MEETING REPORT

Technical Working Group Meeting on Research Priorities for the Monitoring of Salt Iodization Programs and Determination of Population Iodine Status

17-18 DECEMBER 2015
UNICEF HEADQUARTERS, NEW YORK, NY, US
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>COFEPRIS</td>
<td>La Comisión Federal para la Protección contra Riesgos Sanitarios, Mexico&lt;br&gt;The Federal Commission for the Protection against Sanitary Risk, Mexico</td>
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<tr>
<td>EAR</td>
<td>Estimated Average Requirement</td>
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<td>ETH</td>
<td>Eidgenössische Technische Hochschule&lt;br&gt;Swiss Federal Institute of Technology</td>
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<td>FACT</td>
<td>Fortification Assessment Coverage Tool</td>
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<td>GAIN</td>
<td>Global Alliance for Improved Nutrition</td>
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<td>HHIS</td>
<td>Household Iodized Salt</td>
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<td>HIES</td>
<td>Household Income and Expenditure Surveys</td>
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<td>ICCIDD</td>
<td>International Council for the Control of Iodine Deficiency Disorders</td>
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<td>IDD</td>
<td>Iodine Deficiency Disorders</td>
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<td>IGN</td>
<td>Iodine Global Network</td>
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<td>MUIC</td>
<td>Median Urinary Iodine Concentration</td>
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<td>RDA</td>
<td>Recommended Dietary Allowance</td>
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<td>RNI</td>
<td>Recommended Nutrient Intake</td>
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<tr>
<td>RTK</td>
<td>Rapid Test Kit</td>
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<tr>
<td>SIMPLIFY</td>
<td>Salt Iodization: Meeting the needs of Pregnancy, Lactation and Infancy</td>
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<tr>
<td>Tg</td>
<td>Thyroglobulin</td>
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<tr>
<td>TGR</td>
<td>Total Goitre Rate</td>
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<tr>
<td>UIC</td>
<td>Urinary Iodine Concentrations</td>
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<td>UIE</td>
<td>Urinary Iodine Excretion</td>
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<td>UL</td>
<td>Tolerable Upper Intake Level</td>
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<td>UNICEF</td>
<td>United Nations Children's Fund</td>
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<td>USI</td>
<td>Universal Salt Iodization</td>
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<td>WHO</td>
<td>World Health Organization</td>
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SUMMARY

Iodine deficiency is a common cause of preventable mental impairment worldwide. Over the last two decades, there has been remarkable progress towards eliminating iodine deficiency disorders (IDD), as evidenced by decreases in goiter and improvements in iodine status. This progress observed is likely due to the introduction and increased availability of iodized salt in many countries. While it is estimated that 75% of households have access to adequately iodized salt (1), the current metrics employed to track salt iodization programs do not capture the success of these programs. For example, only 6 countries globally are currently classified as meeting the goal of attaining Universal Salt Iodization (USI), defined as > 90% of household salt samples containing at least 15 ppm of iodine in population surveys (1). This shortcoming is related, in part, to insufficiencies in the tools employed to measure the iodine content in salt, as well as the focus on household discretionary salt in the monitoring of programs, even though the amount of iodized salt consumed through processed foods is increasing in many settings. Furthermore, the ultimate indicator of program impact is the iodine status of the population, which is based on urinary iodine concentrations (UIC). Here again, with time limitations related to this indicator have become apparent for the classification of population iodine status.

To address specific challenges related to the monitoring of salt iodization programs and population iodine status, the United Nations Children’s Fund (UNICEF) and the Iodine Global Network (IGN) convened a Technical Working Group Meeting from 17 to 18 December 2015 at UNICEF/Headquarters, New York. The meeting also aimed to provide inputs into the revision of the World Health Organization (WHO)/UNICEF/IGN manual on ‘Achieving Optimal Iodine Nutrition: A Manual for Health Programme Managers.’ The organizing institutions proposed priority topics and meeting participants helped refine the list of topics through a consultative process before the meeting.

