

SimplCath • Rectal Cancer • NASH/Fibrosis

microscope

March 2018

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Issue**

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About CHI Health

CHI Health is the largest not-for-profit, regional health network in Nebraska. It embraces a Mission to nurture the healing ministry of the Catholic Church while creating healthier communities. Based in Omaha, CHI Health has 14 hospitals, two stand-alone behavioral health facilities and more than 150 physician practice groups – in CHI Health Clinic and The Physician Network (TPN) – in Nebraska and southwest Iowa. CHI Health is the primary teaching partner of Creighton University’s health sciences schools. CHI Health is part of Catholic Health Initiatives (CHI), a nonprofit, faith-based health system based in Englewood, Colorado, that operates in 19 states. For more information, please visit CHIhealth.com.

*If you have questions about the content of *microscope* or would like to stop receiving it, please email us at OPTOUTCHIHEALTH@catholichealth.net*

Under the Microscope



Dear Colleagues,

Research is science fueled by faith – the faith that we can find better treatments, medications and ways of looking at a problem in order to see a solution. Faith that we can someday change how we treat dementia or revolutionize how we use invasive procedures. Our researchers’ curiosity is matched by our patients who bravely trust their lives to the possibilities of what is not yet standard of care. Together they are the medical risk takers upon which the future of clinic medicine is based.

CHI Health is proud to be an academic health system that believes in clinical research. We are home to CURE, CHI Health Creighton University Research Exchange, where clinical trials and research are enriched by faculty, students and staff whose goal is to make life better for the patients we are privileged to serve today as well as the patients of the future. The sole purpose of CURE is to support clinical research conducted within CHI Health. Its value is priceless for the patients and families who benefit from curiosity and intelligence; for the physicians, students and residents who have the freedom ask “why;” and for our communities who know we won’t stop until we find an answer. That’s the beauty of research – and as a physician, I am inspired by the tenacity, courage and outcomes we’ve seen from research right here at CHI Health.

Our mission calls us to build healthier communities and our researchers are committed to doing just that – petri dish by petri dish, patient by patient, and question by question – knowing that in the end a patient will be cured, healed or helped. That’s what fuels research at CHI Health and why we are proud to be part of the cure.

Sincerely,

Cliff Robertson, MD
Chief Executive Officer
CHI Health

On Research

Dear Colleagues,

Physicians know medicine doesn’t move forward on its own. It’s prodded into the future when investigators ask interesting and even unusual questions – in clinics, at bedsides and in laboratories.

Scientific leaps that once seemed inconceivable become possible through incremental – and often unheralded – advances. Take the persistent unraveling of the mysteries of DNA. The knowledge gained is now being used right here at CHI Health to target cancer treatment to a tumor’s individual characteristics via the emerging field of theranostics.

This edition of *microscope* shines a spotlight on the research being conducted within CHI Health. There’s much to illuminate. Clinical studies are ongoing in every corner of our organization with 382 active studies at the end of 2017. There is a balance of federally funded, industry-sponsored and investigator-initiated/unfunded trials that are ongoing.

To elevate these efforts, CHI Health, in partnership with Creighton University, is launching CURE – the CHI Health Creighton University Research Exchange. Its unique infrastructure and single point of access will help clinical investigators explore research while exposing students to investigative modalities – and ultimately ensure patients have access to life-saving clinical trials.

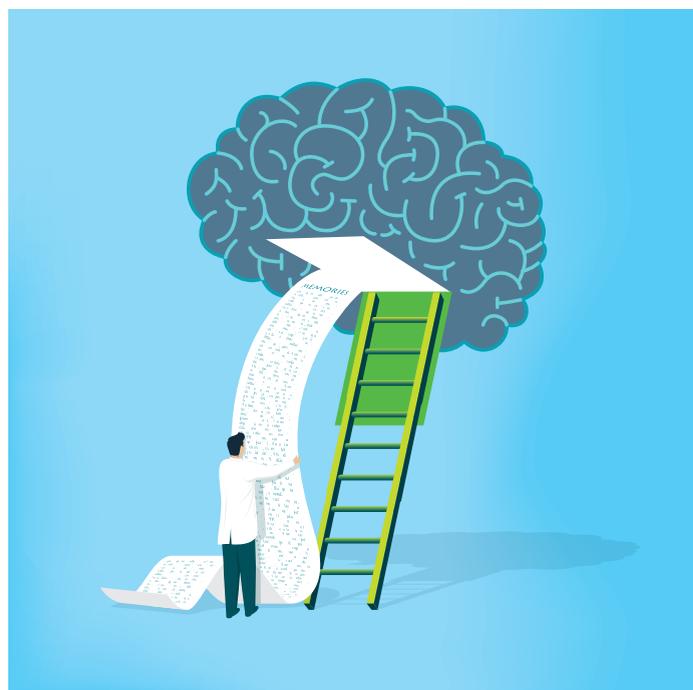
The energy around research at CHI Health is palpable, and we’ve only scratched the surface within these pages. But it’s real progress that starts – often – with curiosity and a question. Enjoy.



Sincerely,

Michael White, MD
Chief Academic Officer
CHI Health

Helping Tomorrow's Alzheimer's Patients



The daughter wondered if her elderly mother was showing early signs of Alzheimer's or just experiencing normal memory loss.

Two CHI Health researchers were able to diagnose the older woman – who did have the debilitating disease.

At the same time, those researchers were helping future Alzheimer's patients.

Physicians Have Major Role in Helping Dementia Patients, Caregivers

As brain function changes with dementia, things that were easy and straightforward for the patient can become difficult and frustrating.

“We not only need to help with the illness part of dementia, we also need to educate, counsel, coach and guide the patient,” said Geriatric Psychiatrist and Medical Director of the CHI Health Behavioral Service Line Arun Sharma, MD. “In short, we generate hope that with proper support, dementia can be managed.”

