment for research across the translational spectrum, from molecules to populations, that is responsive to community priorities, conducted by transdisciplinary, patient- and community-engaged teams, and that improves population health.

Values

The UR CTSI shares the University of Rochester Medical Center's ICARE values: Integrity, Inclusion, Compassion, Accountability, Respect and Excellence. We believe that exceptional patient care starts with exceptional research.

Integrity

The UR CTSI promotes research that is reproducible, community-engaged and compliant with rules and regulations.

Inclusion

The UR CTSI strives to create an inclusive and welcoming environment for all.

Compassion

The UR CTSI manifests its compassion through our goal of improving population health and reducing health disparities in our communities.

Accountability

The UR CTSI meets the commitments it makes to funders and the community. We are accountable to the University, funding agencies, and local and global communities, for whom we provide research and education programs. We are committed to developing metrics of accountability consistent with these values.

Respect

The UR CTSI actively solicits community input to guide its work and acts upon that input. We respect the differing values of the communities we serve: students, researchers, patients and community members. We are committed to the value of team science, which includes fostering a culture of transdisciplinary respect and active engagement with scientists of every background and perspective.

Excellence

The UR CTSI strives to be a national model for excellence in translational science and research education programs. We are dedicated to training and supporting researchers to enable them to achieve the highest quality of work in their fields. We are committed to excellence in translational research at a national level, balancing efficiency, integrity and timeliness.

UR CTSI Directors' Message

Building a New Clinical Research Infrastructure

This past year was another busy and productive one for the UR CTSI. Our team poured their hearts into an application to renew one of our main sources of funding, we brought our new Office of Clinical Research online and it is now leading a major strategic project for the medical center, and our informatics team has been working tirelessly to develop a Research Data Warehouse that will help researchers access basic and clinical data quickly, easily and securely.

Sustaining Our Work Through Funding

This August, our extraordinary team submitted an application to renew our Clinical and Translational Science Award, which provides nearly $5 million annually to the UR CTSI. Twenty-seven faculty and staff toiled over six months to plan, write and review the 2,000-page application. Thanks to their hard work, we were able to submit a stellar application ahead of the deadline.

Our application lays out a set of ambitious goals to expand our work beyond the walls of the university, and we can't wait to get started.

Leading Clinical Research

The Office of Clinical Research, which got its start in the summer of 2018, is advancing full speed ahead. Now nearly fully staffed, the office is leading the Embark Initiative, an effort to strengthen and modernize clinical research at URMC.

Through Embark, we are building a more cohesive, integrated and supportive clinical research environment. New industry-leading electronic research systems will help our clinical research teams spend less time pushing paper and more time doing science.

By streamlining the administrative work behind clinical trials, we hope to recruit more research faculty and staff, attract more clinical trial sponsors, and empower our research teams to conduct more trials.

Ultimately, our goals are to offer more prevention and treatment options, improve access to cutting-edge therapies, and extend hope and better health to our patients and our community.

Building Better Research Data Infrastructure

UR CTSI Informatics makes our clinical research mission possible by expanding access to data. Working with the Office of Clinical Research, the informatics teams plugged the university into the TriNetX global health research network in April 2019.

TriNetX provides a powerful patient cohort discovery tool that helps researchers identify pools of potential clinical trial participants not only from within UR Medicine, but from across the country. Through TriNetX Trial Connect, URMC researchers have the opportunity to collaborate with other institutions, clinical research organizations and health systems on ongoing clinical trials. In just the first five months of participating in the network, URMC researchers accepted 21 offers to collaborate on clinical trials with a combined potential to impact over 13,000 patients.

The informatics team has also been developing a Research Data Warehouse that will integrate basic science and clinical data. The idea is to make more data more accessible to researchers, so they can "follow the data" across all levels of the translational spectrum – turning clinical data into research insights, and research insights into clinical advances.

The warehouse will provide a full gallery of tools to help researchers access the data they need quickly, easily and

securely. This new and improved research data environment will help us compete for research funding, which often requires this sort of data capability, and will help the university attract and retain research faculty.

Training the Next Generation of Translational Researchers

We continue to expand our graduate and post-graduate education programs, and to help researchers achieve sustainable careers. Over the last year, our efforts have guided many early-stage investigators through graduate and post-graduate training and helped them obtain funding to continue their work translating innovative discoveries into clinical therapies and improved population health. We look forward to the coming year, when we will begin working on several innovative translational science programs for undergraduates, as well as programs to help recent university grads join the translational research and clinical trials workforce.

Looking back at the year behind, we are proud that the UR CTSI is a leader in clinical research and data analytics at the university. Looking ahead, we are excited to move these initiatives forward, bringing the university into a new digital era of clinical research and expanding our efforts beyond the walls of the medical center.

Martin Zand, MD, PhD, and Nancy Bennett, MD, MS, Co-Directors of the UR CTSI

Martin S. Zand, MD, PhD

Nancy M. Bennett, MD, MS

NEW CLINICAL RESEARCH TOOLS

The OnCore clinical trial management system helps research teams manage the administrative work behind a clinical trial - from finances to tracking participant visits.

The eRegulatory Management System helps teams securely store and manage regulatory documents – and meet compliance requirements.

The EVAL Research Evaluation System helps track and demonstrate the impact of URMC clinical research to funders and the public.

The Participant Payments system helps manage stipend and travel reimbursements so our study participants can get paid faster.

The TriNetX global health research network helps researchers identify pools of potential clinical trial participants and join ongoing studies from across the country.

