

# Assessment of Iodine Status: Analytical Methods and Quality Control

July 22-23, 2014

## Executive Summary

The Office of Dietary Supplements (ODS), National Institutes of Health (NIH), began an iodine initiative in 2011 to provide new tools to advance investigator-initiated research relevant to iodine status and its relation to health outcomes. The ODS has been working with other government groups, including the U.S. National Institute of Standards and Technology (NIST) in an effort to improve existing analytical methods and develop new approaches to facilitate the evaluation of iodine status, with an emphasis on vulnerable population groups such as pregnant women. Although urinary iodine concentration is the most widely used index of status, participants during this workshop considered the suitability of other indices, including those related to thyroid function. That discussion included the development and use of standard reference methods and materials in addition to concepts fundamental to the quality of laboratory data.

This was the second in a series of three iodine-related workshops sponsored by the ODS. The first workshop, held April 22-23, 2014, focused on exposure, specifically the measurement of iodine intake from both foods and dietary supplements (the United States is one of the few developed countries that does not have mandatory iodine fortification). The third workshop, scheduled for September 22-23, 2014, will consider issues of iodine status in pregnant women, the potential impact of sub-optimal status on pregnancy outcomes and child development, and suitable study designs for addressing iodine status concerns in regions with differing levels of risk.

The first day of this workshop featured presentations grouped into three sessions: (1) Standard Reference Methods and Reference Materials, (2) Improving the Quality of Laboratory Data, and (3) Indices of Iodine Status. The second day included roundtable discussions led by Workshop Chair Dr. Abby Ershow on the topics of laboratory measurement and assay issues as well as measurement and assay issues to consider for potential clinical trials. Major themes, research needs, and suggestions for future research that arose from the presentations and discussions appear below.

### **Laboratory Measurement and Assay Issues**

- There is a need for the development and validation of better biomarkers (beyond urine levels) of iodine intake status suitable for individual assignment (vs. population). More work is needed to determine whether inorganic iodine in serum/plasma/whole blood in humans can be used.
- Standardization of thyroglobulin measures is challenging due to heterogeneity; harmonization may be more feasible.
- T3 and T4 methods standardization (especially for pregnant women) is needed.
- Free T4 measurement is important, especially for pregnant women.
- Suitable patient and population sample pools are needed for use in methods development (size of sample is tbd).
- SRMs needed include: human milk for a range of iodine values (in progress at NIST); blood/serum by trimester for all thyroid hormones (T3, T4, thyroglobulin, etc.); blood spot reference materials, and possibly capillary tube/microsample.
- A point-of-care test for iodine and thyroid status (possibly a SBBR/STTR project) is needed, particularly for use in low-resource environments.

### **Measurement and Assay Issues To Consider for Potential Clinical Trials**

- Maternal iodine status and neurocognitive outcomes of pregnancy require markers of individual iodine status and thyroid function. More precise/sensitive tests are needed. Areas of focus include mild-to-moderate deficiency in pregnancy and lactating women.
- Higher risk (higher prevalence) and lower risk (lower prevalence) regions and countries have similar measurement needs but low resource areas may have a need for more point-of-care testing.
- Intervention studies (diet change, supplement use, etc.) are needed in subpopulations.
- There is a need for descriptive cohorts allowing range of value validation/comparison for methods development.
- Iodine balance studies are needed for some special populations, notably infants (0-12 months). There are complex matrix issues in this population (mixed excreta).
- Cohort intervention and case control designs are needed to determine the impact of overall dietary patterns on iodine status. Examples include high cruciferous vegetable (goitrogen) intake, vegetarian and vegan diets, etc.
- The feasibility of a point-of-care milk iodine content device/system should be explored.
- Potential low intake scenarios should also be explored.