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## IU, Regenstrief study: New noninvasive colorectal cancer screening tool highly accurate

March 19, 2014

INDIANAPOLIS -- An Indiana University and Regenstrief Institute study of nearly 10,000 average-risk, asymptomatic men and women from 90 sites across the United States reports that a multi-target stool DNA test -- a new noninvasive colorectal cancer screening tool that has not yet been approved for sale by the Food and Drug Administration -- detects 92.3 percent of colon cancers, compared to only 73.8 percent of cancers detected by a fecal immunochemical test, the most commonly used noninvasive test today.

Study results have been published online and will appear in the April 3 print issue of the New England Journal of Medicine.

Approximately nine out of 10 Americans older than 50 are thought to be at average risk for colon cancer. Sensitivity -- the ability of a test to detect disease -- is the most important characteristic for cancer screening tests because their primary role is to "rule out" disease.

The multi-target stool DNA analysis is conducted on a single stool sample expelled from the body directly into a container and mailed to a laboratory. The new test, which looks for human DNA mutations present in the stool as well as fecal blood, identified a significantly higher number of colorectal cancers compared to the current standard noninvasive method: fecal immunochemical test, or FIT. The study found that FIT identified 73.8 percent of colon cancers, about 20 percent fewer than the new multi-target stool DNA test.

Colonoscopy, which is presumed to find all colon cancers, was the "gold standard" used as the reference method in the study.

The multi-target stool DNA test's ability to identify cancer did not vary in a statistically significant way by either cancer stage or location within the colon.

"While screening has been shown to reduce both the occurrence of and death rates from colorectal cancer, not enough people get screened," said lead author Thomas F. Imperiale, M.D., of the Indiana University School of Medicine, Regenstrief Institute Inc., the IU Simon Cancer Center, and the Roudebush VA Medical Center in Indianapolis, which was one of the recruitment sites. "If approved by the FDA, this noninvasive option may encourage some of those who currently avoid screening to get tested."

In addition to identifying nearly all cancers, multi-target stool DNA identified the most worrisome of advanced precancerous polyps -- those that were two centimeters or larger and those containing high-grade dysplasia - nearly 70 percent of the time, compared with approximately 45 percent of the time for FIT.

While the multi-target stool DNA test detected significantly more cancers than did FIT, the study also found that the new test produced more false positive results than FIT.

"All screening tests for low-prevalence conditions such as cancers, which include mammography for breast cancer, Pap smears for cervical cancer, and PSA tests for prostate cancer, will have more false-positive test results than true-positive test results," said Dr. Imperiale.

Study participants ranged in age from 50 to 85. Each was screened by colonoscopy and FIT in addition to the multi-target DNA test.

"The multi-target stool DNA test could provide another non-invasive option for colorectal cancer screening if it



Thomas F. Imperiale, M.D.

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is approved by the FDA. While our study provides high-quality information about test performance of this new technology and demonstrated superior sensitivity to FIT, it does not indicate which test is "best" for a particular patient, said Dr. Imperiale. "There are tradeoffs with each screening test. Physician and patient should decide together which test works best for the patient based on a variety of factors including risk of disease, risk of false-positive and false-negative test results, tolerance for the preparation process for colonoscopy and the procedure itself, as well as likelihood that the patient will complete the chosen screening test."

The National Cancer Institute reports that colorectal cancer is the **second leading cause of death from cancer** in the United States. According to the Centers for Disease Control, at least 60 percent of deaths from colorectal cancer could be avoided if all individuals age 50 and older were screened. About **90 percent of people live five or more years** when their colorectal cancer is found early through testing, according to the CDC.

In addition to lead author Dr. Imperiale, co-authors of the study are David F. Ransohoff, M.D., of the University of North Carolina at Chapel Hill; Steven H. Itzkowitz, M.D., of the Icahn School of Medicine at Mount Sinai; Theodore R. Levin, M.D., of Kaiser Permanente Medical Center, Walnut Creek, Calif.; Philip Lavin, Ph.D., of the Boston Biostatistics Research Foundation; Graham P. Lidgard, Ph.D., and Barry M. Berger, M.D., of Exact Sciences Corp.; and David A. Ahlquist of the Mayo Clinic.