Annual Operational Data

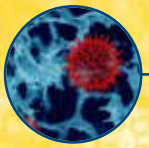
FUNDING TO THE UR CTSI

2018–2019
$14,921,012

LIFETIME*
$117,744,521

JOB CREATION

25 **NEW POSITIONS**
CREATED IN 2018–2019



PILOT & INCUBATOR PROJECT FUNDING

2018–2019
14 **PROJECTS FUNDED**

FUNDING TOTAL
$555,680

LIFETIME*
186 **PROJECTS FUNDED**

FUNDING TOTAL
$7,369,659

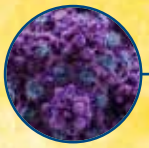
TRAINEE FUNDING

2018–2019
50 **TRAINEES**

FUNDING TOTAL
$1.6M

LIFETIME*
262 **TRAINEES**

FUNDING TOTAL
$16.4M



TRAINEE/GRANTEE EXTRAMURAL GRANTS

2018–2019
10 **EXTRAMURAL GRANTS SECURED**

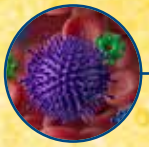
FUNDING TOTAL
$17,082,421

LIFETIME*
169 **EXTRAMURAL GRANTS SECURED**

FUNDING TOTAL
$120,513,666

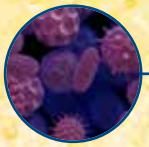
PUBLICATIONS

UR CTSI TRAINEES AND GRANTEES HAVE PUBLISHED **1,433 PUBLICATIONS** TO DATE, WITH **74** IN THE PAST YEAR ON A WIDE RANGE OF TOPICS.



TO DATE, THE UR CTSI HAS:

- **GRADUATED 11 AND ENROLLED 47 GRADUATE STUDENTS** INTO ITS TRANSLATIONAL BIOMEDICAL SCIENCES PHD PROGRAM
- SUPPORTED A YEAR OUT FOR RESEARCH TRAINING FOR **60 MEDICAL STUDENTS** IN ITS ACADEMIC RESEARCH TRACK
- SUPPORTED **21 MD-PHD STUDENTS** IN URMC'S MEDICAL SCIENTIST TRAINING PROGRAM
- FUNDED MENTORED RESEARCH PROJECTS FOR **39 EARLY CAREER FACULTY** THROUGH ITS CAREER DEVELOPMENT PROGRAM



** THE UR CTSI WAS ESTABLISHED IN 2006.*

FUNDING

The UR CTSI provides seed funding to researchers at all career stages to support highly innovative clinical and translational research. Our Pilot and Career Development grants, ranging from $10,000 - $200,000, help researchers gather preliminary information and lay a foundation for future extramurally funded research projects and programs. This early-stage research funding is critical to bridging the gap between scientific discovery and improving human health.

Facebook Groups Could Help Keep People Healthy as They Age

By 2020, there will be more people on earth over the age of 65 than ever before. As the older adult population balloons, so will the number of elder orphans: people 65 and over who live alone with no spouse, companion or children nearby to help them with health decisions, expenses or transportation to and from appointments.

Approximately 13.3 million noninstitutionalized older adults live alone and are at risk for social isolation. Isolated adults are 64 percent more likely to develop dementia and are at greater risk of cognitive decline due to lack of mental stimulation. But the health effects of social isolation extend beyond mental health.

Social isolation can be just as bad as living with a serious long-term illness like diabetes and can increase the risk of high blood pressure and obesity. In fact, the lack of social connections has been shown to have the same impact on your health as smoking 15 cigarettes per day. As a result, socially isolated adults are more likely to visit the doctor, in part just to have human contact, and are more likely to be placed on medication, which adds pressure to the healthcare industry.

Jessica Francis, PhD, a UR CTSI Population Health Research postdoctoral fellow, studies how technology and social media can help combat social isolation and promote access to support for vulnerable populations, such as elder orphans and individuals with Parkinson's disease. Through surveys, interviews and focus groups, she gathers information about their technology use, attitudes toward technology and well-being.

During her recent research, Francis, who works in the UR Center for Health + Technology, measured feelings of loneliness, perception of self, and engagement with and preference for types of technology to determine how participating in virtual communities and Facebook groups impacts these populations.

Francis found that communicating within Facebook groups and other virtual communities can help vulnerable populations seek support, share stories, promote well-being, build a community, stay connected and maintain health as they age.

Dads' Background, Education Impact Babies' Health at Birth

A father's education level, age, and race or ethnicity can have a bearing on how healthy their children are at birth, according to a UR CTSI-supported study.

The study showed babies were most at risk for negative birth outcomes if their dads had less than a high school education. Compared to fathers who had more than a high school diploma, fathers who hadn't finished high school had:

- About a 35 percent greater chance of having a premature newborn
- Nearly 50 percent greater odds of having a low birthweight child (both major causes of infant mortality)
- And that was true regardless of moms' education level – suggesting that at least some paternal factors could be better predictors of poor birth outcomes than maternal factors

"Paternal information is routinely collected during prenatal checkups, but this information has not been utilized to predict birth outcomes," said study author **Ying Meng, PhD**, assistant professor at the University of Rochester School of Nursing and former UR CTSI Population Health Research postdoctoral fellow. "Our study suggests we might be able to make those predictions and prevent negative birth outcomes with programs that focus on – or at least include – fathers."

Meng and study co-author **Susan Groth, PhD**, associate professor at the University of Rochester School of Nursing, examined a decade's worth of birth certificates – nearly 37,000 – to find links between paternal factors and negative birth outcomes while controlling for maternal conditions like employment, gestational diabetes or hypertension, smoking, etc. They focused on major causes of infant mortality like premature birth, low birthweight, and babies born small for their gestational age, as well as high birthweight, which is linked to long-term health issues like obesity.

Their study shows several strong links between paternal factors and poor birth outcomes, which they hope might lead to new social programs that would encourage high-risk dads to play a more active role in prenatal care. For example, programs might provide support and information about how to lower the risk of preterm birth and low birthweight to dads with less than a high school education.

"There are few interventions that include fathers – and most aren't focused on birth outcomes," said Groth. "Future policies and programs targeted at improving birth outcomes should engage fathers in prenatal care."

Vaping Linked to Wheezing in Adults

A new study authored by **Deborah J. Ossip, PhD**, a tobacco research expert and professor of Public Health at the University of Rochester Medical Center, uncovered a link between vaping and wheezing in adults.

People who used electronic cigarettes were nearly twice as likely to experience wheezing — which is often a precursor to other serious health conditions — compared to people who didn't regularly use tobacco products, according to the study funded in part by the UR CTSI.

According to Ossip, the findings are consistent with past research. "The take-home message is that electronic cigarettes are not safe when it comes to lung health," said Ossip, who is also co-director of the UR CTSI's Center for Leading Innovation and Collaboration. "The changes we're seeing with vaping, both in laboratory experiments and studies of people who vape, are consistent with early signs of lung damage, which is very worrisome."

