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— DR. PATRICIA CORBY

SUPPORTING RESEARCH, MENTORING SCHOOL-WIDE

WITH A GROWING TEAM, THE CENTER FOR CLINICAL & TRANSLATIONAL RESEARCH IS SUPPORTING THE ADVANCEMENT OF CLINICAL RESEARCH STUDIES AND MENTORING ACROSS DISCIPLINES

IN 2019, DR. PATRICIA CORBY JOINED PENN DENTAL MEDICINE in the newly created role of Associate Dean for Translational Research with the goal of helping to develop a robust clinical research program at the School through the creation of the Center for Clinical and Translational Research (CCTR). Eagerly taking up the task, Corby is doing just that. Under her leadership, there has been exponential growth in three short years – virtually unimpeded by the pandemic. Today, the CCTR is managing more than \$21 million in clinical grants for projects across disciplines, while supporting principal investigators and mentoring junior faculty and students to excel as clinician scientists.

“With the right support and nurturing service provided by the Center’s staff, faculty and student engagement with the Center has exploded,” says Corby, Associate Professor of Oral Medicine, who led clinical research operations at New York University College of Dentistry and NYU Langone Health before coming to Penn Dental Medicine. “It has been a whirlwind of activity.”

It was just a month after Corby’s one-year anniversary in this role that the pandemic shuttered most activity in March 2020, but not that of the CCTR. It kept going, and even more significantly, it kept growing. In fact, fiscal year 2021 (July 2020–June 2021) was the largest growth period to date with a total of more than \$5.5 million in new clinical grant awards within the year.

“When the pandemic hit, we never stopped,” says Corby, who at the time was in

the midst of her own NIH-funded study (the ARMOR trial) looking at a targeted oral care intervention to improve oral health and prevent toxicities in patients undergoing radiation or chemoradiation for head and neck cancer. With newly adopted safety protocols in place and a valiant corps of trained clinical staff, they continued to see research participants, while also supporting faculty and students to help keep their research activities moving forward. “I am very fortunate for having a wonderful team that gives so much for the betterment of our program,” says Corby.

In June 2020, the CCTR moved from temporary quarters to its home on the third floor of the School’s Robert Schattner Center – the hub of activity for the CCTR with dental bays for seeing participants in active trials, a wet lab, and research pharmacy room, along with the CCTR team offices.



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OPPOSITE: Dr. Patricia Corby, Associate Dean for Translational Research, with Dr. Eugene Ko, who she recently added to the CCTR team as Deputy Director of Clinical Operations.



A SUPPORT, SERVICE CENTER

Providing centralized support to Penn Dental Medicine researchers who conduct human subjects research, the services of the CCTR span the full spectrum of a study, from project conceptualization to closeout. Corby explains that a key focus for her and Director of Clinical Research Operations and Compliance Marta Gabinskiy, who has worked with Corby for the past 10 years, is supporting faculty in producing impactful and relevant grant proposals through the eye of potential funders.

“We do a lot of support on the grant side, adding another level of review,” says Corby, who has more than 20 years of experience designing and running high-impact clinical and translational research projects from various funding sources, such as NIH, foundations and the pharmaceutical industry. “We don’t change the ideas, as they are unique of each investigator, but we know

what reviewers and the NIH expect, so we help put the grants in the context and format they want to see to improve the likelihood of awards. I also believe we can only succeed with this mission with a strong faculty-service orientation and expert staff and systems that can make it as easy as possible for faculty to submit proposals, win the ever-increasing competition for grant funding, and comply with federal and sponsor regulations.”

“Since starting the Center, we have worked with most departments in the school,” adds Corby. “Even our basic scientists are seeing that they can do something translational and are starting to incorporate human subjects into their research.”

“Translational research must be interdisciplinary, and every study that we place, we look for collaborations,” continues Corby. “We have successfully partnered with schools and centers across Penn.” Collaborations have included studies with Perelman School of Medicine, Abramson Cancer Center, Penn Nursing, Penn Center for AIDS Research, Penn Engineering, Penn Vet, and the Wharton School.

GROWTH THROUGH MENTORSHIP

While encouraging all faculty to push the boundaries to find new and useful applications for their work, Corby believes that mentoring junior faculty is foundational to building a strong clinical research program at the School and has made that a priority in her work.

“I think the most important aspect of having the Center is to be able to mentor and start training the next generation,” says Corby. “So this is what we want to do — to push our brilliant junior faculty. Many times you just need to give them one small opportunity, and if they know how to take that and grow, they are going to flourish.”