The meeting brought together 17 technical experts with wide experience in the design, implementation and monitoring of IDD control programs. This meeting report summarizes the content of presentations, discussions, and action points for each priority topic. The meeting identified clear priority areas for the monitoring of salt iodization programs and population iodine status, and developed a roadmap and defined research gaps for the refinement of program guidance to track country progress. It is hoped that addressing these priorities can better demonstrate the likely public health impact of salt iodization programs and generate the data required to improve intervention strategies to cover the iodine needs of all population groups in order to eliminate IDD-related brain damage worldwide.
INTRODUCTION & BACKGROUND

Iodine deficiency is a common cause of preventable mental impairment worldwide. Over the last two decades, there has been remarkable progress towards eliminating iodine deficiency disorders (IDD). The number of countries classified with iodine deficiency (based initially on estimates of the total goiter rate and subsequently on urinary iodine concentration (UIC)) has fallen from 113 to 25 since 1990, while the number of countries with adequate iodine intake has increased from 8 to 131 (2). It should be noted that data on iodine status was only available for 121 countries in 1990, while data are now available for 156 countries.

The progress towards eliminating IDD at the national level is likely due to the introduction of iodized salt in many countries. Even though Switzerland and the United States began adding iodine to salt as early as the 1920s, by 1990 less than one fifth of households globally were estimated to have access to iodized salt. In 1994, WHO and UNICEF recommended universal salt iodization as a safe, cost-effective and sustainable strategy to ensure sufficient intake of iodine by all individuals, and called on all countries to ensure access to iodized salt regardless of whether they had a documented IDD problem or not (3).

Based on these international commitments, programs were established to increase the production and availability of iodized salt. To track these programs, the primary indicator of performance has been the household iodized (HHIS) coverage, and this indicator has been included in the UNICEF State of the World’s Children reports since 1998. After a slow start, salt iodization programs gained strength in the mid-1990s and HHIS access to adequately iodized salt increased to about 70% by 2000 (4) and 76% in 2014 (1).

However, and in contrast to this success, only 6 countries in the world are currently attaining the goal of USI (defined as > 90% of single salt samples containing at least 15 ppm of iodine in population surveys, generally conducted at household levels) (1). This result may suggest that salt iodization programs are unsuccessful public health programs, despite their proven benefits for improving population iodine status. Major reasons for the apparent underperformance of salt iodization programs include:

- **Methods do not account for expected variation in iodine content in salt** - Current methods estimate the proportion of iodized salt samples at the point of production and distribution meeting some cut-off point, e.g. ≥ 15 ppm. However, given the expected variation in the iodine content in salt, it may be more appropriate to estimate whether the average iodine value in all salt samples in a community meets the expected standard. Key monitoring questions concern the potential use of composite samples and whether different types of salt should have different criteria of compliance (5).

- **Unequal amounts of salt used for the determination of iodine** - Variation in the results of added compounds (such as iodine added in the form of iodate) in dry/powder products such as salt is thought to proportionally decrease with higher amounts of sample that are placed into solution. This is a consequence of the intrinsic variability of the compounds among the other particles of the product as either the added compound does not distribute homogeneously in the product or not all particles of the product absorb/adhere the same amount of the added compounds.

- **Current tools used cannot accurately measure the iodine content in salt** - In the global databases used to track household salt iodization coverage, most national coverage estimates are derived from surveys using rapid test kits (RTK) (6), presumably because these tests provide immediate results to survey teams and are inexpensive as well as easy to use. However, even though RTKs are able to detect the presence of iodine in salt, they are not suitable to measure actual salt iodine content (7, 8). Instead, quantitative tools such as titration are required to more accurately measure the iodine content in salt and thus to estimate the correct content of iodine in salt (9).

- **Not all sources of iodine are considered** - In many settings, an increasing amount of salt is consumed through processed foods and condiments (5, 10, 11). The consumption of such salt is not captured through household surveys, which generally only measure table salt used in households. If the salt used in processed foods is iodized, such surveys therefore fail to capture the contribution of these foods to iodine status.
In addition to the points above, the real success of USI programs should be judged against its ability to optimize population iodine status, which is the ultimate indicator of program success. This indicator also captures all dietary iodine sources, which is important from a public health perspective. Given that the majority of iodine consumed is excreted in urine, urinary iodine is a sensitive marker of current iodine intake and can reflect recent changes in iodine status (12). To classify the iodine status of a population, the median urinary iodine concentrations (MUIC) is compared against recommended ranges for different age groups (13). However, currently used criteria to classify population iodine status may need to be updated (14). To illustrate, new median UIC ranges have been proposed to reflect optimal iodine status for school-aged children based on a multi-center study which assessed the association between UIC and thyroid function (15), and similar research is needed for other population groups, such as pregnant women, lactating women and young children. Furthermore, the validity of UIC values under different conditions, such as differences in climate, may need to be reexamined (16).

