RESEARCH HIGHLIGHT

Researching Asthma: in the Community & on the CRC

Wanda Phipatanakul, MD, MS, Boston Children’s Hospital

Using the resources of the Harvard Catalyst Clinical Research Center at Boston Children’s Hospital, Wanda Phipatanakul, Director of the Asthma Clinical Research Center (ACRC) and her team of researchers are able to conduct a multitude of clinical research study visits both in the CRC and in the community in pediatric asthmatics’ homes and schools.

The MAAIT team (The Mouse Allergen Asthma Intervention Study) conducts research visits in homes of asthmatic children. The team is studying if mouse-targeted integrated pest management intervention is helpful in reducing the effects of asthma and mouse allergy in children ages 6 to 17 years old. This NIH funded study is a unique collaboration between Boston Children’s Hospital, Columbia University and Johns Hopkins University. Participants in this study receive asthma management education, pest extermination services, air purifiers, and allergen-proof mattress covers.

Within the Boston Public Schools, working with elementary school students, the SICAS Team (School Inner-City Asthma Study) works to determine the role of the environment and allergens in schools and homes in order to further understand the relationship between allergens and asthma. If there is a meaningful relationship, interventions targeting school classrooms and home environments could help many students with asthma.

Phipatanakul and other researchers within the AsthmaNet Network are also investigating if standard treatments for asthma and wheeze symptoms are as effective in children ages 1 to 6 years as they are in older patients. The study is evaluating whether starting azithromycin at the onset of an upper respiratory tract illness is effective in preventing the development of clinically significant lower respiratory tract symptoms, and if the addition of oral corticosteroids (prednisolone) is effective at reducing the severity of wheezing episode exacerbations. Participants receive asthma supplies, physical exams and patient-specific education on identifying their child’s respiratory symptoms.

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Cultural Competence in Research

On Thursday, November 15, 123 participants from 16 institutions joined us at the Dana-Farber Cancer Institute for the Cultural Competence in Research Symposium, featuring interactive performances by the Derek Bok Players, to explore the themes of engaging diverse communities, establishing trust, obtaining consent from diverse populations, encouraging minority accrual in clinical research, and dealing with stereotypes and unconscious personal bias.

New Nutrition Research Software

A new dietary analysis and nutrient database program is available at all four HCCRC sites.

The Nutrition Data System for Research© (NDSR) is a Windows-based dietary analysis program designed for the collection and analysis of 24-hour dietary recalls, food records, menus, and recipes. It contains a database of more than 18,000 foods, analysis for 163 nutrients and other food components, and offers a variety of hard copy report options and data output files.

Nutrients can be calculated per ingredient, food, meal, and day, including nutrients from dietary supplements.

Each HCCRC site will have a designated NDSR expert dietitian to facilitate training and usage.

While nearly half of attendees were research assistants, study coordinators, investigators, and project managers, we had attendees with roles as diverse as Social Worker, Behavioral Scientist, and Public Health Specialist.

Following each vignette, there was a discussion and Q&A session with the actors and a panel of experts representing human subjects protection, advocacy and research regulations, research nursing, and the research subject experience. Among the panelists, Venatia Gilmer-Jones, a breast cancer survivor, shared her unique perspective as a research subject. Another unique component of the QA was the opportunity for the audience to interact with the actors, still in character, and replay portions of the vignettes. Dr. K. Babu Krishnamurthy, BIDMC, volunteered to fill the role of study PI and engage a mother whose child may be eligible to take part in a research study. The audience had previously witnessed ways in which the PI had engaged the mother and failed, but Krishnamurthy’s alternate approach demonstrated empathy with the mother, winning her over to the realization that joining the study could be in her child’s best interests.

The event was co-sponsored by Regulatory Knowledge and Support Program and Community Health Innovation and Research Program (CHIRP). The Harvard Catalyst Clinical Research Center (HCCRC), the Survey and Statistical Methods and Training Cores of the University of Massachusetts Boston - Dana-Farber/Harvard Cancer Center U54 Comprehensive Partnership to Reduce Cancer Health Disparities, and Dana-Farber/Harvard Cancer Center - Initiative to Eliminate Cancer Disparities.

