Considering diabetes treatment, experts say one size does not fit all

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Patients with type 2 diabetes are generally treated similarly despite the fact that they may have underlying differences that could affect their therapeutic response. Seeking to address this critical health issue, an international multidisciplinary group of experts just issued recommendations for individualized treatment in a consensus statement to be published in the April 2010 issue of the Endocrine Society's *Journal of Clinical Endocrinology & Metabolism* (*JCEM*). The group consisted of experts in diabetes epidemiology, physiology, genetics, clinical trials and clinical care.

Diabetes affects nearly 24 million people in the United States, and close to 250 million people worldwide. Treatment for diabetes is aimed at lowering glycemic levels to as close to the non-diabetic range as safely possible. However, only slightly more than half of patients diagnosed and treated for diabetes reach their glycemic targets leaving a substantial population exposed to prolonged periods of damaging hyperglycemia. Experts believe further insight into the differences between diabetes patients, both physiologic and genetic , should not only help elucidate the pathogenesis of type 2 diabetes, but lead to individualized treatments for patients that will improve glycemic control, maximize individual benefit, minimize risk, reduce diabetes complications, and ultimately provide reductions in global health cost.

"Recent advances in genetics such as the identification of the responsible genes for several forms of Maturity Onset Diabetes of the Young (MODY), now referred to as monogenic diabetes, have established

precedents linking specific drug therapies to defined subtypes of diabetes patients," said Robert Smith, MD, of Brown University in Providence, R.I. and co-author of the statement. "As more genetic factors related to type 2 diabetes are identified and as our understanding of the progression of the disease evolves, we can expect to gain precision in identifying the best drug choices for individual patients and to more effectively halt the progression of diabetes."

"The progress already seen has stemmed from combining discoveries of specific genetic susceptibilities with clinical observations. As we move forward, we should continue to incorporate these and additional clinical observations with new data on the physiology and genetics of diabetes to assess which patients will benefit most from specific treatments," said Robert A. Vigersky, MD, president of The Endocrine Society. "The recommendations in this consensus statement highlight the need for the research community and industry to each play their part in improving our ability to individualize therapy so that patients can get the most accurate and appropriate treatment."

The consensus statement includes a series of recommendations for increasing understanding of the heterogeneity of diabetes and achieving the goal of individualizing therapy and improving treatment response. Statement recommendations include:

- Extend analysis of existing data and data sources - There are already a plethora of data and data sources that could be potentially valuable in individualizing therapy; however, to date, these have been largely underutilized. Pooled analyses or meta-analyses of such data may provide important insights into the relative effectiveness of specific interventions in subgroups of patients with type 2 diabetes and advance our understanding of individualized therapy.

- Expand existing or develop new data registries - All new and existing diabetes registries should systematically collect data to address phenotypic and genetic heterogeneity measures. Not only should these registries collect material for future biomarker and genetic analysis, but registries should be designed to specifically address the heterogeneity of diabetes with hypotheses generated by examining existing data.

- Develop new clinical trials - Future randomized studies of diabetes therapies should, by design, collect phenotypic information relevant to response to therapy.

- Develop new technologies - Targeting therapy toward more appropriate subgroups of patients will require increasingly accurate and efficient methods to measure markers for diabetes heterogeneity and heterogeneous response to treatment.

- Expand basic research - Basic research is needed to explore numerous fundamental issues that underlie the heterogeneous response to diabetes therapies.

More information: The statement, "Individualizing Therapies in Type 2 Diabetes Mellitus Based on Patient Characteristics: What We Know and What We Need to Know," will appear in the April 2010 issue of JCEM.

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