Lead study author **Dongmei Li, PhD**, associate professor in the Department of Clinical and Translational Research, and other colleagues at URMC analyzed data from more than 28,000 adults in the U.S. who took part in the Population Assessment of Tobacco and Health (PATH) study. After adjusting for age, gender, race/ethnicity, body mass index, secondhand smoke exposure and other factors, adult vapers were 1.7 times more likely to experience wheezing and related respiratory symptoms, such as difficulty breathing, compared to non-users.

Senior study author **Irfan Rahman, PhD**, professor of Environmental Medicine at URMC, said the research clearly identifies another health repercussion from vaping. This is particularly concerning given new data released from the Center for Disease Control and Prevention that shows a dramatic uptick in youth vaping. According to the report, in 2018 vaping increased by 78 percent among ninth to 12th graders and 48 percent in sixth to eighth graders.

With the emergence of small, sleek vaping devices like JUULs that are used with nicotine pods in hundreds of different flavors such as fruit, candy and dessert, Rahman fears the number of young people who vape will continue to grow – which could result in serious health consequences, including allergies, loss of immunity and subsequent infections.

Research reported in this study was conducted by the Western New York Center for Research on Flavored Tobacco Products, a program led by scientists at the Roswell Park Comprehensive Cancer Center in Buffalo, N.Y., and URMC.

From Sustaining a Concussion to Conducting Groundbreaking Brain Injury Research

As a young boy growing up in Somalia, **Adnan Hirad, PhD**, was playing with other children one day when he fell into a ditch and hit his head. People around Adnan didn't know what was wrong with him when he lost consciousness. It turns out, he had suffered a concussion.

Adnan didn't give any thought to concussions after that day until years later, when, as a medical student, he attended a presentation about football players and the incidence of concussions by **Jeffrey Bazarian, MD, MPH**, professor of Emergency Medicine, Neurology, Neurosurgery and Public Health Sciences at the University of Rochester Medical Center. Reminded of his experience as a boy, Adnan asked about the long-term health effects of a single concussion.

Learning that there isn't enough information to determine long-term prognosis piqued Adnan's interest. Then an MD/PhD trainee in the UR CTSI's Translational Biomedical Science PhD Program, he applied for a UR CTSI pilot research grant to find a target region for diagnosing concussive brain injury and to form a prognosis of what happens to the brain after multiple hits to the head. The UR CTSI's Pilot Studies Program funded the project, which supplemented existing sports concussion research that began in 2013.

The midbrain was identified as the study target area based on:

1. its association to functions affected by a concussion, such as eye movement and sleep;
2. its unique susceptibility to concussive force; and,
3. its relationship to neurodegenerative disease in people who have been hit in the head numerous times, such as chronic traumatic encephalopathy (CTE).

Diffusion Tensor Imaging (DTI) scans were conducted on 38 University of Rochester football players, both before and after three football seasons. The players wore helmet sensors that captured all hits above 10g force sustained during practices and games, the approximate acceleration of a person hopping off a step or plopping down into a chair. Only two of the players had sustained a concussion during the season. DTI captures large amounts of quantitative data about the condition of white matter — the connections to the brain — for each subject. That data must be decoded and interpreted, then correlated to the impact data from the sensors.

Analyzing all the DTI data from the three seasons through the lens of long-term effects of hits to the head was central to the research. The UR CTSI pilot grant provided funding for the project, including the resources to build computational architecture needed to conduct the data-intensive analyses.

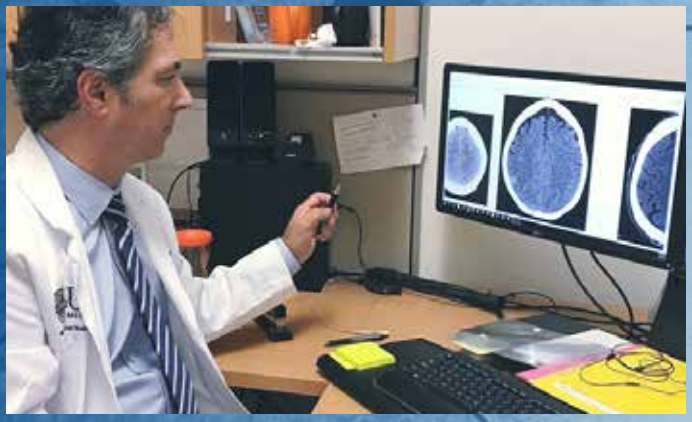
The study, published in *Science Advances*, found that repetitive sub-concussive head impacts–which may not show the signs or symptoms of a concussion–result in structural damage in the midbrain. Rather than being caused by linear force, these structural changes are primarily related to rotational force. Perhaps most striking, there was a significant decrease in the integrity of the midbrain white matter following just one season of football as compared to the preseason.

"While not disputing the fact that head-injury effects are distributed throughout the brain, our findings show that the midbrain may serve as a 'canary in a coal mine' in terms of identifying damage from both concussions and repetitive head hits," Hirad said. "From this study, we know that the midbrain region– because of its link to brain functions often affected by a concussion – is the place to look to identify the impact of non-symptomatic brain injuries."