The study was funded by grants from Exact Sciences Corp. of Madison, Wis., manufacturer of the multi-target stool DNA screening test.

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## *IUSCC news*

March 2014

### Call for abstracts: IUSCC's Cancer Research Day; abstracts due April 18

The IU Simon Cancer Center is currently accepting abstracts for posters to be presented at Cancer Research Day, which is Thursday, May 29.

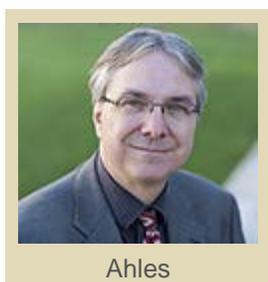
Abstracts should be submitted for one of the following research categories:

- basic science
- behavioral
- population science/epidemiology
- translational/clinical research

Abstracts will be divided and compared by the following groups within each research category:

- clinical nurse
- graduate student
- medical student
- post-doctoral/medical fellow
- research technician
- faculty (not eligible for cash award)

Cash awards will be given for best poster(s) in each research category, by group. A panel of judges will be assigned to review abstracts and posters by research category and group. Individual laboratories may submit multiple abstracts; if space becomes limited, each laboratory will be asked to identify only one poster. Visit <http://cancer.iu.edu/education/crd/index.shtml> to submit your abstract. **Abstracts are due April 18.**



Ahles

Cancer Research Day will take place at the IUPUI Campus Center, 420 University Blvd., Room CE 450 (Multi-Purpose Room). This year, Cancer Research Day will begin with a two-hour symposium on cognitive dysfunction among breast cancer patients. Tim A. Ahles, PhD, of Memorial Sloan Kettering Cancer Center, will deliver the day's keynote address. His research interest is on the cognitive effects of cancer treatment. Watch for further details.

IU Simon Cancer Center Cancer Research Day is an annual event that aims to increase understanding and awareness of IU Simon Cancer Center

research endeavors and encourage collaboration with other cancer research institutions in Indiana.

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## IUSCC news

March 2014

### News briefs

#### 6 earn AACR travel awards

The IU Simon Cancer Center awarded six travel awards for post- and pre-docs and clinical fellows to attend the 2014 American Association for Cancer Research (AACR) annual meeting in San Diego April 5-9.

The recipients, their abstract titles, and their cancer center mentors are:

- A. Jesse Gore, "TGF-beta Cross-talks with the EGF Receptor Family to Promote Proliferation of Pancreatic Cancer Cells with Dysfunctional RB." **Murray Korc**, MD.
- Alyssa Lesko, "Adenomatous Polyposis Coli Mediated Signaling, Self Renewal and Differentiation of Breast Epithelial Cells." **Hari Nakshatri**, BVSc, PhD, **Jenifer Proserpi**, PhD.
- Rasika Mundade, "VBIM Technology Identifies  $\beta$ -catenin Like Protein (BCLP) as a Novel Negative Regulator of NF- $\kappa$ B." **Tao Lu**, PhD.
- Ali Rayet Ozes, "Non-coding RNA HOTAIR Connects DNA Damage Signaling to NF- $\kappa$ B Activation in Cisplatin Resistant Ovarian Cancer." **Ken Nephew**, PhD.
- Yinu Wang, "SGI-110 Alters Ovarian Cancer Stem Cells to Prevent Recurrent and Chemoresistant Ovarian Cancer." **Daniela Matei**, MD, and **Ken Nephew**, PhD.
- Ting Zhao, "Activation of mTOR Pathway in Myeloid-derived Suppressor Cells with Lysosomal Acid Lipase Deficiency Stimulates Cancer Cell Proliferation and Metastasis." **Hong Du**, PhD, and **Cong Yan**, PhD.