Geriatrician Heather Morgan, MD, and Nuclear Physician Samuel Mehr, MD, are part of a \$20 million U.S. two-year clinical trial to test whether lifestyle intervention can help prevent cognitive decline in 2,500 older adults. The trial could also determine whether Medicare will pay for PET scans that look for the sticky amyloid plaque that accompanies Alzheimer's.

Only three researchers in the state of Nebraska were selected for the groundbreaking study.

“Patients say to me, ‘I really want to know if I have Alzheimer's so I can plan for the future,’” Morgan said. “They want to know what they're facing.”

A diagnosis also helps families adjust emotionally to what's ahead. In this case the family made plans to have a family member visit the mother every day so they could spend as much time as possible with her before her health declined.

“CHI Health is proud to make this very important opportunity available to the community,” Mehr said. “The results will be very important to our aging society because providers now will be able to come up with the best possible treatment plan.”

Preliminary findings show that in two-thirds of cases, scan results changed doctors' initial plans for counseling and medications. With early detection, doctors are able to prescribe the right medication to slow the progression of the disease. Additional lifestyle interventions could include physical exercise, nutritional counseling and modification, as well as cognitive and social stimulation.

Results also can help families take advantage of resources to help them deal with their eventual loss. 🌱

Helping the patient and the caregiver also means adapting to changing brain function. “We need to modify activities and expectations,” Sharma said, “to help them negotiate their day in a safe manner.”

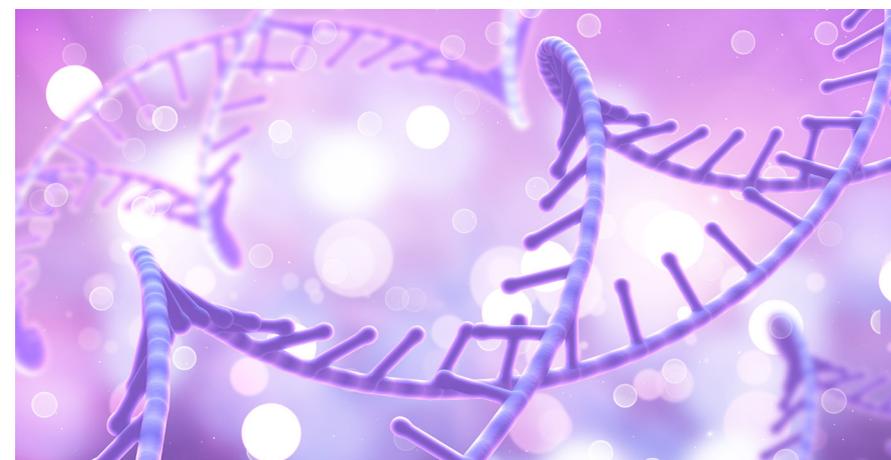
For example, the sleep-awake cycle may be interrupted.

“One approach to the interruption is we structure the day with activities,” he said. These might include music, pets, art and craft work. “This helps stimulate areas of the brain that might be active and functioning well.”

Activities also make the individual feel valued and help improve quality of life.

“These activities even have the potential to reduce depression, anxiety, agitation or other behavioral disturbances that can come with dementia,” Sharma said. “Although patients may not be able to verbalize how they feel and think, we believe their capacity to experience basic human emotions such as love, happiness and sadness is intact.” 🌱

Study Applies Theranostics to Neuroendocrine Tumors (NET)



Three patients have been enrolled in a study of the radioisotope Lutetium-177 (DOTA0, TYR3) Octreotate (Lu177-DOTATATE) at CHI Health, one of 30 study locations in the U.S.

The theranostics application of this drug is being studied for patients with specific types of neuroendocrine tumors, including carcinoid.

“It treats a patient's tumor based on the individual characteristics of that tumor, not as part of a broad protocol,” said Sam Mehr, MD, CHI Health nuclear physician.

“We do the diagnostic study with Ga-68 DOTATE PET; then we change the radioactive isotope from gallium to lutetium to perform a targeted therapy. The tumor-specific receptor can be imaged and then treated by changing the radioactive component of the bioactive molecule.

“When the therapeutic radioactive component strikes the tumor's DNA, it breaks apart the strands of the DNA and that's how it destroys the tumor.”

Lutetium-177 has been used in Europe for 15 years with good results. The radioisotope, which is individually formulated, comes from Italy.

“Those patients who got this drug, their progression-free survival advantage

was greater than 75 percent compared to those who didn't receive this drug,” Mehr said.

The approach also preserves surrounding tissues.

“We almost call these Trojan horses because the radiation is only released once it reaches the cancerous cells. For this disease, it's a potential major improvement,” said Peter Silberstein, MD, CHI Health hematologist and oncologist.

The results were something even a patient could observe.

“At the end of the treatment they showed me the scan afterwards which showed an abundant amount of tumors killed off,” John Hrupek said. “We were doing backflips.”

The treatment resulted in minimal side effects, and Hrupek, who was diagnosed with a pancreatic NET last April, complained only of multiple trips to the bathroom after his first two of the four treatments.

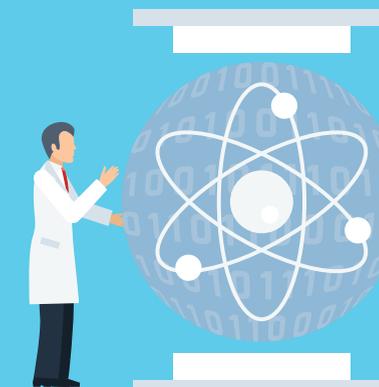
“This is the initial drug in our theranostics program,” Mehr said. “We're establishing a program in theranostics that will also be for prostate cancer and for breast cancer.” 🌱

Update: On January 26, 2018, Lutetium-177 received FDA approval.