The post-2015 development framework calls for increased efforts to reduce inequalities in health and development (17). In the case of monitoring of USI and population iodine status, there should be tools and methods in place to identify population subgroups that are not being reached by USI programs and are at risk for deficient (or excess) levels of intake. This requires improved statistical techniques for the presentation and analysis of iodine status as part of routine surveys.

There is a history of interagency research to address priority research gaps with relevance to iodine programs (15). There is current interagency work ongoing to determine whether universal salt iodization can meet the iodine requirements of all vulnerable groups, including pregnant and lactating women and infants. Even though a general review of research priorities for iodine nutrition was published in 2014 (14), the specific research topics to answer these questions, and in turn inform programmatic actions, need to be identified.

As a result, a Technical Working Group Meeting on Research Priorities for the Monitoring of Salt Iodization Programs and Determination of Population Iodine Status convened by UNICEF and the Iodine Global Network (IGN) took place from 17 to 18 December 2015 at UNICEF, New York, to address specific challenges related to the monitoring of salt iodization programs and population iodine status. The meeting also aimed to provide inputs and inform the revision of the WHO/UNICEF/IGN program guidance on ‘Achieving Optimal Iodine Nutrition: A Manual for Health Programme Managers,’ last published in 2007 (13).

The meeting brought together 17 technical experts with wide experience in the design, implementation and monitoring of IDD control programs. The meeting’s discussion topics were identified through a list of potential priority topics compiled by the organizing institutions and an ensuing consultative process to further refine this list.

This report provides a summary of the deliberations and key action points that were identified at the workshop.

**BOX 1:**

What are processed foods and condiments?

Relevant processed foods and condiments vary from region to region but include the following: bread, instant noodles, pickled vegetables, cheese, biscuits/crackers, processed meat/fish, bouillon/stock, tomato paste, soy sauce, fish sauce and ketchup.
The meeting started with introductory comments made by Roland Kupka (UNICEF) and his words of thanks. The speaker highlighted that the meeting was expected to serve as an important step towards the improvement of the monitoring, and thus the performance, of salt iodization and iodine deficiency control programs. The speaker provided a general outline of the meeting and an overview of the sessions on salt monitoring on day 1 and sessions on iodine status monitoring and the development of the WHO/UNICEF/IGN manual on 'Achieving optimal iodine nutrition: a manual for health programme managers' on day 2. He noted that each day was to start with a review presentation of general concepts followed by technical presentations addressing critical topics. The goal of each technical presentation was to stimulate discussion and identify priority actions to help fill research gaps and clarify how to improve iodine program monitoring.
1.1. WHAT IS A SUCCESSFUL SALT IODIZATION PROGRAM?

Ruth Situma (UNICEF) presented key considerations on the monitoring of salt iodization programs with the goal to frame subsequent sessions on Day 1 of the Consultation. She described that despite evidence of the dramatic benefits of salt iodization programs for improving population iodine status (2), only 6 countries globally currently have been classified as having met the USI goal of >90% coverage of adequately iodized salt at the household level (Figure 1) (6). One major reason for this is the limitation of the current metric, which focuses solely on household iodized salt and fails to capture the fact that salt enters the food chain not just as table salt, but also through processed foods and condiments in many settings. She therefore emphasized that tools are needed to better monitor such sources of salt, and in turn, of iodine. The ultimate goal is to optimize population iodine status, and information on sources of iodine together with data on UIC should guide adjustments to recommended salt iodization levels or other programmatic aspects.

FIGURE 1:
Percentage of Household Consuming Adequately iodized salt 2009-2013 (n=53)

* Data not present refers to data points that were excluded as their most recent estimate is either not in accordance to the standard definition or is earlier than 2009.

Source: UNICEF Global Database, 2015 based on DHS, MICS, other national household surveys and other UNICEF validated surveys.