To learn more about these services, please contact the Nutrition Director at your respective HCCRC site:

- BCH – Nicolle Quinn, nicolle.quinn@childrens.harvard.edu
- BIDMC – Joanna Radziejowska, jradziej@bidmc.harvard.edu
- BWH – Janis Swain, jswain@partners.org
- MGH – Ellen J. Anderson, eanderson@partners.org

https://catalyst.harvard.edu/programs/hccrc/metabolism-and-nutrition-research.html

New Laboratory Navigator

Patrick Sluss, PhD, Associate Professor of Pathology, is available to advise all investigators on which assays to use, blood-sparing methodologies and new assay development. He also co-directs the MGH Clinical Laboratory Research Core facility (MGH CLR).

MGH CLR: Specialty Assays and New Assay Development

As of January 1, 2013, MGH CLR is the preferred laboratory for specialized assays and new assay development for Harvard Catalyst. Investigators interested in taking advantage of discounted pricing on a list of assays as well as accessing per-visit funding support for these assays should go to:

https://clr.mgh.harvard.edu

For questions, please contact:

Pat Sluss, MGH CLR Co-Director and HCCRC Laboratory Navigator
psluss@partners.org or 617-726-4352

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CRC updates

**HCCRC @ BIDMC**

**Off-Unit Research Support**

The new Research Project Management service will help investigative teams successfully launch research projects, providing research support at other locations in the hospital or in the community. Experienced Research Nurses from the CRC will work closely with study team members to develop tools to conduct the study, facilitate the participant activity on other clinical units, and closely monitor study milestones to ensure that projects are completed in a timely way.

CRC staff work collaboratively with investigators to set up the support they need, which may include Research Nursing care performed in other locations, sample processing, research coordination, and project management of research occurring at other locations.

*For questions, please contact:*  
Linda Godfrey-Bailey, Nurse Director, lgodfrey@bidmc.harvard.edu

**HCCRC @ BCH**

**Behavioral Science Consultations**

Investigators whose studies involve behavioral science outcomes are invited to access the Clinical Behavioral Science core, housed within the Department of Psychiatry Program for Behavioral Science. This service, directed by Deborah Waber, Ph.D. and co-directed by Michelle Bosquet Enlow, Ph.D., provides consultation services for the preparation of grants, protocols and clinical trials as well as psychometrician services, including the new NIH Toolbox:

*For more information:*  
www.childrenshospital.org/crc  
Deborah Waber, 617-355-6523, Michelle Bosquet Enlow, 617-919-4680

**BOD POD!**

In Partnership with the GPU (Gastroenterology Procedure Unit), the CTSU Core will soon have the capabilities of measuring % body fat via a BOD POD. The BOD POD uses air displacement plethysmography (ADP) to measure body mass and body volume, with a calculation of body density, percent fat, and percent fat free mass using age and sex-specific equations. ADP is an easy, safe and quick (approximately 5 minutes total test time) procedure. The BOD POD provides accurate body composition data for most children and adults, approximately 10 to 250 kg. The machine is located on Pavilion 5 in the GPU clinic and is available on Mondays, Tuesdays, Thursdays and Fridays.

*For questions or to schedule an appointment, please contact:*  
Michelle Bosquet Enlow, Ph.D., gastrointestinal procedure unit, mboesq@childrens.harvard.edu

**Project Management Services**

Project Management Services may be provided by a single member or a team of clinical research nurse project managers, non-clinical project managers, data managers and study coordinators depending on the needs of the investigator. Under the direction of the PI, CRC staff can assist with the planning, coordination and implementation of a research study. The CRC can provide project management services to studies conducted both within and outside the discrete CTSU, including inpatient units, outpatient settings or in the community.

*Apply via the Harvard Catalyst Clinical Research Center Resource Request:  
http://catalyst.harvard.edu/services/hccrcrequest/*

**HCCRC @ MGH**

**New options for EMR data**

The MGH CRC has implemented a new program to enter clinically-relevant, but “non-sensitive” information in the electronic medical record (EMR) as part of a pilot study at MGH. For years there has been interest, predominantly for safety, to include such information in the medical record. Sharing clinically-relevant data collected during research visits is important for the overall healthcare of research participants. For example, entry of updated allergy histories and vital signs that are obtained by our CRC staff into the EMR provides critical information for primary care providers. Now, for the first time, such information may be made available in the EMR, in protocols where the informed consent allows such sharing.