Expanded Access Protocol for Therapeutic Use of 177Lu-DOTA0-Tyr3-Octreotate in Patients With Inoperable, Somatostatin Receptor Positive, Neuroendocrine Tumors, Progressive Under Somatostatin Analogue Therapy

Study Summary:

Advanced Accelerator Applications is currently pursuing marketing approval for 177Lu-DOTA0-Tyr3-Octreotate (Lutathera). This expanded access therapeutic protocol aims to allow patients suffering from inoperable, somatostatin receptor positive, neuroendocrine tumors, progressive under somatostatin analogue therapy to access the investigational product, 177Lu-DOTA0-Tyr3-Octreotate (Lutathera), prior to its commercial availability.



Iron Repletion Improves Functional Health for Heart Failure Patients



Inclusions:

- Stable Class II-IV CHF on max tolerated therapy
- EF \leq 35%; able to walk for 6MWT
- HGB $>$ 9.0 and $<$ 13.5 OR $<$ 15.0
- Hospitalized for CHF in last 12mo OR NT-pro BNP $>$ 600 (NSR) or $>$ 1000 (AF)

Exclusions:

- Significant liver or kidney impairment
- MI, ACS, TIA or CVA in last 3 months
- Receipt of EPO type drugs in last 3 months
- IV iron or blood transfusion in last 3 months
- Cancer in last 3 years; AF at rate of $>$ 100
- GI bleeding, severe uncorrected valve disease
- Current or planned oral iron supplementation

For study information search [NCT03037931](#)

Five years. That's the estimated life span for 50 percent of the 5.7 million adults in the United States diagnosed with heart failure. But a new clinic trial is expected to test whether an iron infusion will improve those years and add even more for those with this debilitating disease.

The Duke Clinical Research Institute HEART-FID study began March 15, 2017, at 116 hospitals across the country, including the CHI Health Research Center at Creighton University Medical Center - Bergan Mercy and CHI Health Nebraska Heart Institute. Cardiologist Venkata Alla, MBBS, and his team at CUMC-BM are currently screening patients to enroll in this study, as are Cardiologist, Heart Failure & Transplant Specialist Gina Mentzer, MD, and her team at Nebraska Heart. To date, 3,014 people are participating in this five-year, double-blind, placebo-controlled study with the hope of gaining FDA approval of intravenous ferric carboxymaltose as a treatment for heart failure patients.

“That something as simple as IV iron repletion could improve functional health, morbidity defined as cardiovascular hospitalization and mortality for those with systolic heart failure could be life changing for my patients,” Alla said. “And it's only two doses on day 0 and 7 with additional dosing every six months if needed.”

Mentzer adds, “We believe people will have more energy and

less stress when normalization of iron levels and blood counts occurs, so the body can support an already stressed system. Overall, we feel strongly this therapy along with good heart failure management and therapies will allow patients to be able to have more meaningful memories with their loved ones.”

Alla, principal investigator at the Omaha site, explains that iron deficiency, absolute or relative, is a frequent comorbidity present in almost 50 percent of patients with systolic heart failure and is associated with poor prognosis and functional outcomes irrespective of the presence of concomitant anemia. Prior research has demonstrated that iron replacement can improve NYHA functional class, six-minute walk distance and quality of life. While both oral and intravenous supplements can potentially improve outcomes, oral iron supplements can have suboptimal results due to impaired absorption secondary to intestinal mucosal edema in heart failure patients.

“This study is being led by my friend and colleague, Robert Mentz, MD, from Duke. It's an excellent opportunity for our patients in this region to be some of the first ones to receive this advanced therapy,” said Mentzer.

Both teams are actively recruiting patients and remind health care providers that patients can have normal hemoglobin levels and still be iron deficient. To refer a patient to this study, call 402-328-5301 for the Lincoln team or 402-343-8511



Organ Preservation for Rectal Cancer Study Continues Following Patients

Organ Preservation in Rectal Adenocarcinoma: a phase II randomized controlled trial evaluating 3-year disease-free survival in patients with locally advanced rectal cancer treated with chemoradiation plus induction or consolidation chemotherapy, and total mesorectal excision or nonoperative management

Background:

Treatment of patients with non-metastatic, locally advanced rectal cancer (LARC) includes pre-operative chemoradiation, total mesorectal excision (TME) and post-operative adjuvant chemotherapy. This trimodality treatment provides local tumor control in most patients; but almost one-third ultimately die from

distant metastasis. Most survivors experience significant impairment in quality of life (QoL), due primarily to removal of the rectum. A current challenge lies in identifying patients who could safely undergo rectal preservation without sacrificing survival benefit and QoL.

BMC Cancer v.15; 2015 PMC4619249

The first prospective study to investigate feasibility of non-operative management of rectal cancer patients who have a complete response to neoadjuvant therapy is closed to accrual, but patients continue to be followed long term.

CHI Health Creighton University Medical Center - Bergan Mercy is one of 25 locations involved in the study coordinated by Memorial Sloan Kettering and the national Rectal Cancer Consortium.

“We hope to determine three- and five-year survival with total neoadjuvant chemotherapy and radiation for locally advanced rectal cancer and the option of not removing the rectum if patients have a significant clinical response,” said Charles Ternent, MD, CHI Health colorectal surgeon. “The goal is to preserve the rectum if possible and then monitor for regrowth without having to undergo surgery. The option of avoiding surgery and a radical resection of the rectum is appealing for excellent responders because of the potential benefits in quality of life by not having a stoma and by avoiding the risks and changes in bowel function associated with radical rectal surgery.”

Study candidates had a histologically confirmed diagnosis of adenocarcinoma of the rectum, clinical Stage II (T3-4, N-) or Stage III (any T, N+) based on MRI, rectal tumor at baseline which would be considered to require total mesorectal excision (TME), no evidence of distant metastases, no prior pelvic radiation therapy and no prior chemotherapy or surgery for rectal cancer.

