Our second annual Research Day was held on Friday, Aug. 22 at the South Carolina Hospital Association William Yates Conference Center. We had more than 80 attendees from across the state. This event provided attendees with basic knowledge of the creation and design of an appropriate clinical research project through plenary and interactive sessions. In case you missed Research Day, we have summarized the plenary sessions below. If you would like to watch a presentation, video recordings also will soon be posted on our website.

The first plenary session, “Developing A Successful Research Proposal: From Concept to Reality,” was provided by Benjamin Druss, MD, MPH (Emory University). He discussed the steps to create an appropriate research question, how to focus the questions into specific aims and methods of choosing suitable variables. He also provided some of his personal tips regarding the conduct of research, including common mistakes related to the grant submission process and the idea of persistence—one must continually re-work his or her ideas for grants based on previous comments.

The second plenary session, “Randomized Trials on Physical Activity Interventions,” was provided by Steve Blair, PED (University of South Carolina). Dr. Blair focused on providing specific examples of types of clinical studies that he has conducted throughout his career. He showed the progression of complexity a research question can take over time from a simple chart review to a clinical trial.

Jason Hockenberry, PhD (Emory University) provided the third plenary session, “Right Question, Right Design, What Outcomes?” He emphasized the need to determine the research design and the data needed to produce appropriate outcomes. Due to his economics background, he provided real-life examples of comparing treatments based on economic evaluations (cost-effectiveness).

The day ended with an expert panel that included Drs. Druss, Hockenberry and Martin Durkin (Palmetto Health), and prompted a lively discussion about key points from the day and lingering, unanswered questions.

We would like to thank South Carolina Medical Translational Technology (MedTransTech) Program for the support to make this event possible.
Research Billing: The Clinical Trial Policy

Have you ever wondered how and why there is special billing for patients on research studies? Probably not, but as someone conducting/assisting in the research process, you should have a basic knowledge to be able to provide research subjects with appropriate information and to understand Palmetto Health’s requirements.

The first piece of the billing puzzle is the National Coverage Determination (NCD) for Routine Costs in Clinical Trials, also known as the Clinical Trial Policy (CTP), which is published by the Centers for Medicare & Medicaid Services (CMS). On June 7, 2000, the President of the United States issued an executive memorandum directing the Secretary of Health and Human Services to "explicitly authorize [Medicare] payment for routine patient care costs...and costs due to medical complications associated with participation in clinical trials." The first CTP NCD was issued on September 19, 2000. After a few years of implementation, it was reviewed again and the most updated version was released on July 9, 2007.

The beginning of the current CTP defines a routine cost of a clinical trial. A routine cost of a clinical trial includes items and services that are generally available to Medicare beneficiaries, and consists of:

- Items or services that are typically provided absent a clinical trial (e.g. conventional care)
- Items or services required solely for the provision of the investigational item or service (e.g. administration of a non-covered chemotherapeutic agent), the clinical appropriate monitoring of the effects of the item or service or the prevention of complications
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications

The CTP does note that routine costs do not include:

- The investigational item or service, itself, unless otherwise covered outside of the clinical trial
- Items and services provided solely to satisfy data collection and analysis needs and that are not in the direct clinical management of the patient
- Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial

Then the CTP delineates the three requirements that a clinical trial must possess for the routine costs to be payable:

1. The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category and is not statutorily excluded from coverage.
2. The trial must not be designed exclusively to test toxicity or disease pathophysiology; it must have therapeutic intent.
3. Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers; trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

Unfortunately, the three requirements are insufficient to qualify a clinical trial for Medicare coverage of routine costs. Clinical trials should also have the following seven desirable characteristics:

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants’ health outcomes
2. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use
3. The trial does not unjustifiably duplicate existing studies
4. The trial design is appropriate to answer the research question being asked in the trial
5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully
6. The trial is in compliance with Federal regulations relating to the protection of human subjects
7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity

If a trial satisfies the three requirements and the seven desirable characteristics, it is considered qualified to receive Medicare coverage of their routine costs. Luckily, some clinical trials are deemed to be automatically qualified to receive Medicare coverage of their routine costs:

1. Trials funded by NIH, CDC, AHRQ, CMS, DOD and VA
2. Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA
3. Trials conducted under an investigational new drug application (IND) reviewed by the FDA
4. Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place

In summary, the CTP outlines that Medicare will cover the routine costs of clinical trials that are qualified as determined by meeting the three requirements and the seven desirable characteristics. A clinical trial may be automatically qualified if it is deemed. Of note, the routine costs of Investigational Device Exemptions (IDE) clinical trial are handled through a different CMS mechanism. You may review the entire CTP by clicking here.

So you may be thinking: How are IDE clinical trials different? What are the billing/coding requirements? How does Palmetto Health ensure that we remain compliant? Stay tuned for more research billing topics in future editions of the Research Insider.
Research Spotlight: Sultan Siddique, MD, FACC, FHRS

Dr. Sultan Siddique earned his medical degree from New York University School of Medicine. He completed all of his postdoctoral education in Pennsylvania, and is board certified in Internal Medicine, Cardiovascular Disease and Clinical Cardiac Electrophysiology. In his first 10 years, he specialized in electrophysiology in cardiology practices in Pennsylvania until being recruited by Palmetto Heart in 2013.

When asked what he finds most rewarding about his job, Dr. Siddique responded “When patients return to the office after their procedure and tell me they can sing loud and no longer are short of breath because their heart is not racing anymore or the grandmother comes into the office and states that she can now lift her grandchildren without being short of breath. It is making patients feel better that is the major reward for me.”