**HCCRC @ BWH**

**Research Nurse Support Service**

The HCCRC @ BWH offers research nurse support to assist on research protocols on both the ACC and CTC outpatient units, as well as in other units of the hospital and in the community. The outpatient/off unit nurses are able to assist with research protocol services, including history and physicals, biopsies, OGTTs, etc.

*For more information:*  
www.brighamandwomens.org/CCI  
ci@partners.org

**HCCRC @ MIT**

**Nurse-supported off-unit research: Stress & Economics**

Johannes Haushofer, PhD, tapped the resources of the HCCRC at MIT to explore the effects of stress on economic choice, and whether this in turn affects economic behavior in a randomized-controlled trial done outside of the MIT CRC.

Haushofer recruited over 100 research subjects who reported to the at the Sloane School of Management’s Behavioral Research Lab to be assessed by MIT Nursing Director, Catherine Ricardi, RN, DNP, who then administered a placebo, Yohimbine—a naturally occurring alkaloid with stimulant and aphrodisiac effects or Cortisone. Ricardi monitored subjects as they took computer-based tests on economic choice which also assessed subjects’ stress, impatience, mood and impulsivity. Periodically, salivary cortisol was measured.

Haushofer, a postdoctoral fellow in MIT’s Abdul Latif Jameel Poverty Action Lab (JPAL), has unique research interests in neurobiology and its

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Understanding Asthma: continued from page 1

Asthma is one of the most common chronic diseases worldwide and its incidence is increasing, particularly in urban areas of the United States. Every day in America, 40,000 people miss school or work due to asthma.

For questions about Dr. Phipatanakul’s research please call 857-218-5336 or email asthma@childrens.harvard.edu.

HCCRC News: continued from page 2

CIRT: Clinical Investigator Recommended Tools

Investigator-endorsed CT research tools are available on a new HCCRC page. If you are using a tool, program or application that is making your research faster, easier, or safer—tell the community of CT researchers about it.

http://catalyst.harvard.edu/programs/hccrc/clinical-investigator-tools.html

Tools currently listed:

- **Task Tracker**: an open-source study project management tool created by Remo Mueller and Michael Rueschman of Dr. Susan Redline’s Program in Sleep and Cardiovascular Medicine and Sleep Medicine Epidemiology at BWH.

- **Whitehouse Media**: a free consultation service to help you advertise upcoming studies and plan your study’s marketing.

Please share what works for you!

*Email us your links for CIRT and let us know briefly how each has assisted you. Thomas_Naughton@hms.harvard.edu*

Resources RFA Award

Congratulations to the 17 junior investigators receiving awards for investigator-initiated human subjects research. Each will each receive up to $5,000 support for above-standard, fee-based services offered at the five HCCRC sites.

- Rhonda Bentley-Lewis, MD, MBA, MMSc—BWH
- Alina Gavrila, MD, MMSc—BIDMC
- Mark Halko, PhD—BIDMC
- Elizabeth A. Lawson, MD, MMSc—MGH
- Hideo Makimura, MD, PhD—MGH
- Margaret McCabe, PhD—BCH
- Sarah Morton, MD, PhD—BCH
- Meena Nathan, MD—BCH
- Sanjay Patel, MD, MS—BWH
- Melanie Pogach, MD, MMSc—BIDMC
- Luminita Pojoga, MS, PhD—BWH
- Rima Rachid, MD—BCH
- Aditi Rao Saxena, MD, MMSc—BWH
- Frank A. J. L. Scheer, BSc, MSc, PhD—BWH
- Ahmet Uluer, DO, MS—BCH
- Anand Vaidya, MD, MMSc—BWH
- Jonathan Williams, MD, MMSc—BWH

Announcements:

*http://catalyst.harvard.edu/news/**

**Leadership Strategies for the Researcher course, March 21-22, 2013—Applications due January 24**

**Grant Review and Support Program (GRASP)— Applications due January 24, 2013**

**Intro to Clinical Investigation offered May 6-10, 2013—Application opens January 18, 2013**

**KL2 Medical Research Investigator Training (MeRIT) awards—Applications due March 14, 2013**

**New Master's Program in Clinical and Translational Investigation—Applications Due January 25, 2013**