Study seeks women's insights on what works best for uterine fibroids

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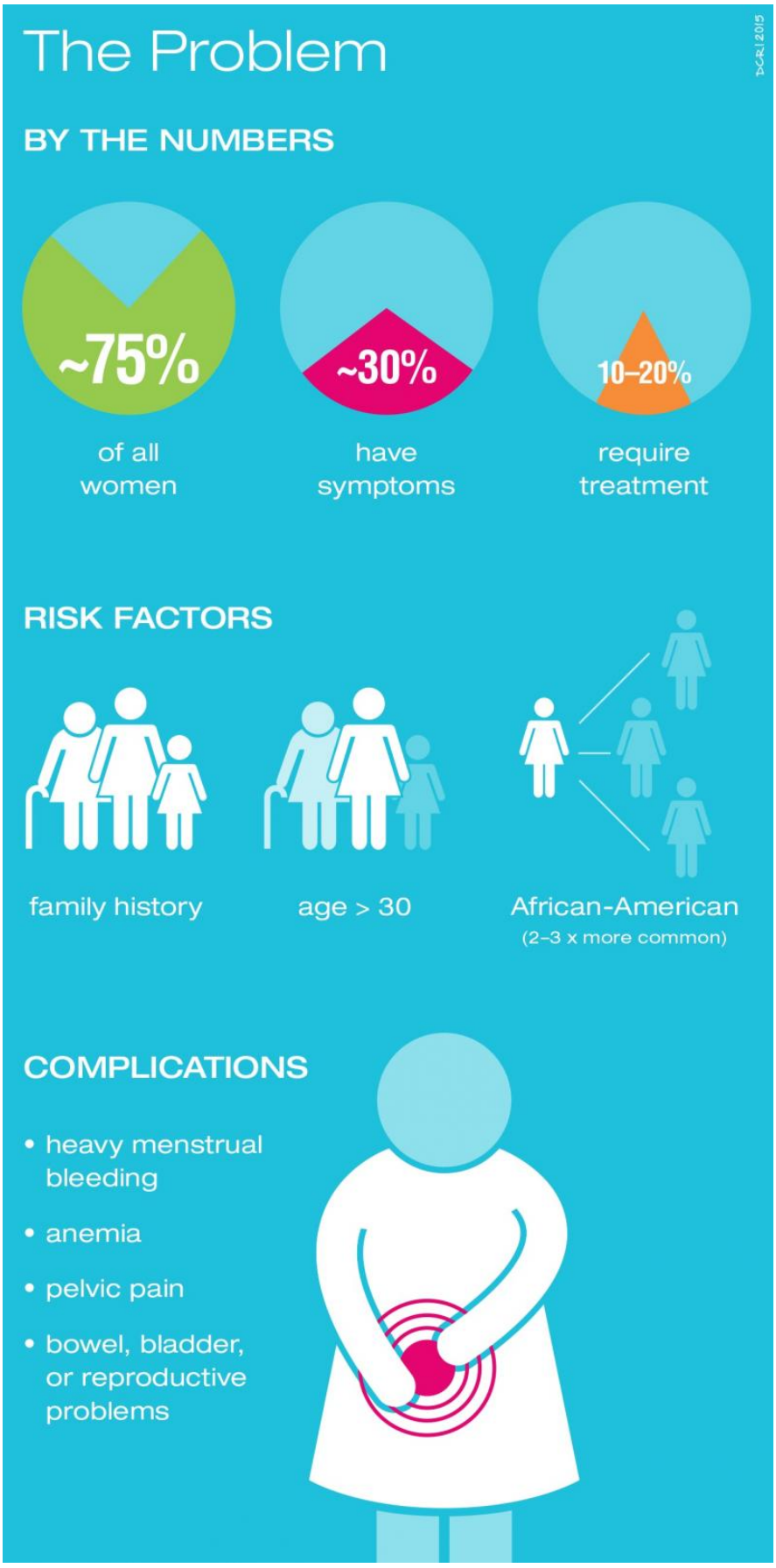
The Problem
BY THE NUMBERS
~75%
of all women
~30%
have symptoms
10–20%
require treatment
RISK FACTORS
family history
age > 30
African-American
(2–3 x more common)
COMPLICATIONS
• heavy menstrual bleeding
• anemia
• pelvic pain
• bowel, bladder, or reproductive problems

A new registry that launches this month gives women who have uterine fibroids the opportunity to help determine which strategies are most effective in treating the common condition.

The registry, called Comparing Options for Management: Patient-Centered Results for Uterine Fibroids (COMPARE-UF), will enroll more than 10,000 women at clinics affiliated with nine medical centers across the country. Participating women will be asked at annual intervals specific questions about the treatments they've elected to receive, and how well the treatments seem to be working for them.

Approximately three years after initial treatment, researchers at the Duke Clinical Research Institute (DCRI) will analyze the patients' feedback to determine which procedures provide the greatest benefit to women – insights that have been lacking for both women and their physicians.

Specifically, studies will focus on symptom relief, reproductive effects, and effectiveness among different patient subgroups, including African-American women, who are disproportionately affected by uterine fibroids.

"This is a common condition – it affects up to 75 percent of women to varying degrees and is the leading cause of hysterectomies in the country – yet we don't know which treatment works best for a given patient," said the study's principal investigator, Evan Myers, M.D., professor in the Department of Obstetrics and Gynecology at Duke University School

of Medicine.

"Patients have clearly stated that they wanted these questions answered, but preferred a registry to randomized trials, particularly because hysterectomy is one of the current options," Myers said.

The registry was funded in 2013 with a $20 million funding award from the Patient-Centered Outcomes Research Institute (PCORI), in partnership with the Agency for Healthcare Research and Quality (AHRQ), which provides scientific oversight and administration.

The DCRI serves as the research and data coordinating center for the five-year project. Enrollments sites include Mayo Clinic Collaborative Network, University of California Fibroid Network, Henry Ford Health System, University of Mississippi Medical Center, University of North Carolina, Brigham and Women/Harvard Clinical Center, Inova Health Systems and the Department of Defense Clinical Consortium. The University of Michigan will become an enrollment site later this year.

Potential participants must have a documented diagnosis of uterine fibroids and be older than 18 and young enough to still have menstrual periods. Current treatments to be evaluated are hysterectomy (removal of the uterus), myomectomy (removal of the fibroids within the uterus), endometrial ablation (laser or heat treatments to destroy the uterine lining), radiofrequency ablation (using radio waves to destroy the fibroid), uterine artery embolization (blocking blood supply to the uterus), and magnetic resonance guided focused ultrasound (using ultrasound to destroy the fibroids). The study will add other treatments, including medications.

"Uterine fibroids have a big impact on women's quality of life, affecting their ability to work and to participate in the things that they enjoy," Myers said. "There are also high costs, both in treatments and in

managing the pain and heavy bleeding that many women experience.

"One of the things that makes fibroids difficult to study is that they cause lots of different kinds of symptoms, and the symptoms can be complex, ranging from fairly minor discomfort to infertility," Myers said. "This registry for the first time will help us collect strong, relevant information from the patients themselves that can then be analyzed to determine what treatments work best for which women."

Patient advocacy groups, which had been integral in helping design the study, said the registry launch this month is a much-anticipated milestone.

"There are far too many women suffering with complications from uterine fibroids. This research effort initiated by AHRQ and PCORI is groundbreaking and crucial," said Sateria Venable, founder & executive director of the Fibroid Foundation. "My hope is that COMPARE-UF will lead the way to more consistently and adequately funded fibroid research. If we focus our efforts, we will reap the rewards - health, fertility and quality of life."

Provided by Duke University