Note: The boundaries and the names shown and the designations used on these maps do not imply official endorsement or acceptance by the United Nations.
In ensuing discussions, it was reinforced that salt iodization programs have been remarkably successful, as evidenced by drastic decreases in goiter prevalence and improvements in iodine status worldwide. It was pointed out that current programs have not been able to demonstrate their success because of the inappropriate metrics that have been adopted. These include the faulty assumption that all salt must contain at least 15 ppm iodine at the household level, while a concentration of 15 ppm iodine was originally meant to be an ‘average’ recommended level, rather than a minimum level. The group concluded that revised program indicators and monitoring tools are needed to better track the performance and, ultimately the impact of IDD prevention and control programs. Such improvements are required for tracking program performance at the global and national levels, which includes regulatory monitoring and food control of the salt industry (see section 1.3) and monitoring of HHIS coverage. Furthermore, research is required to determine the validity and utility of assessing the average amount of iodine supplied by iodized salt to the diet and concomitant effects on population iodine status. Such an approach ensures better alignment with the goals of other food fortification approaches and dietary approaches to minimize deficient (and excess) intakes in populations (18). Finally, it was reinforced that to allow for effective programmatic adjustments, the major sources of iodized salt entering the food chain should be monitored. Such quantification of salt intake will also offer opportunities to link with programs working to reduce the intake of salt in the diet (19).
1.2. WHAT IS THE PERFORMANCE OF RAPID TEST KITS (RTK)?

Jonathan Gorstein (Iodine Global Network) analyzed the performance of the rapid test kit (RTK), a commonly used tool to measure salt iodine content. The RTK consists of a starch/acid solution that causes a blue or purple color change when dripped on iodized salt. These kits have been used for over 25 years to detect the presence of iodine in salt. He explained that RTKs have also been employed to determine the actual iodine content in salt based on the intensity of color change (9), and as such, to generate estimates on the adequacy of iodization levels in salt. RTKs are relatively easy to use, inexpensive, and provide instant results. Owing to their widespread use in household-based surveys, more than 90% of national level estimates in the UNICEF Global Database on Household consumption of adequately iodized salt (6) are based on RTK use. A recent analysis of 25 surveys compared the performance of RTK against established quantitative methods (Gorstein et al, in press). The analysis showed that the RTK is not suited for the quantitative determination of iodine in salt due to poor agreement rates when compared to quantitative methods (Figure 2). These analyses support findings obtained from previous assessments (7, 8). As a result, the presenter recommended that RTK should only be used for obtaining an estimate of household coverage of iodized salt (i.e., salt containing any iodine). This recommendation is in line with previous UNICEF/WHO/International Council for Control of iodine Deficiency Disorders (ICCIDD) global guidance (13) and other expert recommendations (9), but has not been heeded in practice, leading to erroneous use and the proliferation of data which misrepresents program status and performance.

FIGURE 2:
Agreement Rates at Three Salt Iodine Cut-Off Points (adapted from Gorstein et al, in press)

In the discussion, it was mentioned that in addition to technical limitations of the RTK solutions, the poor RTK performance observed in many settings may be due to the fact that the amount of salt collected for sample analysis (often equivalent to one teaspoon) is too small to take into account heterogeneity in salt iodine content, especially if the salt tested is not fine, crystal salt. For the same reason, small salt samples may also present challenges for quantitative assessments such as...
titration. Furthermore, RTK use in many survey and programmatic settings is not standardized and best practices, such as the use of re-check solutions for negative samples, or checking samples for potassium iodide (which require non-standard RTK) are often not observed. Poor performance is also due to a high degree of subjectivity of the person who categorize the intensity of the color, which is exacerbated by the lack of training. Nevertheless, the RTK remains a valuable tool to detect the presence of iodine in salt.

**KEY AGENDA MOVING FORWARD**

1. Use RTK only as a qualitative tool to distinguish between the presence or absence of iodine in salt. Such qualitative use remains a valuable application for program managers to estimate the coverage or proportion of salt with any iodine.
2. Do not use RTK as a semi-quantitative or quantitative tool to determine the iodine content in salt, or to estimate the proportion of salt samples which are above or below a specific cut-off value.
3. Use titration or some other robust, field-friendly quantitative method measure the iodine concentration in salt (21).
4. Request that RTK packaging does not contain color coding guides for different salt iodine levels. Instead, request that the labeling should emphasize that the tools only be used to determine the presence or absence of iodine in salt.

**PHOTO 1:**
Use of Rapid Test Kit to check for the presence of iodine in salt

Salt is tested for the presence of iodine at El Mex Saline Company in the northern city of Alexandria. © UNICEF/UNI2425/Noorani
1.3. WHAT IS THE BEST METRIC TO DETERMINE THE ADEQUACY OF IODINE CONTENT IN SALT?

