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Center for Research & Grants

RESEARCH MATTERS

Center for Research & Grants

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In this issue:

The Newly Created Patient Centered Outcomes Research Institute

by Don Parris, MPH, CCRC

The Patient Protection and Affordable Care Act established a private, non-profit entity called the Patient-Centered Outcomes Research Institute (PCORI) as an independent advisory board with a $3 billion budget to support comparative effectiveness research with a patient-centered focus.

Led by Executive Director Joe Selby, a former director of research for Kaiser Permanente, PCORI has held meetings across the country over the past year to gather input on how the group should focus its research. The organization recently released its research plan and agenda.

PCORI will focus on researching the most effective medical treatments and preventive medicine. It will also look at how health systems can best organize to deliver care, and how to reduce health care disparities in the United States. Lastly, it will make communicating and disseminating information about treatments a priority, with an emphasis on how to convey to patients what works and what doesn't.

On March 5, 2012, PCORI established the following working definition of "patient-centered outcomes research."

Patient-Centered Outcomes Research (PCOR) helps people and their caregivers communicate and make informed health care decisions, allowing their voices to be heard in assessing the value of health care options. This research answers patient-centered questions such as:

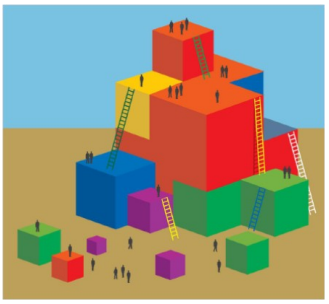
1. "Given my personal characteristics, conditions and preferences, what should I expect will happen to me?"
2. "What are my options and what are the potential benefits and harms of those options?"
3. "What can I do to improve the outcomes that are most important to me?"
4. "How can clinicians and the care delivery systems they work in help me make the best decisions about my health and healthcare?"

To answer these questions, PCOR:

- Assesses the benefits and harms of preventive, diagnostic, therapeutic, palliative, or health delivery system interventions to inform decision making, highlighting comparisons and outcomes that matter to people;
- Is inclusive of an individual's preferences, autonomy and needs, focusing on outcomes that people notice and care about such as survival, function, symptoms, and health related quality of life;
- Incorporates a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination; and
- Investigates (or may investigate) optimizing outcomes while addressing burden to individuals, availability of services, technology, and personnel, and other stakeholder perspectives.

It is hoped that research results generated from PCORI will identify what treatments will lead to the best health outcomes for patients.

Nursing Research Spot Light



Genomes: Our Future

By Eve Butler, RN, PhD and Andy Prentiss, MSN, ARNP, CNS

Genetics is the study of individual genes and their impact on relatively rare single gene disorders. Genomics is the study of all the genes in the human genome together, including their definitions with each other, the environment, and other psychosocial and cultural factors. As of 9/21/2011, there are 2437 diseases that have genetic/genomic tests available for detection. Currently there is a challenge relevant to genetic health literacy with nurses being the bridge to apply genomic discoveries to patient care.

West Virginia University, the National Cancer Institute Center for Cancer Research (a branch of National Institutes of Health), and the National Human Genome Research Institute are conducting a research study to learn more about nurses attitudes relating to how genetics and genomics is used in their practice and how they think genetics and genomics might be used to treat common multi-factorial diseases. Baptist Hospital of Miami has been selected as one of only 22 Magnet hospitals to participate in a study entitled *Expanding RN Scope of Practice: A Method for Introducing a New Competency into Nursing Practice (MINC).* Becky Montesino will serve as Principal Investigator and Laura Carey will be co -investigator; they will be our system dyad.

The specific aims for this study are to determine nurse's beliefs, practices, and competency of integrating into practice genetic and genomics information related to common multi-factorial disease and to assess knowledge of human genetic variation and the use of patient genetic information in therapeutic decision-making.