Throughout his undergraduate education and medical school Dr. Siddique conducted several smaller research studies and continued pursuing his interest in research. During his career as an Electrophysiologist, Dr. Siddique has been a Principal Investigator for defibrillator studies sponsored by Biotronic and Sorin and was a sub-investigator for a study evaluating an atrial ablation tool. Dr. Siddique has co-authored multiple national and international journal publications and contributed to the Chapter Titled “Ablation of unstable ventricular tachycardia” in the 2003 textbook titled “Cardiac Arrhythmias.”

Dr. Siddique is married and has four children under the age of six. His twins (boy and girl), a four-year-old daughter and one-year-old boy keep him busy. He enjoys playing and teaching his children tennis and soccer. Dr. Siddique likes to travel. He stated that living in the South, where it is warm, has allowed him and his family to experience many new places that were not as accessible while living in the North. He and his family regularly take trips to southern nature destinations. They enjoy frequent trips to beautiful beaches and take an annual trip to Marco Island in Florida.

New Research Registration and Billing Form

In efforts to prevent confusion and allow efficiency in the notification process, Palmetto Health Research Compliance has combined the Research Registration and Request for Research Billing forms into one form, Research Registration and Billing form. This new form is to be submitted by the investigator/study staff within 24 hours of a subject encounter (subject visit) that occur at either the Baptist or Richland campuses.

The completed form should be sent via email to Research-Baptist@PalmettoHealth.org or Research-Richland@PalmettoHealth.org depending on the campus location of the subject. Please note if there are modifications to the billing portion of the form (second page) during the subject’s stay, please resubmit the corrected form as soon as possible through the same email process.

You may access current research forms including the Research Registration and Billing form at www.PalmettoHealth.org/ResearchCompliance.
Clinical Research Forum

The Division of Research offers educational programs, Clinical Research Forums (CRF), for investigators, research staffs, IRB members and staff, and others who have research-related responsibilities or interests.

The purposes of the meetings are to provide an avenue for:
- Staying abreast of changes in federal, international and institutional regulations, and good clinical practice guidelines in research to maintain competency in practice
- Being exposed to the broader scope of clinical investigation by hearing presentations of research studies by investigators from various clinical disciplines
- Having the opportunity to network and form professional relationships with others involved in the clinical research arena.

Meetings are held bi-monthly on selected Thursdays from 12:30-1:30 p.m. in Room 130 of 9 Medical Park on the Richland campus. Coffee and water are provided at the meetings, and attendees are encouraged to bring their own lunches.

Information about the meetings, including the yearly schedule, can be accessed on the Research Compliance page of the Division of Research website www.PalmettoHealth.org/ResearchCompliance.

Grant In Aid Awardees

The Richland Memorial Hospital Research and Education Foundation recognizes the importance of resident involvement in research activities as part of a comprehensive graduate medical education experience. It therefore supports meritorious, resident-initiated projects primarily in the areas of health care delivery and social science research by providing funds on an annual basis through the Grant In Aid program.

Congratulations to the following 2014 award recipients:
- Isioma Aninyei, MD, Department of Internal Medicine, Infectious Disease for her project entitled Tenofovir Plasma Concentrations in Obese, Human Immunodeficiency Virus (HIV)-Infected Subjects
- Henrik O. Berdel, MD, Department of Surgery, for his project entitled Control of Soft Tissue Reaction to Implantation of Biomedical Devices with ACT 1 Eluting Absorbable Collagen Coats in a Murine Model
- Melissa Maxey, MD, Department of Surgery, for her project entitled Pneumonia Rates Based on Pre-Intubation GCS
- Elizabeth Nimmich, MD, Department of Medicine, Infectious Disease, for her project entitled Impact of Institutional Management Guidelines and Microbiology Rapid Diagnostics on Empirical Antimicrobial Therapy for Bloodstream Infections

2015 CRF Meeting Dates
- January 8
- March 12
- May 7
- July 9
- September 10
- November 12

Meet the IRB Chair

Edward W. Catalano, MD is the oldest of 11 children. He completed his primary education in Columbia, SC and received his Bachelor of Science from the University of South Carolina. Dr. Catalano earned his MD from the Medical University of South Carolina, where he completed his internship and two years of residency. He completed two more years of residency at The Johns Hopkins Hospital and two years as a Major in the US Army Medical Corp. In 1977, he joined the Pathology Department at Richland Memorial Hospital.

Dr. Catalano is a past president of the SC Medical Care Foundation, the SC Society of Pathologists and the SC Medical Association. He is also a past Chairman of the Board of the SC Medical Malpractice Patients’ Compensation Fund, the SC Medical Association and Pathology Service Associates. Upon his retirement as CEO of Professional Pathology Services, he served as the VP for Medical Staff Affairs at Palmetto Health Richland for three years. He later transitioned to the position of Director of Laboratory Outreach and Referral testing for Palmetto Health Richland.

Dr. Catalano has three children and seven grandchildren. He and his wife, Susie, live on a working cattle farm in northeast Columbia where they care for animals like horses, donkeys, dogs, cats, chickens and peacocks.

For the past twenty years Dr. Catalano has served as Chair of the one, then both Palmetto Health Institutional Review Boards. He is very complementary of the Board members and staff whose goals are to protect human subjects involved in research, to protect Palmetto Health and to facilitate good quality research.