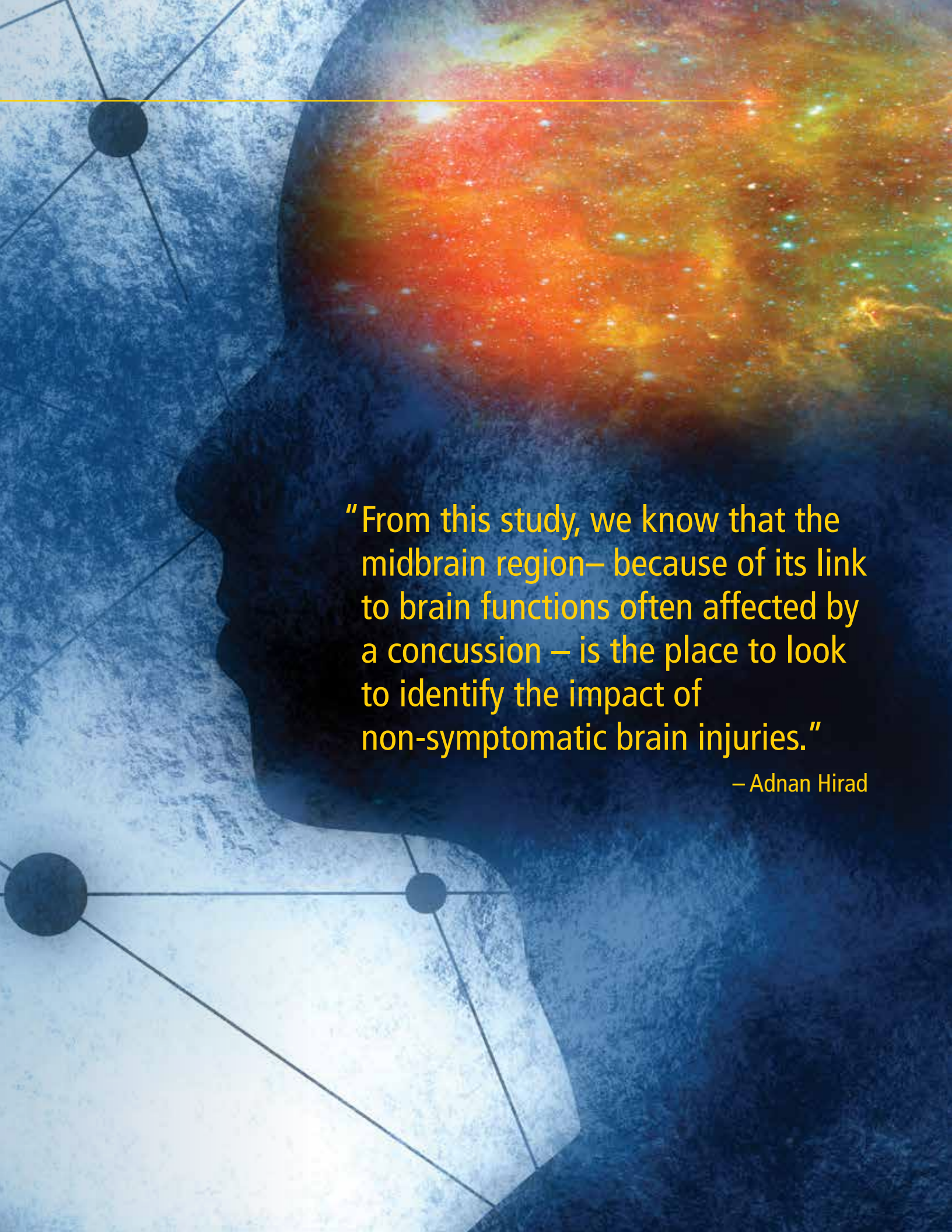
Having completed his PhD and currently in his fourth year of medical school, Adnan plans to conduct further research on the brain. He sees the next stage of the research as clarifying why and how the midbrain is uniquely susceptible to concussive injury.

Photo courtesy of Carnegie Mellon University

Adnan Hirad, PhD



Jeffrey Bazarian, MD, MPH



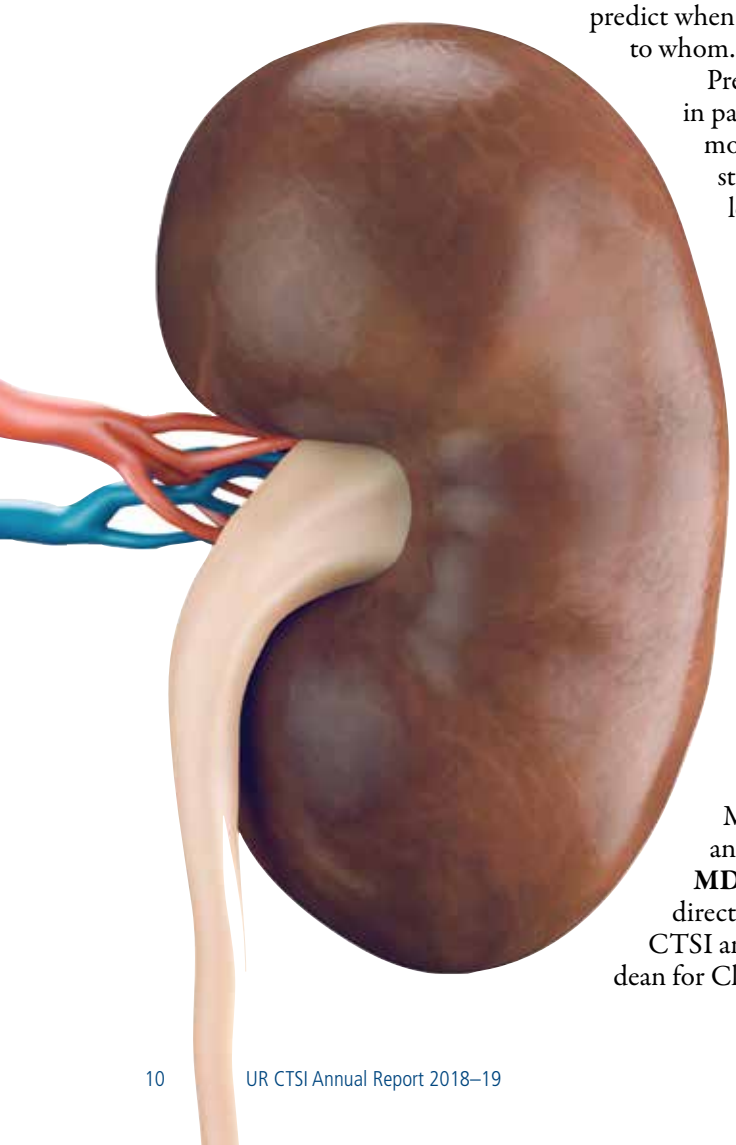
"From this study, we know that the midbrain region– because of its link to brain functions often affected by a concussion – is the place to look to identify the impact of non-symptomatic brain injuries."

– Adnan Hirad

EDUCATION

The UR CTSI is dedicated to training the next generation of clinical and translational researchers. With educational programs tailored to pre- and post-doctoral students, faculty at all career stages and research staff, we have something for everyone. Our offerings range from certificate programs and week-long, intensive trainings to a fully accredited doctorate program.