Omar Dary (U.S. Agency for International Development) provided a historical overview of iodine content recommended for use in iodized salt in Switzerland and the Americas, and subsequently adopted as part of global WHO/UNICEF/ICCIDD recommendations. He described the evolution of these recommendations and emphasized that they were originally based on a range of average content of iodine in salt depending on the population salt intake (15 mg I/kg for salt intakes of 10 g/day, and 30 mg I/kg for salt intakes of 5 g/day) (Box 2), and which then shifted to classify the proportion of individual salt samples that comply with the minimum value of the range. The shift in recommendations from an average iodine content to a recommended range of cut-off points created the expectation that nearly all salt (> 90%) measured in a representative sample of households should fall within the recommended range (21). Underlying these recommendations was the assumption that it is technically feasible to control the addition of iodine to salt at a content which falls within the designated range, regardless of the wide variety of salt that is available around the world. Beyond the differences in the physical characteristics of raw salt, the speaker explained that the production and iodization process for coarse salt (generally processed and packaged by hand) is fundamentally different from the production of washed and refined salt (which is manufactured through an industrial process). As a result of these differences, iodine content in coarse salt generally varies much more widely than in washed and refined salt, even when 50 g of salt is sampled for analysis (Figure 3) (Government Food Control (COFEPRIS), México, 2013, unpublished results). When only 1g of salt is taken for analysis, then even higher degrees of variation would be expected, especially in coarse salt. It therefore follows that to ensure that > 95% of coarse salt is adequately iodized, the entire distribution of salt iodine levels would have to be shifted to the right. However, to obtain such a shift, it would then be expected that a high proportion of salt samples would contain high or even excessive iodine levels (Figure 4). The speaker explained that since food fortification aims to ensure that the intake of a given nutrient is at least the Estimated Average Requirement (EAR) for 97-98% of the target population group while minimizing the risk of excessive intakes (18), salt iodization programs should be viewed and monitored in the same manner. As a result, the additional intake of iodine in populations from iodized salt should be based on the average iodine contents present in samples and not the percent of samples within a range.

The speaker presented an example of a monitoring system which measures average levels of iodine in salt from Guatemala. The system uses composite samples (defined as a combination of a determined number of single samples) which are collected at both the household level and for product quality control in production facilities. This novel approach enables the calculation of a single iodine value for the composite sample that can be taken to reflect the average iodine content of the respective salt supply. The speaker emphasized, however, that additional quantitative testing of individual samples should be performed at production level for product quality control and to ensure adequate manufacturing processes. Nevertheless, given the likely variability of iodine concentrations from salt types that are not refined, a high proportion of single samples from such salt collected at production levels may fall outside the limits set by national salt iodization standards.
BOX 2:
Evolution of WHO recommendations on salt iodine content

1993
Indicators for assessing iodine deficiency disorders and their control programmes
Report of a Joint WHO/UNICEF/ICCIDD consultation

<table>
<thead>
<tr>
<th>Content (l) (mg/kg)</th>
<th>Recommendation</th>
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<tr>
<td>30 (40) (average)</td>
<td>During production in plastic bags, in dry and cold weather (if weather is hot and humid) if salt intake is: 10 g/day.</td>
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<tr>
<td>40 (50) (average)</td>
<td>Same as above, but with salt is stored in large bag.</td>
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<tr>
<td>60 (80) (average)</td>
<td>During production in plastic bags, in dry and cold weather (if weather is hot and humid) if salt intake is: 5 g/day.</td>
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<tr>
<td>80 (100) (average)</td>
<td>Same as above, but with salt is stored in large bag.</td>
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1994
Iodine and health
Average daily salt intakes vary from country to country. Usually consumption levels are within 5-15 g/day range for children and adults. No increase in salt consumption is called for. Rather, the recommended level of salt iodization should be adjusted to provide approximately 150 μg of iodine/day actually consumed, taking into account "..."

1996
World Health Organization, UNICEF, ICCIDD. Recommended iodine levels in salt and guidelines for monitoring their adequacy and effectiveness.
"...in order to provide μg of iodine/day via iodized salt, iodine concentration in salt at the point of production should be within the range of 20-40 mg of iodine (or 34-66 mg potassium iodate) per kg of salt. When all salt used in processed food is iodized, the lower limit (20 mg) is recommended. Under these circumstances, median urinary iodine levels will vary from 100-200 μg/l."

