

Discussion: Thyroid function tests are commonly ordered. Interpretation of these tests relies on the provider's understanding of thyroid physiology in addition to interferences with medications and other conditions. High doses of biotin, which people take as supplements for multiple sclerosis, or metabolic disorders, or for healthy nails and hair, can cause thyroid function test abnormalities. Streptavidin and biotin are used in some immunoassay platforms to capture antigens (TSH, free T4) or antibodies. High levels of serum biotin can inhibit the formation of T4 antibody complex, which results in a falsely high free T4 result.

Conclusion: Thyroid Function tests should be interpreted very cautiously, especially in the setting of discordant clinical findings. Prior to ordering these tests, should attempt to obtain a detailed history of medications including over-the-counter supplements, which are commonly not reported during medication history.

References: Elston, Marianne S., et al. "Factitious Graves' Disease Due to Biotin Immunoassay Interference—A Case and Review of the Literature." *The Journal of Clinical Endocrinology & Metabolism*, vol. 101, no. 9, 30 June 2016, pp. 3251-3255., doi:10.1210/jc.2016-1971. Koehler, Viktoria F., et al. "Fake News? Biotin Interference in Thyroid Immunoassays." *Clinica Chimica Acta*, vol. 484, 30 May 2018, pp. 320-322., doi:10.1016/j.cca.2018.05.053. Soh, Shui-Boon, and Tar-Choon Aw. "Laboratory Testing in Thyroid Conditions - Pitfalls and Clinical Utility." *Annals of Laboratory Medicine*, vol. 39, no. 1, 13 Jan. 2019, pp. 3-14., doi:10.3343/alm.2019.39.1.3.

Diabetes Mellitus and Glucose Metabolism

CLINICAL AND TRANSLATIONAL GLUCOSE METABOLISM AND DIABETES

Elevating the Patient Voice in Type 1 Diabetes Clinical Trials: A Comparison of In-Depth Exit Interviews and Diabetes-Specific Questionnaires

Claire Ervin, MPH¹, Vijay N. Joish, PhD², Colleen Castro, BA¹, Dana DiBenedetti, PhD¹, Emily Evans, MPA¹, Amy Carroll, PhD², Pablo Lapuerta, MD².

¹RTI Health Solutions, Research Triangle Park, NC, USA,

²Lexicon Pharmaceuticals, Inc., The Woodlands, TX, USA.

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Healthcare decisions are more effective when the patient voice is included in clinical research, and the Food and Drug Administration encourages the patient's voice in drug development and regulatory decision-making. Clinical trials should not only demonstrate the effect of a drug on clinical outcomes but should also demonstrate that these outcomes are important or meaningful to patients. Several qualitative and quantitative methods are available to collect patient experience data (e.g., traditional patient-reported outcome [PRO] measures, interviews with clinical trial participants). We aimed to understand if in-depth exit interviews were more effective assessments of the patient experience in recent type 1 diabetes (T1D) clinical trials than existing diabetes-specific PROs. In-depth qualitative interviews were conducted with 41 adults with T1D who had completed or withdrew from a phase 3 study of sotagliflozin, a dual inhibitor of SGLT1 and SGLT2. A targeted literature

review was conducted to identify diabetes-specific PROs used in randomized controlled clinical trials of novel T1D medications reported over the past 5 years. Included trials had to investigate a pharmaceutical intervention for adults with T1D and report a diabetes-specific PRO. The concepts assessed in the PRO measures were mapped against those elicited during the 41 exit interviews. A total of 336 publications were identified in the literature search of which 26 were eligible for analysis. Eight diabetes-specific PROs were identified and reviewed from which 54 concepts related to the patient experience were identified. The patient exit interviews included 42/54 (78%) of the patient experience-related concepts identified across all 8 PROs from the literature review. Of the 8 PRO instruments, the Diabetes Quality of Life Measure (DQOL) covered the most concepts (18/54, 33%), followed closely by the Audit of the Diabetes-Dependent Quality of Life (ADDQoL; 16/54, 30%). Some of the most prominent concepts from both approaches were related to impact on life and family; fear of complications; and impact on physical activity, lifestyle and social perceptions. There were several concepts identified in the exit interviews that were not covered in any of the 8 PRO instruments (related to keeping blood sugars within a desired range, ability to manage changes in insulin use). Overall, the exit interviews appeared to provide a more comprehensive picture of patient experience domains. Although existing diabetes PRO measures cover a range of concepts and may adequately assess changes in certain outcomes, data from patient exit interviews provide more comprehensive insights into the patient experience. Exit interview data may provide a more detailed understanding of the disease burden and impact of treatment on improvements in well-being, daily functioning, and treatment satisfaction.

Genetics and Development (including Gene Regulation)

GENETICS AND DEVELOPMENT AND NON-STEROID HORMONE SIGNALING II

Modifications of FOXO1 and GATA4-NKX2.5 Signaling Induce Human Enteroendocrine Differentiation

Daniel Richard Zeve, MD, PhD, Eric Stas, MS, Manasvi S. Shah, PhD, David T. Breault, MD, PHD.

Boston Children's Hospital, Boston, MA, USA.

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Enteroendocrine (EE) cells are the most abundant hormone-producing cells in the human body and are vital for metabolism, as well as intestinal and pancreatic function. They have been implicated in the pathogenesis of multiple diseases including diabetes mellitus. Although recent studies have identified multiple signaling pathways (including Wnt, MAPK, BMP and Notch) that can induce low levels of EE cell differentiation, the production of functional human EE cells *in vitro* remains challenging, making their study and therapeutic utilization difficult. To improve this, we employed the human intestinal organoid culturing system, as it mimics intestinal epithelial homeostasis, allowing for differentiation of multiple epithelial cell types. Using a small scale, directed screen, we targeted