UR CTSI-Supported Study Aims to Predict, Prevent Acute Kidney Injury



Acute kidney injury, a sudden decline in kidney function, occurs frequently among hospitalized patients, causing serious, long-lasting effects and even increased risk of death. It is often preventable, but we lack the ability to reliably predict when it will happen and to whom.

Prediction is difficult in part because most previous studies have only looked at single hospitalizations for all patients – ignoring past patients' data. Those studies missed the opportunity to discover health factors or patterns that reliably precede acute kidney injury.

Samuel Weisenthal, a University of Rochester Medical Center MD-PhD student, and **Martin Zand, MD, PhD**, co-director of the UR CTSI and senior associate dean for Clinical Research at URMC, took a different tack, focusing on re-hospitalized patients. The pair and their colleagues analyzed electronic health record data from 34,000 patients' prior hospitalizations to develop a risk score for acute kidney injury that could help doctors intervene and prevent it. They identified factors that predict acute kidney injury and used machine learning to develop a risk score that could be calculated for patients at the time of re-hospitalization.

"Developing an accurate risk index for acute kidney injury in re-hospitalized patients could have a major impact on hospital care, particularly if it could allow preventive intervention or better tailored treatments from the time of hospital admission," said Zand.

With early risk identification, a variety of preventive strategies can be implemented. For example, acute kidney injury caused by radiocontrast dye or chemotherapy can be prevented by administering fluids or altering a patient's treatment plan. When these factors are adjusted accordingly, patients fare better, and the cost and length of stay can be decreased.

While such predictive systems require extensive validation before clinical deployment, this work is a step toward creating acute kidney injury predictions, specifically for re-hospitalized patients.

"This study will hopefully help move us in the direction of an automated, locally-trained tool that leverages sometimes hidden, longitudinal electronic health record data to estimate acute kidney injury risk without manually ordering tests or collecting and entering data," Zand added.

TBS Program Director, Members Recognized for Contributions to Community and Research

Timothy D. Dye, PhD, director of the UR CTSI's Translational Biomedical Science (TBS) PhD Program, and two TBS students, **Hanna Murphy** and **Raven Osborn**, were recognized for their contributions to research and the community in the fall of 2019.

Dye, who also serves as associate chair of Obstetrics and Gynecology at the University of Rochester Medical Center, was awarded the URMC Faculty Diversity Award. Established in 2013, the award recognizes the contributions and accomplishments of medical school faculty who demonstrate an exceptional commitment to the values of diversity, inclusion, and multiculturalism in the medical school community. This award included a $500 prize, which Dye's team donated to UR Street Outreach, a medical school program that brings medical care to Rochester's unsheltered homeless population.

Dye is a medical anthropologist and social epidemiologist who specializes in applied public health, particularly within marginalized, isolated, and global populations, and with a focus on social and cultural determinants of health. His research focuses on developing and understanding community-driven solutions to public health problems and brings this knowledge and commitment to his students.

Senior Associate Dean for Graduate Education **Richard Libby, PhD**, awarded the Dean's Admissions Bonus Award to Hanna Murphy for her outstanding merit and promise for future contributions to her field. Murphy is pursuing a doctorate in the Infection and Immunity: From Molecules to Populations (IIMP) track of the TBS program. The award included a $1,000 bonus.

Raven Osborn received the Medical & Graduate Student Achievement Award: Dr. Marvin J. Hoffman Award for Community Outreach. Osborn is a leader in the Rochester Young Scientists Club, where she helps develop curricula for fifth- and sixth-grade students from Nathaniel Rochester Community School No. 3 to get them thinking like scientists. The program includes mentoring the students, tours of laboratories at the URMC, and a public poster session where the students present their original projects to family and friends.

The awards were presented during the University of Rochester School of Medicine and Dentistry's convocation ceremony.

Timothy D. Dye, PhD

Hanna Murphy

Raven Osborn

Spike Patterns May Help Identify Networks Generating Epileptic Seizures

Patients with epilepsy can spend days or even weeks undergoing highly invasive pre-surgical evaluation. The procedure involves surgically implanting electrodes into the brain and waiting for a seizure to occur.

What if a patient could go from weeks of invasive monitoring to just a half-hour of recording?

Samuel B. Tomlinson, a fourth-year medical student at URMC, and his mentor, **Eric D. Marsh, MD, PhD**, associate professor of Neurology and Pediatrics at the Children's Hospital of Philadelphia, study interictal spikes – electrical activity that occurs between seizures and could help identify seizure origin without the long wait.

