

Treatment priorities set in new national research effort

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Treatment regimens often evolve without strong scientific evidence of their benefits and drawbacks, particularly in comparison to other drugs or approaches.

Now Duke Medicine is participating in a large national initiative aiming to fill in that missing information.

In separate articles published Feb. 24, 2014, in the *Annals of Internal Medicine*, teams led by the Duke Clinical Research Institute detailed the research priorities necessary to address gaps in knowledge about two conditions - [bipolar disorder](#) among adolescents and early breast tumors in women.

The two diverse conditions provide similar challenges for patients, doctors and health system administrators: The diagnosis is often not clear-cut, while typical treatments come with a trade-off of benefits and serious side effects.

Collaborating with clinical experts, patients, patient advocates, and other stakeholders, the two Duke-led teams worked to identify and rank the important gaps in knowledge that should be the focus of new research.

Aiming patient-focused research efforts and dollars at such clinical uncertainties is the mission of a national initiative called the Patient-Centered Outcomes Research Institute (PCORI), which was established three years ago under the Affordable Care Act. Using funds from the

insurance mandate, PCORI is working to improve the quality of research, speed it into clinical practice, and assure that it answers the most pressing questions and concerns of patients.

In the case of bipolar disorder among adolescents and young adults, the Duke researchers noted that establishing this diagnosis is particularly complex, and the condition can be difficult to distinguish from other behavioral disorders, including attention deficit hyperactivity disorder. Yet the use of antipsychotic drugs for this condition has increased dramatically over the past two decades, and carries with it a high risk of weight gain, diabetes and other problems.

"This is clearly an important area of clinical uncertainty that will benefit from more research," said Matthew J. Crowley, M.D., assistant professor of medicine in the Division of Endocrinology, Diabetes and Metabolism at Duke and lead author of the study addressing research priorities for adolescents with bipolar disorder.

Likewise with ductal carcinoma in situ – tiny breast lesions detected via mammography – considerable uncertainty has evolved over whether to treat the condition as cancer. Many of the lesions may never progress to life-threatening invasive cancer, while treatment plans call for mastectomy, lumpectomy and radiation.

"We don't have a good handle on how to distinguish between the cases that will develop into invasive cancers, and those that are harmless," said Jennifer Gierisch, Ph.D., assistant professor of medicine in the Division of General Internal Medicine at Duke and lead author of the breast cancer paper. "There is a lot of uncertainty about what a diagnosis means and how to proceed around a diagnosis. Our goal is to identify research priorities to address these questions and reduce the uncertainty for both patients and doctors."

Members of the Duke Clinical Research Institute have been key players in the PCORI initiative, led by Robert Califf, M.D., who is a co-principal investigator of PCORI's national clinical research network. The group will amass, coordinate and manage the database of medical information that researchers can use to learn how well treatments work.

PCORI has also funded research at Duke, including the work of the two teams that identified research priorities in bipolar disorder and breast cancer. PCORI has provided additional funding for other Duke Clinical Research Institute members to:

- Track the effectiveness of stroke treatments, particularly among older people, women and minority patients;
- Determine the benefits and risks of different stroke rehabilitation services after hospitalizations;
- Develop and expand a network of patients, advocates and doctors around pediatric arthritis and other rheumatic diseases;
- Study the effectiveness of treatments for aortic heart valve disease, comparing "real-world" outcomes for two different methods of valve replacement;
- Compare the results of randomized trials, which are considered the gold standard, against observational studies.

"We are pleased to be able to contribute to such an important national enterprise," Califf said. "Patients deserve to know the comparative risks and benefits of treatment alternatives, and PCORI is providing the focus to provide this critical knowledge."

Provided by Duke University Medical Center

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