The travel award partially covers travel costs for attending the meeting.

#### Nominations sought for Broxmeyer, Champion awards

The IU Simon Cancer Center is seeking nominations for the newly created Hal Broxmeyer and Victoria Champion Award for Outstanding Publication.

Nominations can be submitted in these categories:

- graduate students
- post-doctoral fellows (< 8 years as a post-doctoral fellow)
- clinical fellows/residents
- epidemiology/behavioral/population science (specifically for the Champion award)

Here are the criteria:

- Nominees must be first author (not to share co-first authorship)

The nominee's manuscript has to be cancer-focused and published in the previous calendar year

- Nomination letter is to be written by a mentor who should be a cancer center member
- Nomination letter should describe the author's contribution, impact of the publication, and how the author's research has helped in extramural grant application. Please include the manuscript along with the letter.

Awardees will be selected based on impact of the publication as judged by the review committee. **Nominations are due April 1**; winners will be announced during [Cancer Research Day](#) in May. A monetary award will be presented to first-place winners. All categories may not be awarded if none of the nominations meet expectations.

Questions? Contact Dr. Hari Nakshatri at [hnatshat@iupui.edu](mailto:hnatshat@iupui.edu). Nomination letters should be sent to [iusccrn@iupui.edu](mailto:iusccrn@iupui.edu) by April 1.



A group of dedicated volunteers, including IU faculty member Dr. Chite Asirwa, reach the top of Mt. Kenya, the second highest in Africa behind Kilimanjaro, after a four-day ascent in late February. They proudly displayed the IU, Moi University, and Moi Teaching and Referral Hospital flags atop the mountain. [More](#).

### Registration is open for 24 Hours of Booty

The IU Simon Cancer Center's 24 Hours of Booty cycling team, Pedaling Cures, is already preparing for this year's event on June 27. Pedaling Cures represents the caregivers, researchers, patients, and their friends and family linked together by the common goal of improving treatment and care for cancer patients in Indiana and beyond. Last year, Pedaling Cures collectively rode more than 3,800 miles and raised more than \$10,000 for cancer research at the IU Simon Cancer Center. For more information about the event, to register, or to sign up to volunteer, visit [24 Hours of Booty](#).



### Form a team for Relay for Life

The family friendly Relay for Life of IUPUI is around the corner. The overnight

community fund-raising walk is 5 p.m. April 5 to 5 p.m. April 6 at the Taylor Courtyard, which is located west of the Kelley School of Business. Funds raised during Relay for Life are used to provide services such as rides to treatment through the American Cancer Society's Road to Recovery program and make-up and wigs through its Look Good Feel Better program. Also, money raised is used to fund research grants. In fact, more than \$7 million in ACS grant funds have been distributed to Indiana researchers. It's not too late to be a part of this event. Form a team and sign up for the Relay for Life of IUPUI at [www.relayforlife.org/IUPUIIN](http://www.relayforlife.org/IUPUIIN). The IU Simon Cancer Center is a sponsor of this year's relay.



### Reminders: funding opportunities

#### Hester Scholarship applications due April 1

The IU Simon Cancer Center is accepting applications for the Marilyn Hester Scholarship to assist medical and/or PhD students pursuing degrees in biomedical sciences. The application is due April 1. [more >](#)

#### iCTSI seeks Young Investigator Awards applicants; deadline is April 1

The Indiana Clinical and Translational Sciences Institute is seeking applications for its Young Investigator Awards in Clinical-Translational Research. [more >](#)

#### Wright Scholarship applications due April 25

Applications are open for the William J. Wright Scholarship, which is awarded to third- and fourth-year medical students who have had a strong academic career and wish to pursue a career in the care of cancer patients. [more >](#)

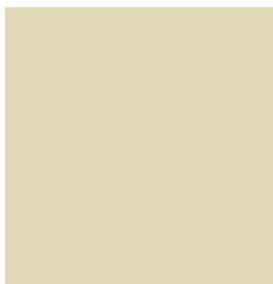
#### ACS Institutional Research Grant Competition; applications due May 1