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<tr>
<th>Content (l) (mg/kg)</th>
<th>Recommendation</th>
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<tr>
<td>20 (average)</td>
<td>For providing 150 μg/day in 10 g salt/day, and 30% loss. Nothing is mentioned for salt intake of 5 g/day, but the range of &quot;averages&quot; is stated 20-40 mg/kg; a &quot;range&quot; is so born.</td>
</tr>
<tr>
<td>15 (average)</td>
<td>In households. In later editions, the average became &quot;minimum&quot; and the concept of &quot;adequate&quot; iodized salt was born.</td>
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2001
"...95% of salt for human consumption must be iodized according to government standards for iodine content, at the production or importation levels; "the percentage of food-grade salt with iodine content of at least 15 ppm, in a representative sample of households, must be equal to or greater than 90%""

2007
"Iodine concentration in salt at the point of production should be within the range of 20-40 mg of iodine per kg of salt (i.e., 20-40 ppm of iodine) in order to provide 150 μg of iodine per person per day."

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<tr>
<th>Content (l) (mg/kg)</th>
<th>Recommendation</th>
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<tr>
<td>20-40 (range)</td>
<td>&quot;the percentage of food-grade salt with iodine content of between 20 and 40 ppm in a representative sample of households must be equal to or greater than 90%&quot;</td>
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2014

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<th>Estimated salt consumption, g/day</th>
<th>Average amount of iodine to add, mg/kg salt (RNI + 30% losses)</th>
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<tr>
<td>3</td>
<td>65</td>
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COMMENTS

In 1993, WHO/UNICEF/ICCIDD recommend salt iodine contents with the goal to provide 150 μg of iodine/day taking into account different salt intake levels, climatic conditions, packaging and distribution characteristics. The contents were set high due to concerns about iodine losses in salt between the point of production and consumption.

The average salt iodine contents for these different conditions recommended in the 1993 document were re-endorsed in a WHO technical document published in 1994.

In 1996, WHO/UNICEF/ICCIDD took into account additional data which suggested that the degradation of iodine in iodized salt was lower than previously expected as well as data indicating the possible adverse effects of excessive iodine intake.

In 2001, the ‘goals’ of USI achievement were established:
> 95% of all salt at production adequately iodized (> 15 ppm)
> 90% of all salt at households adequately iodized (> 15 ppm)

In 2007, the agencies reiterated that the salt iodine content at the point of production should be within the range of 20-40 mg of iodine per kg of salt (i.e., 20-40 ppm of iodine) in order to provide 150 μg of iodine per day and to ensure median urinary iodine concentrations in the adequate range. However, the document further reinforced shifts from recommended average salt iodine content to recommended ranges by stating that the percentage of household salt with an iodine content between 15 and 40 ppm in a representative sample of households must be equal to or greater than 90%.

In 2014, WHO reverted to recommendations based on average iodine content for food grade salt. Recommendations were based on the ability to ingest the recommended nutrient intake of 150 μg iodine/day in the presence of 30% of iodine losses between production and consumption, and a 52% bioavailability of iodine. Losses depend on the iodization process, the quality of the salt and packaging materials as well as the climatic conditions, and may thus be higher or lower than 30%. The document also mentions that the monitoring of UIC will allow for further adjustment of the recommended salt iodine contents.
In ensuing discussions, it was stressed that the experience of using composite samples in Guatemala should be documented and published in a peer-reviewed journal with clear recommendations on required composite sampling procedures. There was some concern raised that the use of composite samples could mask disparities and therefore make it difficult to identify sub-groups consuming salt with insufficient iodine content, and who may therefore be at risk of IDD. The challenges of interpreting results of salt testing and their implications on programs were discussed. Experiences were shared from Eastern European and Central Asian settings where national salt iodization programs have been very effective (as reflected by optimal population iodine status), but where the coverage of adequately iodized salt (≥ 15 ppm iodine) has been ~ 70%. In one example cited, the apparently suboptimal coverage led program managers to invest in expensive behavior change programs to improve storage conditions of iodized salt in an effort to increase the coverage of adequately iodized salt. These approaches were pursued even though they not supported by evidence and in spite of the fact that the population iodine needs were being met. It was also mentioned that the universally recommended level of 15 ppm of iodine at the household level is no longer justifiable, since the optimal salt iodine content depends on national salt consumption patterns and the physiological needs of different target groups.
PART A: Iodized coarse salt in Mexico (2013); Regulation: 30 ± 10 mg I/kg

Coarse salt has a large variation (mean of 41.3 mg I/kg with a standard deviation of 31.0) with 24.6% of all samples containing less than 20 mg I/kg and 19.8% of samples containing less than 15 mg I/kg. For the analyses 50g of salt was sampled.