Following IRB approval, the study will involve a pre-assessment survey to assess personal genomic competency levels and an institutional status survey (completed by the dyad), and a baseline Genetic/Genomic Nursing Practice Survey (GGNPS) to be completed online by bedside registered nurses. Survey assessments will be repeated following a year long hospital intervention program.

This study will support Magnet Hospital awareness, integration, and utilization of genomic information in nursing to facilitate excellence and innovation in professional nursing practice through the use of evidence-based genomic information which can influence quality patient care.
Jenkins, J., NIH, 2012

Centers for Medicare & Medicaid (CMS) Services Delays Data Collection for Sunshine Act to 2013

From modernphysician.com May 4, 2012

CMS has again extended the implementation of the Physician Payments Sunshine Act and will not require drug and device manufacturers to begin collecting data on payments to providers until 2013.The Physicians Payments Sunshine Act is a provision in the Patient Protection and Affordable Care Act that is intended to increase public accountability and transparency. The CMS said in a May 3 blog post that it plans to issue a final rule this year and that it will not require data collection before 2013. The final rule had been expected to be released in June.

"In order to provide time for organizations to prepare for data submission and to sufficiently address the important input we received during the rulemaking process, CMS will not require data collection by the applicable manufacturers and applicable group purchasing organizations before January 1, 2013," the CMS said. After missing an October 1, 2011 deadline to establish procedures for reporting data on payments to providers, the CMS later issued a proposed rule in December, just weeks before organizations were expected to begin collecting data. At that time, the agency had recommended delaying data collection. The agency said it received more than 300 comments during the 60-day comment period.

In an April 4 letter to CMS acting Administrator Marilyn Tavenner, Sens. Chuck Grassley (R-Iowa) and Herb Kohl (D-Wis.) urged implementation of the provision.

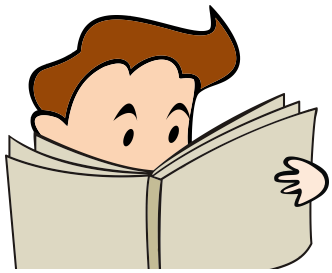
"Our goal is to promote the implementation of the law as expeditiously as possible," Grassley and Kohl wrote. "We are disappointed that regulations implementing the Sunshine Act were not complete by the statutory deadline of October 1, 2011."The provision will require drug and device companies to report payments or gifts to physicians and teaching hospitals. It also requires manufacturers and GPOs to report physician ownership and investment interests.

New and Updated Research Policies

Does your job involve working on or supporting research or clinical trials? If so, you may want to learn about the updates to research policies and procedures, which are in the process of implementation. Baptist Health has implemented these updates as part of its research compliance improvement effort.

The current research compliance improvement phase includes the following policies and procedures:

- Effort Reporting - BHSF-1330.01 (NEW)
- Registration of Research Patients - BHSF-1340.10 (NEW)
- Billing for Humanitarian Use Devices (HUDs) - BHSF-1340.11 (NEW)
- Charge Capture and Segregation of Charges - BHSF-1340.12 (NEW)
- Clinical Trial Budgeting - BHSF-1340.13 (NEW)
- Medicare Coverage Analysis (MCA) - BHSF-1340.14 (NEW)
- Clinical Trial Patient Account Processing - BHSF-1340.07 (REVISED)
- Billing Compliance for Clinical Trials - BHSF-1340.08 (REVISED)



Click here for more information.

If additional guidance is required on any of the above topics, please contact the Research Compliance Team by emailing ResearchCompliance@baptisthealth.net.

ACRP 2012 Global Conference & Exhibition

Ethics, devices, recruitment, oh my! As a novice coordinator, you can easily become overwhelmed by the myriad guidelines, regulations, and responsibilities in the clinical research industry. Alas, there is hope. The Association of Clinical Research Professionals (ACRP) is *the* professional organization for clinical researchers. Aside from courses, webinars, and literature, they hold a yearly conference and exhibition for researchers, sponsors, and vendors to come together and share their knowledge and expertise. This year, the conference was held in Houston, Texas from April 14th to 17th at the George R. Brown Convention Center.