This grant provides support for beginning investigators to enable them to initiate their independent research program. [more >](#)

### Cancer center members in the news

- **Susan Hickman**, PhD, was a finalist in the Advancements in Health Care category at this year's Indiana Business Journal's [Health Care Heroes](#) awards. Dr. Hickman focuses on ethical issues in end-of-life care.
- IU and Purdue cancer researchers collaborated and discovered a link between prostate cancer aggressiveness and the accumulation of a compound produced when cholesterol is metabolized in cells, findings that could bring new diagnostic and treatment methods. Their findings, published in the March 4 issue of the journal *Cell Metabolism*, also suggest that a class of drugs previously developed to treat atherosclerosis might be repurposed for treatment of advanced prostate cancer. Cancer center members **Michael Koch**, MD, **Liang Cheng**, MD, and **Timothy Masterson**, MD, were among the authors of the paper.

- **Safi Shahda**, MD, recently was honored by [Hoosier Oncology Group](#) as the inaugural recipient of the [Danny Danielson Translational Innovation Award](#). The \$10,000 award, granted by the Walther Cancer Foundation through the generous support of Danny Danielson, is given twice each year to an investigator to support the correlative components of clinical trial protocols when financial support is not otherwise available. The correlatives under





Shahda

investigation must have a future clinical application, such as development of new treatment strategies or identification of patient subsets for specific treatment therapies, and/or provide hypotheses for future clinical trials. Dr. Shahda, a medical oncologist specializing in gastrointestinal malignancies and conducting phase I clinical trials, will use the award to collect tumor samples from patients with pancreatic cancer. Samples will be collected before and after treatment, with the goal of learning why some patients benefit from treatment while others do not.

- The first patient in the country has been enrolled in a clinical trial using the new PD-1 inhibitor, lambrolizumab or MK-3475. The study is looking at potential activity of this immunotherapy agent in 20 different cancer types, including colorectal, breast, pancreatic, ovarian, and others. **Bert O'Neil**, MD, is the principal investigator.
- **Milan Radovich**, PhD; **Sunil Badve**, MBBS, MD; **Yunlong Liu**, PhD; **Anna Maria Storniolo**, MD; and colleagues wrote "Next-generation Transcriptome Sequencing of the Premenopausal Breast Epithelium Using Specimens from a Normal Human Breast Tissue Bank," which appeared in [Breast Cancer Research](#). The researchers completed the first ever next-generation transcriptome sequencing of the epithelial compartment of 20 normal human breast specimens by using resources of the Komen Tissue Bank. They concluded: "These data constitute the beginning of a reference data set of the normal mammary gland, which can be consulted for comparison with data developed from malignant specimens, or to mine the effects of the hormonal flux that occurs during the menstrual cycle."
- Four cancer center members -- **Brian Calvi**, MD; **Melissa Fishel**, PD; **Steven Johnson**, PhD; **Hari Nakshatri**, PhD -- are among the recipients of basic science pilot grants from the Indiana Clinical and Translational Sciences Institute. [more](#) >
- IU School of Medicine Dean **Jay Hess**, MD, PhD, one of the nation's leaders in epigenetics of leukemia, presented "Speeding the Clinical Translation of Discovery" at IUPUI's annual Translating Research into Practice address. [Watch](#). >
- **Hari Nakshatri**, BVSc, PhD, recently received a Cancer Research Award from the Society of Asian American Scientists in Cancer Research for his outstanding contributions to cancer research. As a result, Dr. Nakshatri has been designated a 2014 IUPUI Prestigious External Award Recognition (PEAR) awardee. He will be honored during the Chancellor's Academic Honors Convocation April 25.



Sun

- **Jie Sun**, PhD, has been selected to serve as associate scientific adviser to the scientific journal *Science Translational Medicine*, a sister publication of the journal *Science*.