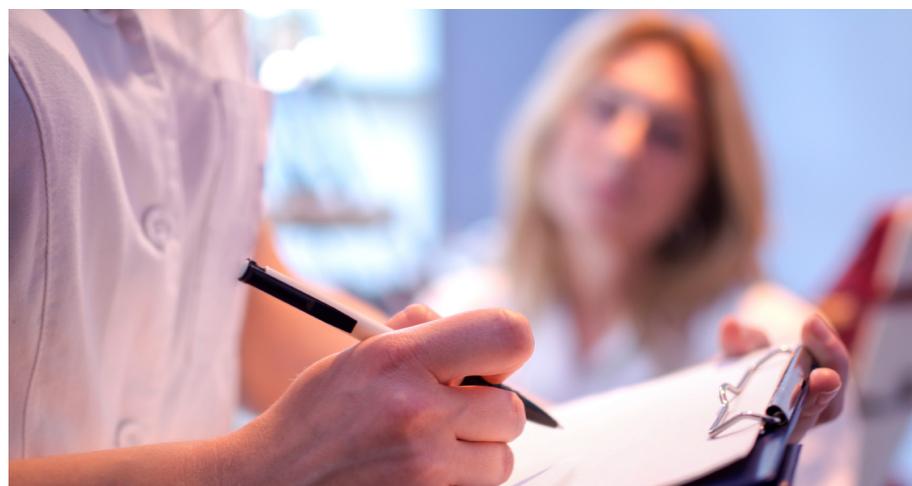
Rodney Rihner of Harlan, Iowa, was enrolled in the study after being diagnosed with rectal cancer in 2016. He completed chemotherapy and radiation in 2017. “It was to me a Godsend that surgery was unnecessary,” he said.

Rihner will return for follow-up every three months for two years, and every six months for the next three years.

“I feel safe without having the surgery because they watch me closely. I guess that's why they do the clinical trials,” he said. “If it can help someone else down the line, that's a good thing.”

Rihner is one of nine patients actively enrolled in the study at CHI Health. 🌟

National Clinical Trial Enrollment Rate Reaches 36% in Grand Island



The CHI Health St. Francis Cancer Treatment Center in Grand Island has developed into a shining star, gaining national attention for providing leading edge cancer care to central Nebraskans.

Led by M. Sitki Copur, MD, FACP, medical director of Oncology Services, and his commitment to clinical trials, the St. Francis Cancer Treatment Center (SFCTC) has the ability to deliver an advanced level of care in a rural setting.

“Today’s clinical trials are tomorrow’s best care,” Copur said. “It takes a lot of work and infrastructure to bring cutting-edge treatments to our community.”

Clinical trials compare new treatments to standard treatments and contribute to a better understanding of treatment benefits and risks. They test the ideas drawn from the clinical observations as well as from the theories and discoveries made in the basic science laboratory and are the very source of continued progress and innovation in cancer care.

“Beyond a doubt there is absolute and clear evidence learned from patient participation in clinical trials in all cancer types,” Copur said. “In this day and age, it is unthinkable to provide comprehensive, high quality cancer care without clinical trials and without an established infrastructure to enable that. Clinical trials are no longer an optional or additional virtue of a cancer program but an integral and crucial part of quality cancer care.”

St. Francis has been involved in national cancer clinical trials for 22 years, which has enabled its team to develop the skills and infrastructure to provide this very crucial need in cancer care for rural Nebraska populations.

Initially, SFCTC was an affiliate of the University of Nebraska Medical Center and NCI-designated Eppley Cancer Institute. Later, it became one of the initial 16 pilot sites for the NCI Community Cancer Center Pilot (NCCCP) and most recently, SFCTC was selected as one of just 35 community sites through the NCI Community Oncology Research Program (NCORP) grant as part of the CHI Institute for Research and Innovation (CIRI). CIRI has worked closely with CHI cancer centers across the country to build the CHI Oncology Research Alliance.

During all of these periods, St. Francis has consistently outperformed its peers in the clinical trial arena, receiving several national awards. With the help of the most recent NCORP grant, the SFCTC’s clinical trials enrollment rate has reached an all-time high of 36 percent, which is unprecedented for a community-based cancer program like St. Francis. The national average for participation in clinical trials is 3-5 percent in general and around 15 percent at the most highly rated academic centers.

As of December 2017, SFCTC’s clinical trial portfolio was at a record high with a total 77 clinical trials. They consist of Cooperative Group, Investigator Initiated, Treatment, Cancer Control/Prevention, Cancer Care Delivery, Quality of Life and Biospecimen trials.

SFCTC diagnoses and treats about 700 new cancer patients each year. The facility offers medical and radiation oncology in one location with a full spectrum of cancer care services from prevention, screening, diagnosis and treatment to survivorship, palliative care and end of life care – all under one roof. 🌟



M. Sitki Copur, MD
Oncology Medical Director
CHI Health St. Francis

Cancer Patient Gets a Second Chance in Grand Island

Less than one year ago, Tammy Fairley’s world was jolted by the words every cancer patient fears.

“The doctor called me and basically said, ‘Sorry, there’s nothing I can do for you,’” Fairley said. “It’s time for you to get your affairs in order and you should seek hospice care.’ That was shocking.”

Diagnosed with Stage 3 ovarian cancer in February 2015, Fairley underwent chemotherapy where she was living in Charlotte, North Carolina. The effects of the treatment left her unable to work, so the 51-year-old native of Shelby, Nebraska, moved back to her home state where she continued treatment in Lincoln and Omaha.

Last July, Fairley wasn’t feeling well and, shortly after undergoing a CT scan, received the discouraging outlook.