Corby currently mentors nine junior faculty — all of whom have active pilot projects with some also working on funded trials as co-investigators and others beginning trials of their own. As part of that mentorship, Corby helps junior faculty identify collaboration opportunities with senior investigators who have NIH-sponsored studies and are willing to provide the right mentorship.

ABOVE: Members of the CCTR team in one of the clinical bays where they see trial participants.

THE NEXT STEP

One of Corby's mentees and a former co-investigator on her ARMOR trial — Dr. Eugene Ko — now has the opportunity to pay it forward as part of the CCTR team. This summer, following a national search of candidates, Ko was chosen to fill the newly created position of Deputy Director of Clinical Operations. In this leadership role — a next step to support the continued growth of clinical research activities — Ko will focus on mentoring students involved in research through the CCTR and provide oversight to the portfolio of clinical studies conducted at the center.

"We have grown so much with the mentorship of student research," says Corby. "In addition to our DMD students and post-doctoral residents, the School has a growing number of master's programs and all these students are engaged in research."

With Ko's appointment, the CCTR will begin to build a new arm of mentorship for these student investigators on clinical and translational projects. "Eugene is a tremendous addition," says Corby.

An Assistant Professor of Clinical Oral Medicine at Penn Dental Medicine since 2018, Ko's own research is centered on the advancement of oral health through translational research and novel medical devices and technologies. He is currently leading two projects. In his FIRE Trial — a collaboration with The Wharton School that just recently opened for enrollment — Ko is testing the efficacy of a smartphone app to assess real-time chronic pain data in burning mouth participants.

"A major problem with chronic oral pain disease, including burning mouth, is that we rely on patient memories to recall their pain experiences over long periods of time," says Ko. "Our project will capture pain as it happens, which can lead to a better universal definition of burning mouth syndrome and improved understanding of when and how often pain occurs."

Ko is also working on a medical device project co-sponsored by Penn Health Tech and the School's Center for Innovation & Precision Dentistry to develop new solutions

STUDIES ACROSS DISCIPLINES

So what are the studies that makeup the current portfolio of clinical projects at the School? Presently, the Center for Clinical and Translational Research (CCTR) is involved in active clinical research projects across disciplines, ranging from oral/systemic health topics, cariology, HIV, cancer, and pain management to studies focused on medically complex individuals and improving oral health for persons with disabilities. Along with NIH- and industry-sponsored studies, internal pilot studies have been funded by departments within the School, the Office of the Dean, and other schools and centers across Penn.

Here are some of the current NIH-funded clinical research projects:

The OHART Study

PI: Dr. Temitope Omolehinwa, Dept. of Oral Medicine

Co-Is: Dr. Patricia Corby, Dr. Sunday Akintoye, Dept. of Oral Medicine; Dr. Vincent Lo Re, Penn Center for AIDS Research; Dr. Doug Schaubel, Perelman School of Medicine

A collaboration between dental and medical experts, this prospective study will identify oral-systemic non-AIDS-associated comorbid diseases (non-infectious diseases) in a large population of HIV individuals. The goal is to determine key oral health manifestations associated with the development and severity of these diseases. A better understanding of the interplay between oral and systemic inflammation can inform clinicians about novel preventive treatments aimed at reducing inflammation among people living with HIV.



The Rembrandt Study

PI: Dr. Laurel Redding, Penn Vet

Co-I: Dr. Yu Wang, Dept. of Periodontics, Dr. Patricia Corby (mentor)

This collaborative study with Penn Vet is an observational study of patients who will be receiving dental implants. The purpose is to determine whether owning a pet changes the disruption and recovery of a person's microbiome after they have received antibiotics for a dental implant. The hypothesis is that pet owners may benefit from having more resistance to developing a common infection caused by *C. difficile*, which is a bacterium that causes an infection of the colon.

Bariatric Study

PI: Dr. Dana Graves, Dept. of Periodontics

A collaboration with the Bariatric and Weight Loss Surgery Program at Penn Medicine, the purpose of this study is to determine whether diabetes alters the subgingival microbial composition and/or bacterial RNA expression by comparing bacteria obtained from diabetic and nondiabetic individuals undergoing bariatric surgery.

