DHRHealth Institute for Research & Development
To Discover · To Innovate · To Excel

December 2019

The Research Spectator

Clinical Innovations for Our Smallest Patients

In the Neonatal Intensive Care Unit at the DHR Health Women's Hospital, multiple clinical trials are underway in newborn babies. Providing advanced clinical care options for some of our most fragile of patients will ultimately provide a new and possibly improved standard of care.

While two of the current studies are evaluating an infant formula in preterm infants, the third is testing a new way to protect babies who are going into their first respiratory syncytial virus (RSV) season.

RSV is a common infection that most children have by the time they are two years old. In most cases, the virus causes mild symptoms, but for others such as premature infants and those younger than six months, it can cause severe illness. Prevention of this disease is a public health priority, yet there is no safe and effective treatment.

Currently there is only one approved medication for RSV prophylaxis-SYNAGIS® (*palivizumab*). Babies who are born prematurely (at or before 35 weeks) and are unhealthy receive SYNAGIS® ,an anti-body injections given monthly over a period of five months, before going into their first RSV season. Healthy babies who are born after 35 weeks, were able to receive the anti-body injection being evaluated in the clinical trial.

Unlike SYNAGIS® , MEDI8897, the drug currently under investigation, is delivered to babies in one single injection.

Providing opportunities for our smallest patients to become healthy is the goal of clinical research in NICU. Our efforts will contribute to a wealth of knowledge that can assist in creating new vaccines, treatment options and medications that can help babies during their first few months, and ultimately develop into healthy adults.

Excellence in Cancer Care

The Commission on Cancer (CoC) accreditation, a program of the American College of Surgeons, recognizes cancer care programs for their commitment to providing comprehensive, high-quality and multi-disciplinary patient-centered care that includes integration of innovative clinical research. Clinical research advances science and ensures that patient care approaches the highest possible level of quality. As part of the CoC requirements for research, programs are required to accrue patients who:

- Are diagnosed and/or treated, or enrolled in a cancer-related clinical research study within the program or facility; and/or
- Are diagnosed and/or treated, or enrolled in a cancer-related clinical research study within a staff physician's office of the program or facility; and/or
- Are diagnosed and/or treated at the program or facility, then referred for enrollment onto a cancer-related clinical research study at another program or facility; or
- Are referred to your facility for enrollment into a cancer-related clinical research study.

Currently at DHR Health, there are numerous ongoing trials in the area of oncology, as well as those supporting the Border Biospecimen Repository at DHR Health (B^2RAD). The B^2RAD focuses on the collection of biospecimens for genetic analysis, which may aid in the development of new diagnostics, prognostic and therapeutic tools to benefit patients.

To help maintain the CoC accreditation, prospective subjects accrued in clinical trials must be monitored and reported annually and are a component of evaluation at the time of survey for re-accreditation. DHR Health first received its CoC accreditation in 2015; becoming the first CoC accredited program in the Rio Grande Valley. In 2018, DHR Health was re-accredited for another three-year period.

Dr. Dynio Honrubia Neonatologist

Dr. Dynio Honrubia is a neonatologist, and Clinical Research Scientist, Research Academy at DHR Health Institute for Research and Development Dr. Honrubia received his medical degree from the University of California, Los Angeles and completed an internship and residency at UCLA-Cedars Sinai Medical Center in Los Angeles. He then continued his education at Children's Hospital Boston, at Harvard Medical School with a fellowship in neonatology.

Dr. Honrubia has held previous positions at Cedars-Sinai Medical Center, Children's Hospital Boston, Christus-Spohn Health System and is currently the Director of Perinatal Services at DHR Health Women's Hospital.

Currently, Dr. Honrubia has three actively enrolling trials at the DHR Health Women's Hospital. Two of the studies will compare human milk fortifiers in preterm infants, and the other to evaluate the efficacy, safety, pharmacokinetics and antidrug antibody response for a drug in healthy late preterm infants entering their first RSV season.

Because of Dr. Honrubia's experience in research and expertise in the care of newborns, he acted as the principal investigator of a federally funded trial testing a potential Zika vaccine. In 2016, the Women's Hospital became the first private intermediate site for the use of Omegaven, a potentially life-saving treatment made with fish oil that was used in babies where oral or enteral nutrition is insufficient or contraindicated .

The Role of Research in Becoming a Level I Trauma Center

On May 1, 2019, DHR Health announced that it is now a functioning Level I Trauma Center. One of the requirements for Level I Trauma Center is verification by the American College of Surgeons is that the center must "operate an organized teaching and research effort to help direct new innovations in trauma care." To meet this requirement, programs must publish 10 peer-reviewed trauma-related articles in journals included in MEDLINE and also demonstrate four specified trauma-related scholarly activities over a three-year period. Trauma related articles must be from at least three disciplines including:

- Neurosurgery
- Emergency Medicine
- Orthopedics
- Vascular Surgery
- Critical Care
- Rehabilitation
- Radiology
- Anesthesiology
- Nursing

Through collaboration with the Trauma team at DHR Health, there are many trauma-related studies being conducted, one of which has already been submitted for publication. These studies are specifically in the areas of rehabilitation, critical care and neurosurgery, and orthopedics.

DHR Health Joins NIH Stroke Trials Network to Help Bring Innovative Stroke Care to the Rio Grande Valley

DHR Health is now a part of the National Institutes of Health (NIH) Stroke Trials Network, also known as StrokeNet. The NIH StrokeNet was initiated in 2013, and is composed of 27 Regional Stroke Centers in the USA. It provides multidisciplinary infrastructure to conduct clinical research while advancing new treatments for acute stroke, stroke prevention, and recovery and rehabilitation of patients who have suffered a stroke. This system aims to streamline stroke research by establishing centralized administrative processes, reducing time and costs of clinical trials, and maintaining a comprehensive data sharing system. In addition, NIH StrokeNet offers an educational platform for physicians and clinical trial coordinators.