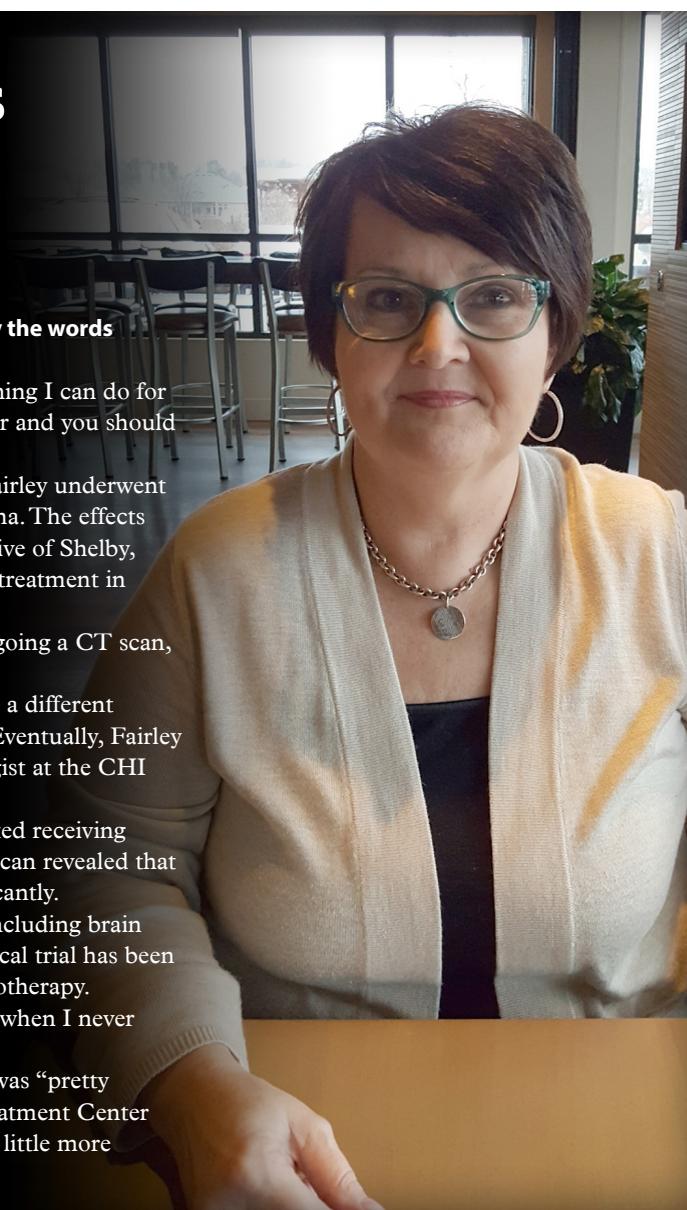
After a few days of contemplation and tears, Fairley spoke to a different physician in Omaha who helped her search for a clinical trial. Eventually, Fairley was given the name of David Crockett, MD, a medical oncologist at the CHI Health St. Francis Cancer Treatment Center in Grand Island.

With Crockett’s help, Fairley entered a clinical trial and started receiving infusion treatment at the end of August. Fairley’s most recent scan revealed that four of the six tumors were gone and two others shrunk significantly.

Although Fairley said she still deals with some side effects, including brain fog, aches and fatigue, the treatment she’s receiving in her clinical trial has been much more tolerable than her previous experiences with chemotherapy.

“Things are going great,” Fairley said. “I got a part-time job when I never thought I would work again in my life.”

After seeking treatment in much larger cities, Fairley said it was “pretty surprising” to find a clinical trial at the St. Francis Cancer Treatment Center in Grand Island, a central Nebraska city with a population of a little more than 50,000. 🌟



Determining Quality of Cancer Care

To measure the quality of a cancer program in a fast and accurate way, M. Sitki Copur, MD, FACP, said to look at its track record for how many and what types of clinical trials are available, as well as the program’s ability to offer them. Also key, Copur said, is a cancer program’s enrollment rate in clinical trials.

“It takes an army of dedicated, well-trained, knowledgeable professionals to accomplish this goal and it is an automatic best measure of that cancer program,” said Copur, medical director of Oncology Services at the CHI Health St. Francis Cancer Treatment Center in Grand Island.

Consensus statements by American Society of Clinical Oncology, the American Federation of Oncological Services and the European Society for Medical Oncology have listed patient access and opportunity to participate in relevant clinical trials as basic requirements of quality cancer care.

“This is exactly what we have been doing at St. Francis for the last two decades,” Copur said. “We frequently hear from our patients who have been to the Mayo Clinic or to MD Anderson that they were asked, ‘Why are you here when you have the best cancer program in Grand Island at St. Francis?’” 🌟



Research Looks at Cyberbullying and Adolescents

Approximately 90 percent of adolescents worldwide use social media. They carry it with them in their pockets and backpacks and take it to bed at night. Essentially, they have 24/7 accessibility to social media right in the palm of their hands. Always on, always available, connecting and possibly harming their mental and behavioral health at alarming rates.

“More and more of our youth patients hint at social media as being a factor leading to anxiety, insecurities and depression,” said Jesse Florang, EdD, therapist at CHI Health Richard Young Behavioral Health. “Surprisingly, there is limited research for mental health professionals to draw upon to help us improve current assessment procedures and treatment practices to account for this relatively new phenomenon created by advancing technology.”

Gone are the days of stolen lunch money in the hall. Today’s bullies find the vulnerable online. Last year 72 percent of

adolescents reported being cyberbullied at least once and only one-third reported their victimization to an adult.

According to Florang, that number is only going to increase. “We wanted to better understand what we are fighting against, so we could do something as mental health professionals to help.”

The recently finalized research project, “Relationships between Cyberbullying and Depression among Adolescents in an Acute Inpatient Psychiatric Hospital,” was that help. Florang, Suzanne Goetz, RN, PhD, and Linda Jensen, PhD, studied 100 (70 female/30 male) adolescent inpatients at Richard Young in Kearney, Nebraska. The study used a three-part self-report survey including the Cyber Peer Experiences Questionnaire, the Center for Epidemiological Studies Depression Scale and demographic data from all participants. The findings suggest:

- A substantial association between cyber victimization and cyber aggression.
- A moderate association between cyber victimization and depression.
- Females are more likely to have experienced cyber victimization and participated in cyber aggression than males.