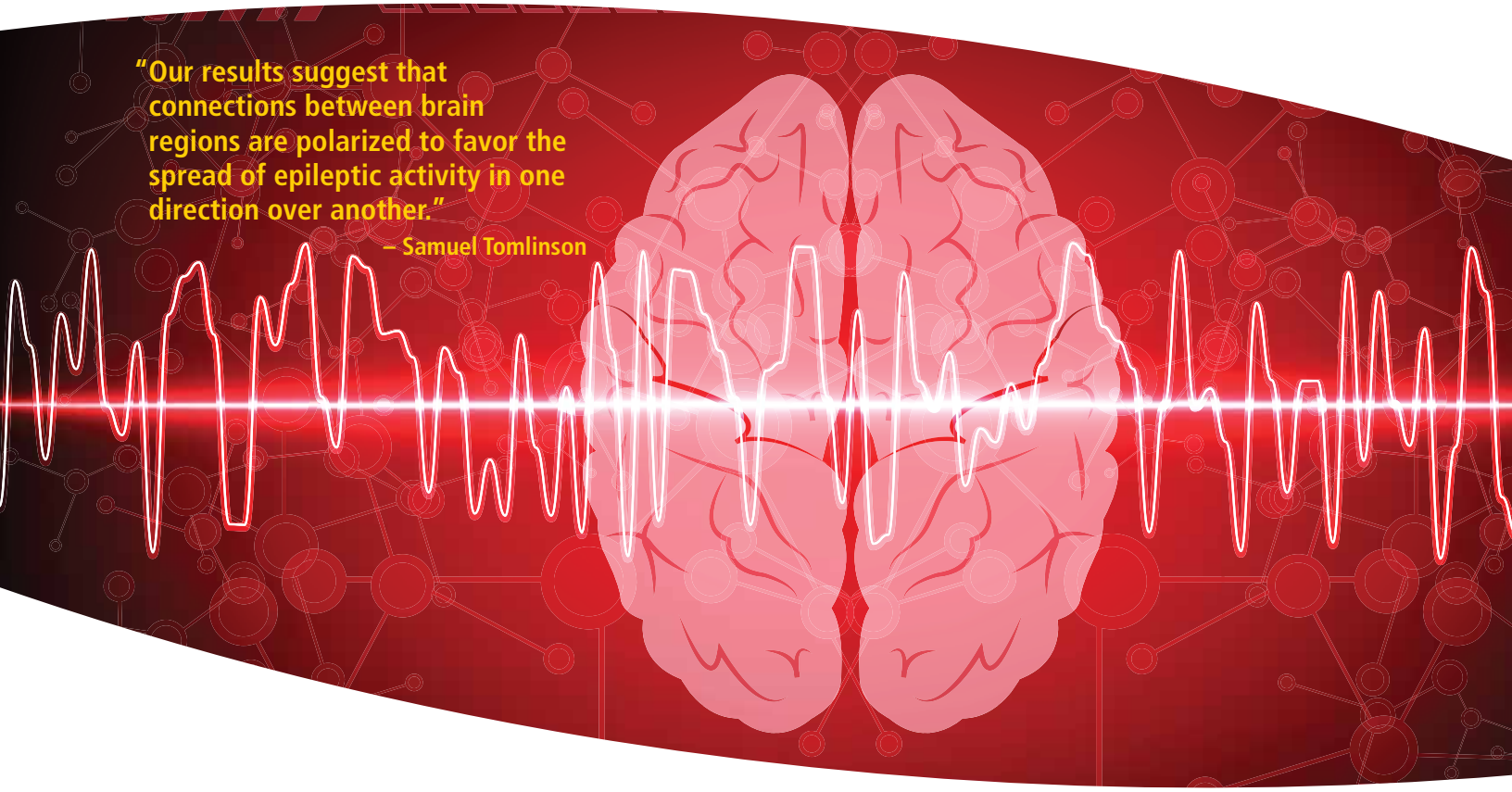
Marsh and Tomlinson have published a series of research papers on this subject since 2012, when Tomlinson was an undergraduate student at Swarthmore College. Their latest research, which was funded by **the UR CTSI through its Academic Research Track Program** and appeared in *Epilepsia*, explored the long-term reproducibility and stability of interictal spike patterns over time.

Using invasive electroencephalography (EEG) recordings captured from the surface of the cortex, the latest research focused on whether electrical recordings of the brain can identify the networks generating epileptic seizures.

Analyzing the EEGs of 12 children with refractory epilepsy enabled the researchers to determine that interictal spikes propagate through highly-reproducible trajectories across the epileptic cortex. "We believe that these trajectories contain information about the underlying circuitry of the patient's seizure network," Tomlinson said. "In particular, our results suggest that connections between brain regions are polarized to favor the spread of epileptic activity in one direction over another."

"During the past year's research, we found that spike propagation patterns are incredibly stable, which tells us that the network underlying them has certain fixed properties," Marsh added. "Local spike modules all have a pattern among themselves, which relate to triggering an epileptic seizure."

Marsh and Tomlinson see their latest research on interictal spikes as an extension of their long-term effort to understand the pathophysiological mechanisms of seizures. For Tomlinson, this project is the latest evolution of his interest in translational research that improves the surgical approach to epilepsy. He plans to continue this work during his journey to become an academic neurosurgeon.



CLINICAL RESEARCH

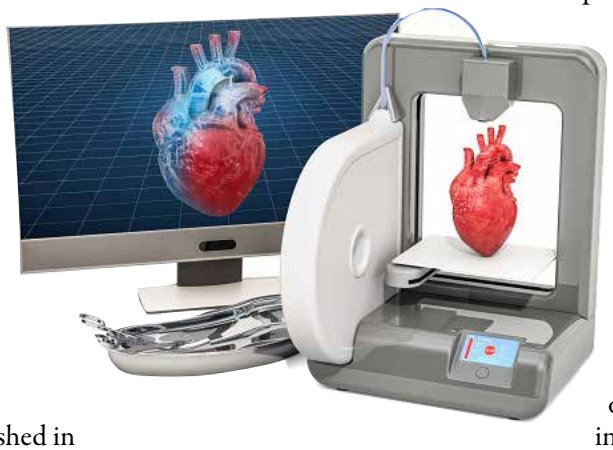
From dedicated clinical research space and staff, to industry-leading clinical trial management tools, the UR CTSI helps research teams conduct clinical trials and other health research studies. We connect researchers with clinical trial opportunities and staff to support studies, help attract and keep study participants, and navigate regulatory hurdles.

3D Printing Can Produce New Organs, But How Do We Regulate It?

Scientists can now use 3D printing to produce realistic organs to practice surgeries, bio-matrices to support damaged tissues, or even new ears to replace those that are injured or affected by congenital birth defects.

Yet, as the promise of 3D-printing technology expands into the medical field, so does the need for appropriate regulation of these products by the Food and Drug Administration (FDA).

A discussion about the emerging science and regulatory considerations of 3D printing began in the fall of 2017. A subgroup of participants led by **Joan Adamo, PhD**, director of Regulatory Support Services at the UR CTSI, and **Scott Steele, PhD**, director of UR CTSI Regulatory Science Programs, furthered this discussion with findings and recommendations published in the *Journal of Clinical and Translational Science*. This article was part of a broader effort initiated by the UR CTSI and the Regulatory Science to Advance Precision Medicine Working Group of the Clinical and Translational Science Awards (CTSA) Program.



The biggest challenge to assess the safety and efficacy of 3D printing medical technology, according to Adamo and Steele, is that the field is rapidly evolving. New uses for this technology will likely be developed faster than appropriate regulation can be analyzed and established. Therefore, it is important to consider exactly which steps in the process are being regulated, and who is responsible for each step.

For a single 3D-printing process, there may be several articles to regulate, each offering a separate regulatory path to licensing, clearance or FDA approval. The "ink" used in 3D bio- printing, which is often composed of cell-based or cell-derived material; the hardware and software to design the printed product; and the printed product itself are all logical points of regulation. The authors recommend regulating these emerging technologies where it will have the broadest impact on future technologies.

