

FOR IMMEDIATE RELEASE:

Treatments, Not Prevention, Dominate Diabetes Research

Durham, North Carolina - April 8, 2013 - Research for diabetes is far more focused on drug therapies than preventive measures, and tends to exclude children and older people who have much to gain from better disease management, according to a Duke Medicine study.

By analyzing nearly 2,500 diabetes-related trials registered in ClinicalTrials.gov from 2007-10, the authors provide a broad overview of the research landscape for diabetes. The effort is part of the Clinical Trials Transformation Initiative (CTTI), a public-private partnership founded by the U.S. Food and Drug Administration (FDA) and Duke University to identify and promote practices to improve clinical trials.

The findings, published April 5, 2013 in the journal *Diabetologia*, suggest that current research efforts may not adequately address diabetes prevention, management or therapeutic safety.

"It's important that clinical trials enroll patients who are representative of populations affected by diabetes and its complications," said Jennifer Green, MD, associate professor at Duke University School of Medicine and member of the Duke Clinical Research Institute. "Our study is just a snapshot in time, but it can serve as a guide for where we need to focus attention and resources."

Green and colleagues culled data from the clinical trials website for studies aimed at diabetes or conditions related to diabetes. ClinicalTrials.gov, a collaboration between the National Institutes of Health and the FDA, is a registry of trials conducted in the United States and 174 other countries.

Of 2,484 trials related to diabetes identified by the researchers, 75 percent focused on diabetes treatment, while 10 percent were designed to test a preventive measure. Most of the interventions – 63 percent – involved a drug, while 12 percent were behavioral.

"We don't know what the right ratio of these different types of trials should be, but this is a good starting point for discussion," Green said.

The researchers also found that most clinical trials enrolled small numbers of patients at a limited number of sites, were completed in less than two years, and did not represent a geographically broad mix of patients.

Type 2 diabetes generally develops among adults, with older adults being at greatest risk. Diabetes rates are also increasing among children and adolescents, particularly those living in wealthier nations.

According to the research group, older people were explicitly excluded from 31 percent of trials, and were the main focus of only 1 percent of the studies. Similarly, just 4 percent of diabetes trials were aimed at people ages 18 and younger.

"When trials are excluding patients who are older or younger, it's questionable whether the trial findings can be applied to people in those age groups," Green said. "We really don't understand how best to manage disease in these patients – particularly among patients of advanced age. So the exclusion of them from most studies and the small number of trials that specifically enroll older individuals is problematic."

The research group also found that only small numbers of diabetes trials were designed to assess the effect of interventions upon events such as heart attack, stroke, or death.

"We will see many more such trials in the future, given the recent emphasis on assessing diabetes medications for cardiovascular safety," Green said.

In addition to Green, study authors include W. C. Lakey, K. Barnard, B. C. Batch, K. Chiswell and A. Tasneem.

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