By successfully becoming a part of StrokeNet, DHR Health Neuroscience Institute has demonstrated significant experience and expertise in successfully conducting advanced clinical research in patients suffering from stroke and the ability to enroll underrepresented populations. The multidisciplinary team at DHR Health Neuroscience Institute provides access to the full spectrum of specialty services involved with stroke care including, emergency medicine, minimally invasive neurosurgery, interventional neuroradiology, vascular neurology, neuro-critical care, neuroimaging, stroke rehabilitation, and pediatric neurology.

NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

Successful Implementation of Research RVU Model

Until recently, conducting clinical research at DHR Health was somewhat disruptive for the physicians and for the flow of patients in both outpatient and inpatient settings. This was despite of the fact that many physicians at DHR Health understood the value of clinical research and the benefit that this advanced and innovative clinical care will bring to their patients and the community.

Upon establishment of the DHR Health Institute for Research and Development, we embarked on seeking feedback from the end-users of how best to "enable" conducting clinical research at this Institution. Our objective was to identify key challenges and to find a solution that while compliant with Federal, State and Institutional rules and regulations would also facilitate enhancement of clinical research capacity in the Rio Grande Valley.

One of the most frequent areas of concern expressed by the physicians was the lack of a process that would allow seamless integration of clinical research into their standard practice and their target wRVU's. The requirement to keep "logs" of time spend on research-related activities was not only cumbersome but extremely disruptive for the physicians. Recognizing this limitation, we have developed a model of Research RVU (rRVU), which we have shared with many physicians in the system and sought their valuable feedback and approval.

Goals for Research RVU Model

Conduct clinical research and provide advanced clinical care in a process that is as minimally disruptive to providers as possible	Minimize referral to where physicians retain their own patients to ensure continuity of care	Ensure that the involvement in research contributes to target RVUs	Reimburse RMF and partner physicians for their effort in research

Similar to wRVUs, rRVU value will also be based on time and effort of research-related activities unique for each study. Given the fact that patients accrued in research studies are more complex with multiple co-morbidities, the rRVU calculated will be at a higher level for a research visit vs. that for standard of care. Additionally, working with the DHR Health Revenue Cycle department, a process has been developed to facilitate billing and collection related to rRVU's ensuring that research-related effort by the physicians is credited in a timely manner.

To learn more about rRVU's, please write to Sohail Rao, MD, MA, DPhil (s.rao@dhr-rgv.com) or Lisa Trevino, Ph.D. (lis.trevino@dhr-rgv.com).

Clinical Research Facts

According to Clinicaltrials.gov, there were 2,119 registered clinical studies at the end of the year 2000. Researchers project that there will be over 306,000 studies by the end of 2019!

Top 3 Questions from Research Patients

1. How does participating in a clinical trial benefit me?

More than 90% of the population in the RGV is of Hispanic origin. However, less than 1% of participants of Hispanic origin are involved in clinical trials the United States. It is imperative to engage and involve more people of Hispanic origin in innovative clinical trials that would not only benefit them but would also assist in developing treatment strategies that are most effective for a predominately Hispanic population. Those who participate in clinical trials also gain access to advanced and promising treatments that are free of cost, and may be more effective than the current standard of care.

2. What happens during a clinical trial?

First, you will need to give your permission to take part in the study or clinical trial. Before any tests can be done to see if you are eligible for the clinical trial, you will need to give your written consent that you want to be a participant in the study. Once you've signed the consent form, you'll be ready to participate in the study. It is important to note that each study is different. Depending on the study, visits may be as short as a one-time blood draw or may take the course of several months. Each study will require different tests and procedures and these should be explained to you during the informed consent process. Participating in a study is voluntary. You can decide, at any point, for any reason, to withdraw from a study.

3. How is my safety protected?

Protection of patients in clinical trials is the paramount responsibility of the institution in which the study is being conducted. Federal, State, and institutional policies and procedure govern the conduct of clinical research. All institutions involved in clinical research are required to provide assurance that research will be conducted ethically while maintain the privacy and confidentiality of the patient, ensuring patient safety, and that all studies are reviewed and approved by the Institutional Review Board.

December 2019/January 2020

Institutional Review Board Meeting
December 11, 2019 | 12:30 PM
DHR Health Institute for Research and Development
Collaboration Room | 5323 S. McColl Road
Edinburg, TX

DHR Health 14th Annual Community Health Fair
January 18, 2020 | 8:00 AM—12:00 PM
Edinburg Conference Center at Renaissance
118 Paseo Del Prado
Edinburg, TX 78539

The 14th Annual DHR Health Community Health Fair provides the community with free educational and informational health services, as well as free screenings.

The DHR Health Institute for Research and Development will be providing free fibroscans to community members, and information about current enrolling studies.

Want to participate in one of our current clinical trials?

Call (956) 362-2390 to see if you qualify to participate in one of our enrolling trials.

Team Spotlight: Jorge Alejandro Bernal, MD

Jorge Alejandro Bernal, MD is Clinical Research Fellow at DHR Health Institute for Research and Development and is a graduate of the Universidad Autonoma de Guadalajara School of Medicine. Growing up within the RGV community, Dr. Bernal has developed a deep interest in the chronic disease determinants of this community. At the DHR Health Institute for Research and Development, Dr. Bernal is involved in numerous cutting-edge and innovative clinical trials in the areas of NAFLD/NASH, cardiology and hepatocellular carcinoma. Dr. Bernal is actively seeking innovate strategies to improve the healthcare of residents in the Valley and is committed to continue his career as a practicing physician to serve the needs of this community that he calls home.

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