To help regulatory science keep pace with rapidly advancing 3D-printing technologies, the authors recommend developing educational opportunities. By training individuals in the process, development and regulatory science of 3D-printing, the group believes regulation will develop at a similar speed as the technology.

The 3D-printing field represents an exciting avenue for medical advance. Ensuring that the technology makes it to patients in a safe and consistent manner will take work. Fortunately, stakeholders from government, industry, academia and nonprofit sectors are already working together to ensure the future workforce is well educated, and these new technologies can reach patients as quickly as possible.

TriNetX Network Helps URMC Attract More Clinical Trial Sponsors

In April of 2019, the University of Rochester Medical Center joined the global TriNetX network, which provides research institutions and industry partners with real time access to longitudinal clinical data. This partnership, which was spearheaded by the UR CTSI, has already greatly expanded the medical center's access to advanced clinical trials.

The network enables potential industry sponsors of clinical trials to get patient counts from URMC to see if we have a patient population that meets criteria for a specific clinical trial. In URMC's first five months in the network, pharmaceutical companies invited us to take part in 32 clinical trials and the UR CTSI's Office of Clinical Research has connected researchers with 21 of those studies, posing a great potential benefit for our patients.

TriNetX is also a tool, implemented in partnership with URMC's Information Systems Division, that can help URMC researchers identify potential participants for their own clinical studies.

Using the TriNetX tool, researchers can search a limited dataset from about 1.5 million UR Medicine electronic medical records, and easily filter their results without having to re-build their search. That limited dataset includes information like demographics, diagnoses, procedures, medications, labs and more.

"Our goal in joining this network is to bring high quality, cutting-edge clinical trials to URMC for the benefit of our community," said **Martin Zand, MD, PhD**, senior associate dean for Clinical Research at URMC and co-director of the UR CTSI.

TriNetX provides access to longitudinal clinical data in near real time and uses state-of-the-art analytics to help researchers identify potential study participants based on specific criteria. Researchers can use the TriNetX tool to see how many patients meet their study's criteria and can help them adjust their criteria to ensure they can recruit a large enough pool of participants.

The system provides visually appealing and easy-to-understand graphs and charts, showing not only historical data from patient visits but also predictions of future patient enrollment opportunities.

"This new tool makes clinical data more accessible, helping researchers develop hypotheses and test the feasibility of their studies," said **Jeanne Holden-Wiltse, MPH, MBA**, director of Informatics at the UR CTSI.

COLLABORATION

The UR CTSI provides research teams with various opportunities to partner with other clinical or translational researchers—both near and far—as well as physicians, research staff and the community. We help you make connections that can move your research forward.

Improving Doctor-Patient Discussions About Drug Costs

Many patients struggle to comply with their doctors' orders because they cannot afford their medications. Yet, many doctors fail to discuss drug-cost concerns with their patients.

According to a study conducted in collaboration with the UR CTSI's Greater Rochester Practice-Based Research Network (GR-PBRN), a simple, one-hour training session on the importance of these conversations could help turn this around.

Published in the Annals of Internal Medicine, the study suggests physicians and staff are more likely to discuss drug costs with their patients after attending a one-hour training session covering how important drug costs are to patients, how to screen for patients in need and how to help patients save money on medications. The training nearly doubled the rate of cost-of-medication conversations in six of seven primary care practices involved in the study – from 17 percent to 32 percent.

GR-PBRN is a network of 147 primary care practices who work together to address community-based healthcare issues and improve clinical practice. Five GR-PBRN member practices participated in the study: Canalside Family Medicine, Culver Medical Group, Penfield Family Medicine, Rochester Internal Medicine Associates and Clinton Crossings Internal Medicine.

"It is important for patients to understand they have options and that their doctor does not want the cost of medications to be a burden that prevents them from taking them. This training is a way to provide physicians and practice staff with tools for broaching the topic with patients," said lead study author **Kevin Fiscella, MD, MPH**, co-director of the GR-PBRN and professor of Family Medicine and Public Health Sciences at the University of Rochester Medical Center.

Other URMC researchers involved in the study included **Subrina Farah, MS; Robert J. Fortuna, MD, MPH; Mechelle Sanders, BA; and Jineane V. Venci, PharmD.**

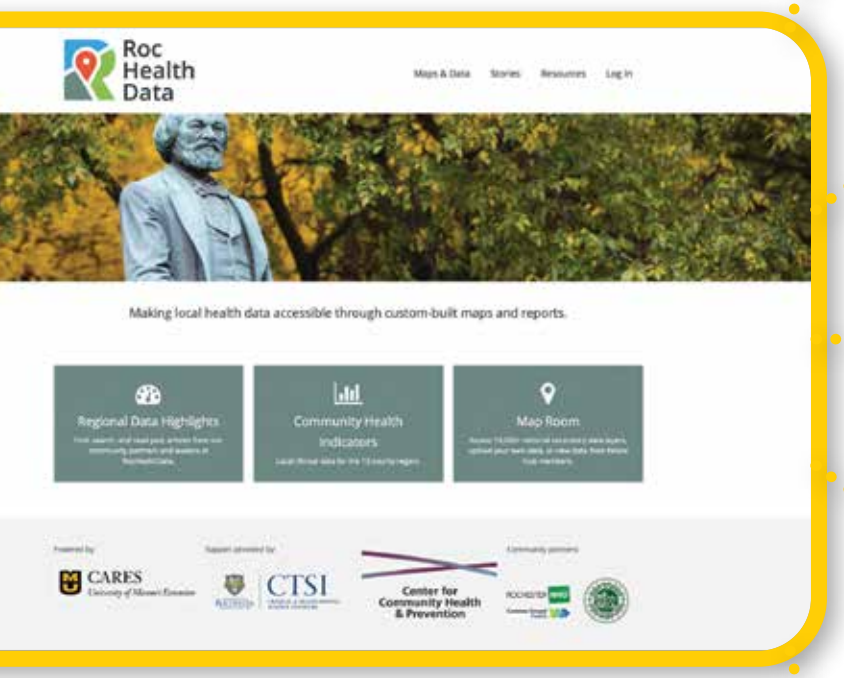
Now that the study showed that training can increase the frequency of drug-cost conversations, the researchers' next step will be to see whether those conversations helped patients comply with their doctors' orders – to help achieve the ultimate goal of improving health.

