

Rochester spearheads FDA initiative to speed development of new therapies

November 1 2010, By Emily Boynton

Pain is the most common symptom leading patients to see a physician in the United States, yet the most widely prescribed medications – opioids and non-steroidal anti-inflammatory drugs (NSAIDs) – have major drawbacks, including the potential for misuse and abuse and adverse effects that limit long-term use. While scientists have made great strides in understanding the physical and chemical processes that occur when people feel pain, new treatments with improved safety and effectiveness are still needed for the more than 76 million Americans with acute and chronic pain.

In response to this huge public health need, the U.S. [Food and Drug Administration](#) recently selected the University of Rochester Medical Center to lead a new initiative to accelerate the identification of improved [pain](#) treatments. Rochester was awarded a \$1 million contract to launch the program – a partnership where public and private organizations, including professional societies, patient advocacy groups, industry and government, will collaborate on multiple projects to help bring more treatment options to patients.

“Today, the state of pain treatment is in crisis, as we continue to rely heavily on medications that have been around for thousands of years (opioids and NSAIDs) and that leave much to be desired in terms of safety and effectiveness,” said Dennis Turk, Ph.D., the John and Emma Bonica Professor of Anesthesiology & Pain Research at the University of Washington, who will work closely with researchers at Rochester on the new initiative.

Why the major lag in new treatments for pain? The problem is not a lack of potential medications: A multitude of studies testing experimental therapies have been conducted or are underway. The problem is that many trials fail, whether for low back pain, osteoarthritis, neuropathic pain, or a host of other pain conditions, because they are unable to show a new medication provides meaningfully greater pain relief than placebo.

Although some drugs under investigation may have little or no effectiveness when it comes to minimizing pain, researchers believe other factors may play a role in the disappointing results of many recent studies: The way pain clinical trials are designed and carried out may hinder or limit their ability to distinguish truly effective pain treatments from less effective treatments or placebo.

“Clinical trials come at a great cost, take a substantial amount of time to carry out, and require significant effort from the patients who participate,” said Robert Dworkin, Ph.D., professor in the Department of Anesthesiology and the Center for Human Experimental Therapeutics at the University of Rochester Medical Center and director of the new initiative. “We need to understand why so many pain studies have failed to show efficacy so we can make changes that will increase the likelihood that future studies will identify new treatment options for patients who are suffering from pain.”

The partnership, known as Analgesic Clinical Trial Innovations, Opportunities, and Networks (ACTION), will analyze a wide range of clinical trials of treatments for acute and [chronic pain](#), looking specifically at the approach and procedures used in each trial. Researchers hope to identify problems or gaps in trial design and implementation, and find ways to bridge these gaps to speed the development of new safe and effective medications.

“An effective therapy may fail to show significant pain relief in a study

because the optimal patients were not enrolled or the research design and methods had important limitations,” according to Dworkin. “There is a whole range of things that could lead to falsely negative study results, and our goal is to determine what they are, and what we can do to modify them in future studies.”

Turk, the associate director of the new initiative who will work closely with Dworkin to analyze the design of past and present pain trials added, “We really need to make an effort to improve the studies we are conducting to expedite the development of new safe and effective treatments. As the population continues to age, pain is only going to become a larger and costlier problem.”

In addition to the University of Rochester Medical Center, researchers and physicians from the American Academy of Neurology, American Academy of Pain Medicine, American Pain Society, American Society of Anesthesiologists, International Association for the Study of Pain and Outcome Measures in Rheumatology, as well as representatives from the National Institutes of Health, the U.S. Department of Veterans Affairs, patient advocacy organizations, and pharmaceutical companies such as Endo, Johnson & Johnson, NeurogesX and Pfizer are participating in the initiative.

“One of the issues with pain is that it cuts across so many specialties – anesthesiologists, rheumatologists, emergency department physicians, and others are all interested in pain – and the result is that pain doesn’t really have a single home,” said Denham Ward, M.D., Ph.D., chair of the Department of Anesthesiology at the University of Rochester Medical Center. “This initiative is crucial because it is bringing together all the key players in pain research and treatment, and the University of Rochester is proud to be leading this charge.”

Provided by University of Rochester Medical Center

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