What an experience! As a first-time attendee, I was astounded by the sheer number of sessions and topics contained in the program. Over 125 sessions were designed to save you time, money, and reduce on-the-job risk. Twelve topic areas were organized into basic, intermediate, and advanced levels. So whether your focus was Business & Finance, Devices, or Regulatory, you had industry professionals at your disposal to discuss best practices. Perhaps you wanted to learn more about Clinical Study Management & Delivery, Global Issues in Clinical Trials, or Technology & Innovation. Knowledgeable speakers and panel members were generously available for one-on-one inquiries throughout the conference. Personal interests shifted my focus towards Physician Interest and Career & Professional Development in Clinical Research. These sessions provided networking opportunities with veteran coordinators and support from experienced ACRP staff.

The conference exposure to scores of sessions, over 25 informational posters, and mingling with vendors was an excellent opportunity to get the most current information and advice on the issues facing this industry. I came back energized, engaged, and eager to put into practice the latest risk-based approach processes at our site. The scope and quality of educational offerings definitely exceeded my expectations and I look forward to attending next year's conference in Orlando, Florida from April 13th to 16th at the Orange County Convention Center. Hope to see you there!

Key Components in Developing a Research Concept or Program Award

By: Allison Bivin

The healthcare industry continues to see a healthy stream of funding due to federal initiatives focused on reducing healthcare costs. Although the competition is greater, funding is accessible when the research concept or program is well developed. This is the perfect time for Baptist Health South Florida to pursue outside funding resources.

When seeking funding for your research concept or program, the idea should be as fully developed as possible. It is easier to tweak an idea to match funding opportunities requirements than it is to write for the purpose of specific funding. However, the most important skill applied throughout the development process is planning.

The planning process associated with the development of a fundable concept requires constant review of deadlines, realignment, and flexibility. Other key aspects to a well developed concept include a good deal of data collection and assessment, access to resources and consideration of timeframes.

When developing the concept collaboration is extremely important. The Center for Research & Grants suggests that you invite a small group of people, subject matter experts, who will serve as an Advisory Board to help to move your research concept forward. These people should be those who are "doers". You can farm out assignments and use each person's strengths to help you achieve your concept development deadline. Helpful tools such as Gantt Charts, Calendars, and SharePoint sites are great for keeping a project concept moving forward in the right direction.

An often overlooked part of the development of a research concept is the budget. The budget can influence an alteration in the overall concept. It is wise to first develop a simple budget and add to the budget as the writing process moves forward. A helpful tip: When writing, put a dollar sign symbol ($) next to any part of the concept that may have a financial impact. This will help you in the review and development process.

Another important aspect to a strong, fundable concept is including viable partners. These days funding is based upon a strong network of partners. Consider local and National organizations that work to support the goals you have in mind. Often overlooked is the value of internal partners; take the time to learn about Departments or Divisions of BHSF that may have a similar mission.

Some other things to consider are institutional policies and procedures associated with Research, such as Award Develop and Management, Finance, Travel, Procurement and more. Most importantly, reach out to the Center for Research & Grants for assistance. Our staff has extensive knowledge and experience and can help to guide you in the right direction.

EDUCATIONAL EVENTS

Date & Time	Event	Location
Wednesday, 6/20/12 12:00 pm - 1:00 pm	Statistics: Demystifying Journal Articles	BHM - Oasis I (The Palm)
Wednesday, 6/20/12 12:00 pm - 1:00 pm	State of Science: Grand Research Rounds at SMH	SMH - Classroom D
Friday, 7/20/12 8:30 am - 10:00 am	Statistics: The Basics	HH - Mango Classroom
Tuesday, 7/24/12 12:00 pm - 1:30 pm	Shipping Biological Specimens and Related Hazards	BHM - Oasis II (Pineapple)
Tuesday, 8/21/12 12:00 pm - 1:30 pm	Papers, Papers, Papers - The Art and Science of Maintaining Study Documentation	BHM - Classroom 2