Part B: Hypothetical situation to ensure that 95% of iodized coarse samples (based on 2013 Mexico data) have iodine levels > 15 mg I/kg.

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**FIGURE 4:**
Situation of Iodized Salt in Mexico, 2013
KEY AGENDA MOVING FORWARD

1. Document and publish evidence on the use of composite samples to determine average salt iodine levels (based on Guatemala experience) in peer-reviewed literature to allow for evidence-based policy changes for global tracking of iodized salt. The paper should include a clear historical perspective on the evolution of global standards and recommendations.

2. Establish the appropriate number of single samples required for a composite sample for quality control of different types of salt and specify acceptable variation applicable to different types of salt.

3. Develop protocols and field test methodologies for composite testing at production and household levels and test these methodologies in settings around the world where different types of salt are in use, and where multiple producers are contributing salt to households and thus to the composite sample. As much as possible, make use of existing panels of salt specimens.

4. Test methodologies for salt iodine monitoring that replace the current recommendation on ensuring that > 90% of all salt at households adequately iodized (> 15 ppm) with estimates on the coverage of salt with any iodine and on average iodine content.

5. Ensure adequate manufacturing practices by using qualitative tests to check the constant addition of iodine and quantitative tests to determine mean iodine levels as well as variations around the mean.

6. Seek links with other food fortification programs when revising salt iodization monitoring tools


8. Make sure that salt iodization programs maintain an equity focus with the goal of meeting the iodine nutritional needs of all target groups.
1.4. DO FORTIFICATION ASSESSMENT COVERAGE TOOL SURVEYS HOLD PROMISE TO REPLACE CURRENT POPULATION-BASED DESIGNS TO MEASURE COVERAGE OF ADEQUATELY IODIZED SALT AT HOUSEHOLD LEVELS?

Greg S. Garrett (Global Alliance for Improved Nutrition) presented on the potential use of the Fortification Assessment Coverage Tool (FACT) to provide data on the reach and performance of large-scale salt iodization programs. In brief, FACT aims to determine whether target population groups, such as women of reproductive age, are reached with meaningful amounts of micronutrients from fortified foods. To date, FACT surveys have primarily focused on estimating the contribution of fortified flour and oils, with only a secondary focus on salt (Table 1). FACT also defines populations according to a risk profile to better understand the intersection between consumption of fortified foods and vulnerability. To date, 12 FACT surveys have been completed in 10 countries, 10 of which included iodized salt. These surveys demonstrated substantial variation in HHIS effective coverage (defined as salt iodine content in line with national standards). To illustrate, in a survey conducted in Abidjan (Cote d'Ivoire), effective coverage was more than 80%, while national estimates from Ghana and Senegal were less than 40%. Subgroup analyses from Senegal indicated that iodine content in household salt was an important determinant of the iodine status among women from deprived households, but not for women of non-deprived households. The speaker outlined that the FACT survey methodology is modular and could be further tailored to the specific monitoring requirements of salt iodization programs by obtaining and analyzing the latest industry salt production data to segment industry between large, medium, and small salt producers, highlight their market share and penetration, and to thus quantify approximate supply from these different producers, which may have varying abilities to produce high-quality, iodized salt. Secondly, at the household level, future iterations of FACT will look to accommodate the collection of data on the consumption of processed foods that constitute key sources of dietary salt as well as on brands of salt (the ability to collect such data may vary across contexts, however). The FACT instrument and its related tools will be made available in the public domain by mid-2016.

**TABLE 1:**
Standard indicators used in the Fortification Assessment Coverage Tool

<table>
<thead>
<tr>
<th>DIMENSION</th>
<th>INDICATOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Availability (Production)</td>
<td>Number of people with availability of fortified food</td>
</tr>
<tr>
<td>Quality</td>
<td>Proportion of foods that meet appropriate standards</td>
</tr>
<tr>
<td>Access</td>
<td>Proportion and number of population consuming fortifiable food</td>
</tr>
<tr>
<td>Effective Coverage</td>
<td>Proportion and number of target population consuming food fortified according to standard</td>
</tr>
<tr>
<td>Outcome</td>
<td>Quality of the diet, percentage recommended nutrient intakes contribution</td>
</tr>
<tr>
<td>Impact</td>
<td>Percentage micronutrient deficiency</td>
</tr>
</tbody>
</table>
In ensuing discussions, the concept of ‘fortifiable’ salt was covered. That is, the monitoring of other mass fortification efforts such as wheat flour fortification focus on ‘fortifiable’ flour produced by industrially milled flour (which operates at a large scale) (22). This is based on the assumption that flour from smaller mills is substantially harder to fortify. The group suggested that the concept of ‘fortifiable’ salt, whose definition may depend on specific settings and types of salt used, may help with priority setting within salt iodization programs, as small producers with limited resources may find it difficult to produce adequately iodized salt. Lastly, there was a short discussion on the use of Household Income and Expenditure Surveys (HIES) and their potential to quantify the frequency of consumption of key processed foods that contain iodized salt.