Implications from the findings:

- Adolescents would benefit from programs designed to promote the social skills necessary to appropriately cope with cyberbullying.
- Orem’s self-care theory can be a beneficial guide for health care professionals to develop treatment plans and provide care for adolescents through identifying problems and teaching independence.
- Adolescent psychiatric hospitals need to ensure that they are assessing cyberbullying through risk assessments and initial psychiatric evaluations.
- More research should place emphasis on developing gender specific groups, classes and assessment tools due to the differences found between males and females in regard to cyberbullying.

The report has been submitted to several journals for publication.

“We hope our study shows the need for inpatient psychiatric hospitals, like ours, to update assessment and treatment procedures to account for the impact cyberbullying has on the adolescent population,” said Goetz. “Technology is growing, changing at faster and faster rates. To help our patients, we too must keep pace.”



With image guidance and robotics, waterjet ablation therapy is delivered for controlled, heat-free removal of targeted prostate tissue. Photo credit: PROCEPT BioRobotics

Study Assesses Waterjet Technology for Treating Large Prostates

Half of men age 51 to 60 develop pathological benign prostatic hyperplasia (BPH), and that stat increases to 80-90% for men in their 70s and 80s.

Now, at 16 sites across the continent, high-velocity waterjet technology is being used to resect and remove prostate tissue. One of those sites is the result of teamwork among urologists Andrew Trainer, MD, Andrew Arther, MD, the research group at Adult Pediatric Urology & Urogynecology, PC, and CHI Health Creighton University Medical Center - Bergan Mercy.

The Investigational Device Exemption (IDE) study, WATER II, focuses on the safety and effectiveness of treating large (80-150 g) prostates with Aquablation – water ablation therapy. Twelve males with benign prostatic hyperplasia were treated at CUMC-BM and will be followed for up to 12 months.

The previous study, WATER, in which smaller prostates (30-80 g) were studied (203 participants total, 4 at CUMC-BM) recently released its initial findings.

A summary of the reported findings in the WATER study comparing Aquablation to TURP includes:

- Significantly improved BPH symptoms in both treatment groups as measured by the International Prostate Symptom Score (IPSS) at six months with 100 percent of Aquablation patients improving from baseline
- Superiority in IPSS storage symptom sub-scores ($p < 0.05$)
- Superiority in IPSS improvement with Aquablation in men with prostate volume greater than 50 ml as compared to TURP ($p < 0.01$)
- Superiority in peak urinary flow rates (Qmax) at six months
- A significantly lower rate (4 to 1 ratio, $p < 0.001$) of sexual side effects in Aquablation compared to TURP at three months
- Superiority in ejaculatory function (MSHQ-EjD) and incontinence scores (ISI) at three months

Game On: Study Evaluates Laparoscopic Simulator Versus Video Game Controller

Can video gaming prepare a whole new class of surgeons?

A 2007 study reported surgeons who played video games for more than three hours per week made 37 percent fewer errors, were 27 percent faster and scored 42 percent better on laparoscopic surgery and suturing drills than surgeons who never played video games.

That comes as no surprise to John Coté, MD, a laparoscopic surgeon and long-time video game enthusiast. He thinks the more important question may be: “Is it the game or the controller?”

Built around that supposition is the prospective random study currently taking place at Creighton University Medical Center - Bergan Mercy.

A laparoscopy surgery-inspired video game named Underground uses a controller – a \$261 peripheral from the Netherlands – to mimic the inverted axis experienced during real laparoscopic procedures. Coté, primary investigator, and an “Underground Crew” of second-year med students are enrolling CUMC-BM medical students and residents.

“We’re rating their proficiency on the lap simulator to determine if higher scores are associated with playing Underground, versus playing Underground with the inverted axis controller, versus no video game play.”

Coté expects those using the controller will have higher marks. “The biggest hurdle when learning laparoscopy is mastering inverted axis,” he said. It takes a lot of practice. And this could be a very cost-effective way, with less time limitations, to get that needed practice.”

Research Helps Patients Beat Unexplained Shoulder Pain



The patient had shoulder pain but tests couldn't pinpoint the cause. Another couldn't sleep because of the discomfort. A third couldn't do even the most basic of everyday activities like shower, cook or drive a car. None of them knew what was causing the pain.

CHI Health Orthopedic Surgeon Matthew Dilisio, MD, set out to "explain the unexplained."

And he did. With his research team, Dilisio discovered "new ways the shoulder tendon degenerates that are invisible to other testing modalities." This opened the door to treatment options for patients who couldn't be helped before. Even with previous MRIs and surgeries they hadn't found relief.

By analyzing discarded symptomatic biceps tendons in the shoulder after surgery, Dilisio and his research team found a novel degenerative process that explained why a seemingly normal tendon can cause so much pain in patients.

"Now that we better understand these unique inflammatory pathways of the biceps tendon," he said, "we are able to easily treat these problems with a minimally invasive 20-minute procedure."

The procedure is biceps tenodesis, in which the tendon is removed from the shoulder joint and re-attached farther down the humerus.

"The results of this surgery are excellent," Dilisio said, "and many patients who previously had unexplained shoulder pain can now be helped with this procedure." He's seen patients get back to simple everyday activities, sleep through the night again

and participate in favorite activities.

With his experience in biomechanics research, Dilisio was also able to study the fatty infiltration of the shoulder. After surgery, fat can sometimes invade the tendon area, preventing healing and blocking muscle tissue. "It's as though you've just changed the tires on a car with no motor," he said.