New Website Highlights Regional Health Outcomes

A new website supported by the UR CTSI and the Center for Community Health and Prevention enables health researchers and community partners to map local health outcomes and social determinants of health.

RocHealthData.Org contains extensive information on the region's health challenges and resources, shown in both map and report formats, with advice and input from Common Ground Health, the Monroe County Department of Public Health, and the Rochester Regional Health Information Organization (RHIO). Data are built within the CARES Engagement Network, a publicly accessible data-sharing platform containing thousands of layers of mapped data.

The local hub site uses this national information backbone to build a site for local data and allows users to generate maps by geographical area and topic, such as food insecurity, tobacco use or mental health status.



Researchers and community partners who register at the site may also share data in report or map form with the larger community, which is often required by funding agencies.

Never-before-presented clinical measures of the region's health — from the Rochester RHIO's Community Health Indicators Report — are also available at the site. The 13-county data report contains health measures including obesity, prevalence of smoking, blood pressure control rates and diabetes-control rates. This is the first local population health dataset that makes clinical data available at a granular level – by county, by age and by sex. The report also includes full-year 2017 anonymous data with more than 600,000 observations. These data will be updated annually.

The site also highlights hub members' research each month. Previously the site has featured projects that map cancer rates across our region to better inform care and prevention efforts, provide helpful tools for asthma sufferers, and help communities members find anything from their closest farmers market to convenient fishing and kayaking spots.

Renewed CDC Funding Allows Expansion of Deaf Health Research

The Centers for Disease Control and Prevention recently awarded $3.75 million in funding to the Rochester Prevention Research Center: National Center for Deaf Health Research (NCDHR), which is located within the UR CTSI.

This renewed funding will enable the center to continue its important research and community-outreach efforts in Rochester and to expand its programming to Deaf communities in Buffalo and Syracuse over the next five years. One such program is Deaf Weight Wise, which aims to combat obesity among Deaf ASL-users and scientifically track success.

With the new funding, NCDHR will partner with community-based organizations in all three cities to run Deaf Weight Wise and train new program counselors. This work will be done by Deaf counselors, and all program research materials, including curricula, surveys and interviews, will be adapted and translated into ASL.

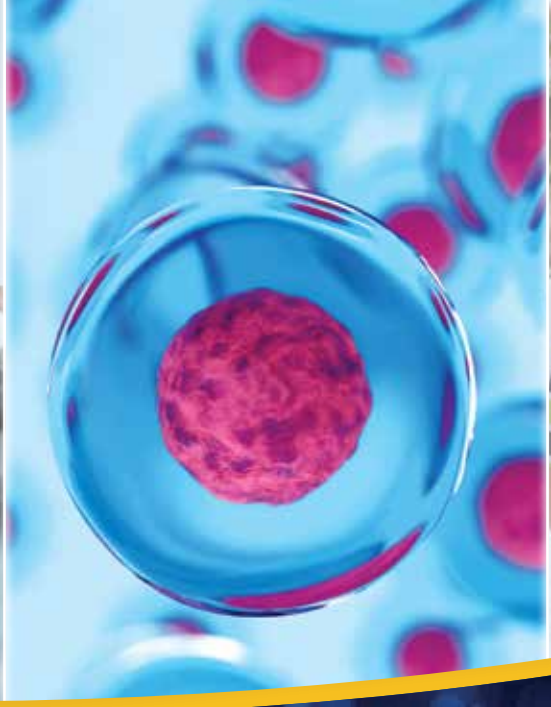
"We greatly appreciate our partnership with the CDC, to eliminate health disparities among Deaf sign language users and people with hearing loss," said **Stephen Dewhurst,** PhD, associate vice president for Health Sciences Research at URMC. "This latest award begins the 16th year of consecutive funding as a Prevention Research Center and is a testament to the outstanding work of NCDHR's leadership and staff. It will enable us to continue and expand our collaborations with Rochester's Deaf community, and the national Deaf community at large."

NCDHR is the only research center in the world that works with Deaf sign language users and people with hearing loss to promote health and prevent disease through community-based participatory research. It is one of 25 institutions to receive the latest round of awards from the CDC's Prevention Research Centers program, a network of academic researchers, public health agencies and community members that conducts applied research in disease prevention and health promotion.

dww 2.0
{deaf weight wise}

HL2 Workplace Tool-Kit

This work is a product of a Health Promotion and Disease Prevention Research Center supported by Cooperative Agreement Number 5 U48DP005026-05 from the Centers for Disease Control and Prevention. The findings and conclusions in this article are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention.


What is the UR CTSI?

The **University of Rochester Clinical and Translational Science Institute (UR CTSI)** is the research engine for the University of Rochester Medical Center (URMC), helping research teams work faster and better. Investigators, research coordinators and administrators will all find helpful programs and services at the UR CTSI, which is located in URMC's Saunders Research Building.

Not sure what you need, or how to find it? Contact the Research Help Desk at ***researchhelp@urmc.rochester.edu*** for access to research-related services and expertise provided by the UR CTSI and many other organizations across the University.

Planning a new study? Get a roadmap of helpful services and required approvals.

Need space or experienced staff for your clinical study? The Clinical Research Center, conveniently located in the medical center, provides dedicated research space and skilled nurses, research nutrition staff, and study coordinators for inpatient and outpatient research studies.

Find out what's happening! The UR CTSI Weekly Update starts your week off right with research-related news, events and funding opportunities. The UR CTSI Stories blog provides useful information on programs, services and more. Follow the UR CTSI on Facebook, LinkedIn, Twitter and YouTube. Check the UR CTSI website, ***ctsi.urmc.edu***, for all the details.

Support our work! Consider making a donation to the UR CTSI at giveto.urmc.edu/ctsi.

UNIVERSITY of ROCHESTER MEDICAL CENTER

CTSI
CLINICAL & TRANSLATIONAL SCIENCE INSTITUTE

Clinical and Translational Science Institute
Saunders Research Building, Suite 1.200
265 Crittenden Blvd, | Rochester, NY 14642-0708
(585) 275-0653 | ctsi.urmc.edu |