Gum Inflammation Trial

PI: Dr. Dana Graves, Dept. of Periodontics

This study is investigating how periodontitis (typically non-painful chronic inflammation of the gums around the tooth that can lead to bone resorption and tooth loss) and peri-implantitis (typically non-painful chronic inflammation of the gums around the dental implant that can lead to bone loss and loss of the implant) affect the outer layer of the gums compared to normal tissue.

for feeding devices in infants with cleft palate, who require specialized bottles. In collaboration with Penn Engineering, his Baby Seal project is designing an adaptor that converts any regular bottle into a specialized one.

For Ko, he was attracted not only to the responsibilities and opportunities of this new role, but also to the nimble environment he observed within the CCTR. “I was impressed with how incredibly responsive the Center was during the height of the pandemic,” recalls Ko. “While we were adjusting to the novel concept of ‘social distancing,’ the staff at the Center was figuring out how to continue the ongoing clinical studies, which still had to be in person.”

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— DR. EUGENE KO

“To see the energy and momentum of the Center made me enthusiastic to join the team,” he continues. “Plus, to be working with Pat as a colleague and ongoing mentor is an invaluable opportunity to learn.”

For Corby, the addition of Ko will allow her to devote more time to supporting faculty in developing new projects and pursuing funding with the goal of continuing to help take clinical research to new levels.

“We can only be successful, if we continue to secure new grants and explore novel areas of research,” she says. “We need the evidence that clinical research provides to improve the care we deliver to our patients. That’s how we continue to grow as healthcare providers.” ■

STUDIES ACROSS DISCIPLINES

A selection of some of the current projects that have industry support or are internally funded:

The HUM Brush Study

PI: Dr. Katherine France, Dept. Oral Medicine;
Co-Is: Dr. Eugene Ko, Dr. Patricia Corby

The purpose of this study is to evaluate the experience children diagnosed with Autism Spectrum Disorder Level 1 or 2 have using a smart/interactive toothbrush. The HUM Kids toothbrush connects to an interactive game on a phone or tablet, which guides the child’s brushing. This study will document children’s and caregivers’ experiences using the toothbrush.



Pain Management in Implant Patients

PIs: Drs. Elliot Hersh and Katherine Theken, Dept. of Oral Surgery/Pharmacology

This double-blind pilot study will evaluate the anti-inflammatory and pain management effects of an over-the-counter (OTC) regimen of naproxen sodium (Aleve) versus acetaminophen in patients receiving dental implants. It will also confirm that naproxen sodium in the OTC dosage range is a good alternative to immediate-release opioid formulations, which are subject to misuse, abuse, and diversion in this patient population.

The Role of Dentists in Vaccination

PI: Dr. Katherine France, Dept. of Oral Medicine

This study aims to determine patient attitudes around the role of the dentist in vaccinations for both COVID-19 and human papilloma virus (HPV). By comparing attitudes and awareness of patients concerning the vaccines, the aim is to further understand the ways that dentists can play an important role in public health, including through vaccination campaigns and also understand patients’ willingness to be vaccinated by dental professionals.

Pediatric Toothpaste Study

PI: David Hershkowitz, Div. of Restorative Dentistry

This study will test how effective a new toothpaste is in reducing cavities. The toothpaste contains arginine, an essential amino acid that is naturally found in saliva and produced by the human body. The study will compare regular fluoride toothpastes to the arginine toothpaste.

Povidone-Iodine Oral Rinse Study

PI: Dr. Patricia Corby

This povidone-iodine oral rinse study is testing whether a mouth rinse containing povidone-iodine reduces the amount of the Covid-19 virus in the mouth.

Early Fungal Infection & Cavities

PIs: Dr. Yuan Liu, Dept. of Preventive & Restorative Sciences and Center for Innovation & Precision Dentistry (CiPD); Dr. Michel Koo, CiPD, and Dr. Pat Corby (co-primary mentors); Dr. Brian Fisher, Perelman School of Medicine (mentor)

This is an observational study to evaluate the association between early oral Candida infection (oral thrush) and dental caries in infants. The purpose is to determine if children diagnosed with oral thrush in the first year of their life are at higher risk of developing dental caries later.

Periodontal Disease and Vascular Calcification in Undiagnosed type II Diabetes Mellitus

PI: Dr. Adeyinka Dayo, Dept. of Oral Medicine; Dr. Patricia Corby (mentor)

The hypothesis of this exploratory study is that periodontal bone loss and circumferential and/or linear patterns of medial arterial calcification (a condition characterized by the presence of diffuse calcium deposits along the medial layer of the arterial wall) detected by cone beam computed tomography can serve as a marker of undiagnosed/progressive T2DM.