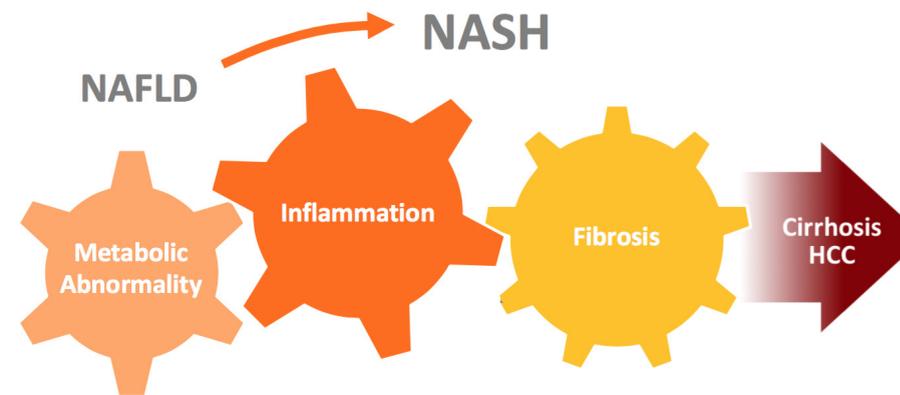
To get answers, he teamed up with Devendra Agrawal, PhD, in Creighton University's Department of Clinical and Translational Science. He had previously studied the negative inflammatory effect of fat on cardiac tissue. The two of them, along with postdoctoral researcher Finosh Thankam, PhD, discovered a significant upregulation of certain proteins, known as TREMs, in shoulders that demonstrated arthritis. These molecules are a potential therapeutic target for novel medications that may help patients suffering from joint pain.

Their findings were recently published in *Molecular and Cellular Biochemistry*. Dilisio has published numerous articles over the past year.

The orthopedic surgeon also explored a possible link between shoulder tendon problems and vitamin D deficiencies. The work was a "springboard," he said, to his work on the fatty infiltration of the shoulder.

Dilisio and his team just submitted a \$2.5 million grant application to the National Institutes of Health. Everyone's work "is going to put our orthopedic department on the map," he said. 🌱

Global Study Evaluates Obeticholic Acid Treatment for NASH with Fibrosis (REGENERATE)



Adapted from Arun Sanyal, NASH Symposium Paris June 2015

For Nate Collins, routine labs indicated fatty liver disease or NASH six months ago. "It was definitely unexpected, but not terrifyingly so," he said.

The biopsy taken as part of a research study revealed NASH, and he was placed on the study's treatment protocol.

Collins is one of six CHI Health patients enrolled in this study, which is evaluating obeticholic acid treatment for nonalcoholic steatohepatitis with fibrosis.

"We are the only center in Nebraska invited to participate in this study. It's a phase three, five-year multicenter worldwide trial," said Sandeep Mukherjee, MD, CHI Health gastroenterologist/hepatologist.

The REGENERATE study will assess whether obeticholic acid treatment decreases fat and scarring in the liver, specifically evaluating the effect of obeticholic acid treatment compared to placebo on histological improvement and liver-related clinical outcomes in patients with non-cirrhotic NASH with liver fibrosis.

After starting the obeticholic acid, Collins noticed a decrease in his appetite and has subsequently lost 25 pounds. "So far, I've had no negatives, only positives," he said.

This is one of several research studies taking on this serious health concern.

"Fatty liver disease is a global epidemic. It's a chronic, insidious disease," Mukherjee said.

"What's alarming is people with an average build and body mass index are now getting fatty liver disease. It's happening all over the world and it's been seen in India and southwest Asia. There's a study from India of thin, underweight farmers who have fatty liver disease and we don't yet know why."

Mukherjee is currently enrolling patients in this study, Randomized Global Phase 3 Study to Evaluate the Impact on NASH with Fibrosis of Obeticholic Acid Treatment (REGENERATE), and will be involved in another study later this year. 🌱

Alert Boosts Hepatitis C Screenings

One lifetime hepatitis C screening is resoundingly recommended for all patients born between 1945 and 1965 regardless of risk factors, because an estimated 75 percent of those with hepatitis C were born during that time frame.

To spur primary care providers to meet that guideline, Robyn Tepy, PharmD, CHI Health pharmacist, worked with IT to create a Hep C Baby Boomer alert in EPIC. It went live at all CHI Health primary care clinics on December 1, 2016. Tepy tracked these results:

Four months before the alert:
482 patients screened,
20 identified with hep C

Four months after the alert:
5,685 patients screened,
107 identified with hep C

"By having an alert, we were able to test and identify patients earlier in the disease process," Tepy said. "That's good news, because we are now at a point that we have medicines that are curative in as little as eight weeks."

Next, she plans to gather data for a longer time frame – the year before the alert and the year after. "We are also going to look at the reasons patients weren't screened," she said.

Tepy also studied the affordability of hepatitis C medications and found this:

"On average, 98 percent of patients pay less than \$10 for a month of hepatitis C treatment. The highest copay was \$50, and that was only one patient. There's a lot of good, supportive programs out there to help with drug costs."

From Research Lab to “Shark Tank” to Helping Women Everywhere



Dr. Feloney and Dr. Rocha-Sanchez are owners of F&S Medical Solutions, LLC, the developer of SimplCath.

Urethral catheterization is a routine medical procedure that drains the urinary bladder. But a woman’s anatomy can make guiding the catheter difficult.

Until now.

CHI Health Urologist and Urogynecologist Michael Feloney, MD, had an idea for a device that anyone could use to insert a catheter correctly. He teamed up with Sonia Rocha-Sanchez, BS, MS, PhD, a professor of Biomedical Science and assistant dean of research at Creighton University School of Dentistry – and the two designed SimplCath.

“It’s the only device on the market to assist women’s catheterizations in any setting,” Feloney said. “It takes the guesswork out.”

“Up to now, catheters have been designed for the male and adapted for the female urethra,” Rocha-Sanchez said. “This is a unique and simple device designed specifically for the woman’s anatomy.”

SimplCath can be used by medical personnel and caregivers, as well as patients who self-catheterize. It can be used in hospitals, nursing homes and clinical environments as a disposable device, or as a reusable device at home.

As part of the trials, nurses just out of nursing school and those with 20 or more years of experience were asked to use the device in the clinical setting.

“Every single nurse was able to insert the catheter correctly on the first attempt,” Rocha-Sanchez said.

Patients ranged from a 21-year-old to a woman in her 70s. One weighed less than 100 pounds; another weighed more than 300 pounds.

One patient in the clinical trial was so excited she told researchers she wanted to keep the test device. Because it allowed her to urinate more easily and independently, she would be able to travel – something she hadn’t done in a long time.

SimplCath can save money by reducing the number of nurses required to catheterize from two to one. It can also reduce the risk of catheter contamination during insertion. Catheter-associated urinary tract infections (CAUTIs) are among the most common infections in hospitals.

Feloney and Rocha-Sanchez were finalists in the Nebraska InnovateHER 2017 Challenge, which looks for products or services that have an impact on the lives of women.

“The competition felt a little like ‘Shark Tank,’ but friendlier,” Rocha-Sanchez said. “We were in front of business people and they were asking about marketing strategy, profit margins and bottom lines.”

The two are making a presentation to the Department of Defense to help provide care to female combatants. “No matter the setting, the SimplCath will change the way we catheterize women,” said Feloney. 🌟



Why is urethral catheterization necessary?

- Lack of urinary control
- Urinary incontinence
- Urinary retention
- Hospitalized, bedridden or unable to walk to restroom

Why are urinary catheterizations difficult to do in women?

- Location of urethra (inside vagina, above vaginal canal) limits access
- Women’s bladders vary in size and shape due to age, weight, childbirth, other factors



Research Stretches from Omaha Metro to Central Nebraska

CHI Health offers a full spectrum of research opportunities and efforts to discover, develop and optimize high quality patient care.

“We are very fortunate at CHI Health to have clinical research resources available through our existing research department and look forward to the collaborative development of the Creighton University Research Exchange (CURE),” said Kayleen Joyce, MS, CCRC, research director for CHI Health. “CURE will provide an infrastructure to support participation in research opportunities for physician investigators wanting to answer their own research questions or apply to external funding.”

CHI Health has clinical research staff that supports the Omaha facilities and clinics on the Creighton University Medical Center - Bergan Mercy campus and at other CHI Health locations.

In Omaha, CHI Health has a regulatory staff that maintains investigator and research staff training documents and provides Internal Review Board (IRB) submission assistance. The research start-up team handles all research budgets and contracts, which includes working with legal services and outside counsel to negotiate study agreements that contain required CHI provisions and negotiate study budgets with third parties.

Omaha’s research coordinators, many whom are tenured nurses and certified clinical research coordinators, are deployed across several service lines with the most active areas being cardiology, oncology, nephrology, gastroenterology, surgery, pulmonary and women’s health.

The CHI Health Nebraska Heart Clinical Research team is dedicated to conducting clinical research trials to advance treatments for cardiovascular and other chronic diseases. Nebraska Heart has been involved in clinical research since 1995 and its staff has 80+ years of combined clinical research experience.

The Nebraska Heart Research medical directors are Peter Gallagher, MD, and James Wudel, MD. Cardiologists, surgeons

and anesthesiologists serve as investigators for various studies. The research department also includes nurses, clinical exercise physiologists, certified clinical research coordinators and a financial analyst.

The team is actively involved in Lincoln at the CHI Health Nebraska Heart Medical Office, the CHI Health Nebraska Heart Hospital, and at its outpatient clinics in Hastings and Grand Island.

“Our involvement in inpatient and outpatient phase II-IV clinical research studies has contributed substantially to the advancement of medicine as well as the development of

Research programs at the community level can enhance the patient care experience.

new drugs, devices and therapies,” said Corey Godfrey, MSPE, CCRC, research manager at Nebraska Heart.

Paul Edwards serves as a CHI Health research manager, working at CHI Health St. Elizabeth, and also oversees research at CHI Health Good

Samaritan in Kearney and CHI Health St. Francis in Grand Island.

At St. Elizabeth, Edwards said research is mainly focused on burn trauma, wound care, NICU and interventional radiology. The St. Elizabeth Regional Burn and Wound Center is internationally recognized for outstanding research and providing the latest treatments and procedures for serious burns or for wounds that won’t heal.

While located in smaller population centers, Edwards said Good Samaritan and St. Francis both possess experienced and dedicated research staffs. Research at Good Samaritan and St. Francis focuses mainly on oncology and both programs participate in the National Cancer Institute’s Community Oncology Research Program (NCORP). 🌟

**We Value
Your Feedback!**

Please share your thoughts about this issue of *microscope* and your ideas for future stories at CHIhealth.com/MicroIdeas

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**WE'RE ESTABLISHING
A PROGRAM IN
THERANOSTICS
THAT WILL ALSO BE FOR
PROSTATE CANCER AND
FOR BREAST CANCER.**

No matter the setting,
the SimplCath will change the way we catheterize women.

66. *microscope*

**On average, 98 percent of patients pay less than
\$10 for a month of hepatitis C treatment.**

**We were
doing
backflips.**

It was to me a
Godsend that
surgery was
unnecessary.

72 PERCENT OF ADOLESCENTS REPORTED BEING CYBERBULLIED
at least once and only one-third reported their victimization to an adult.

We almost call
these Trojan horses
because the
radiation is only
released once it
reaches the
cancerous cells.

CHI Health Hospital Locations

NEBRASKA

- Grand Island
CHI Health St. Francis
- Kearney
CHI Health Good Samaritan
- Lincoln
CHI Health St. Elizabeth
CHI Health Nebraska Heart
- Nebraska City
CHI Health St. Mary's

Omaha

- CHI Health Creighton University
Medical Center - Bergan Mercy
- CHI Health Immanuel
- CHI Health Lakeside
- CHI Health Midlands
- Plainview
CHI Health Plainview
- Schuyler
CHI Health Schuyler

IOWA

- Corning
CHI Health Mercy
- Council Bluffs
CHI Health Mercy
- Missouri Valley
CHI Health Missouri Valley