**KEY AGENDA MOVING FORWARD**

1. Explore the option of using FACT to map the brands of salt to industry segments to better understand fortifiable vs non-fortifiable salt.
2. Demonstrate the association between UIC and calculated iodine intakes in future FACT.
3. Seek collaboration with the George Institute to better align the monitoring of dietary iodine and dietary sodium in FACT surveys.
Jonathan Gorstein (Iodine Global Network) presented an overview of the increasing importance of monitoring the potential use of iodized salt contained in processed foods and condiments. These food items are increasingly consumed in many settings and if they are produced using iodized salt, they can be expected to make substantial contributions to dietary iodine intakes (5, 10, 11). Nevertheless, very few national IDD control programs include the use of iodized salt in processed foods and condiments as part of national USI legislation or actively monitor their use or potential contribution to dietary iodine intakes. As already discussed in this report, program monitoring is often limited exclusively to the determination of household iodized salt coverage through population-based surveys. This lack of effort to account for all sources of iodine in the diet may contribute partly to the disconnect observed in a number of countries between indicators of HHIS coverage and iodine status. For example, countries such as Ghana (23) and Indonesia (Basic Health Research Survey 2013, unpublished data) reported in national surveys that a low proportion of households use adequately iodized salt while the national iodine status, as measured by MUIC, is adequate. The presenter provided an overview of recommended actions to assess the use of iodized salt in processed foods and condiments at policy, production and supply, and operational levels (Table 2). The development of these tools builds on work performed by the Global Alliance for Improved Nutrition (GAIN) as part of the GAIN-UNICEF Partnership Project. As salt consumption patterns change, and an increased proportion of the total salt in the diet is derived from processed foods and condiments, it will be important to develop concrete program-relevant tools to track the use of iodized salt in these products. As with other aspects of USI programs, it will be important to manage messages, so that there is not an increased consumption of salt, but rather that the salt already included in these products is iodized.

In discussions, it was reinforced that UIC should serve as the ultimate indicator of success for IDD prevention and control programs. Specific care should be taken that legislation specifies that salt contained in processed foods and condiments should be iodized in order to prevent loopholes whereby processed foods are produced using non-iodized salt. In many settings, regulatory monitoring systems for iodized salt are under-resourced, possibly because food control systems generally focus on products that pose imminent health risks to populations, rather than the longer-term risks posed by IDD. Given these low levels of investments, such systems should focus on major producers of processed foods and condiments, rather than conducting more resource intensive regulatory monitoring of all salt producers. In some cases, market-level surveillance may also be indicated.
KEY AGENDA MOVING FORWARD

1. Explore and adapt the use of available instruments such as FACT and HIES to better identify and quantify the frequency of consumption of key processed foods and the potential contribution of iodine from iodized salt used in these products (explore links with Tufts University).

2. Ensure that mandatory legislation on salt iodization covers salt added to processed foods & condiments.

3. Finalize and field test draft program guidance on the use of iodized salt in processed foods and condiments and make it available to program managers through the IGN and partner websites. Focus monitoring efforts of salt used in processed foods and condiments at the supply/production level rather than at the household level.

4. Develop advocacy tools to highlight that processed foods and condiments are increasingly becoming important sources of dietary salt in many settings, and that their reach, distribution, and amounts of iodine are important to track as part of overall national USI program monitoring.

**TABLE 2:**
Recommended actions for monitoring of processed foods and condiments at policy, production and supply, and program levels

<table>
<thead>
<tr>
<th>PROGRAM LEVEL</th>
<th>RECOMMENDED ACTIONS FOR MONITORING OF PROCESSED FOODS AND CONDIMENTS</th>
</tr>
</thead>
</table>
| ENABLING ENVIRONMENT AND POLICY | • Review existing legislation for requirements on use of iodized salt in processed foods   
• Review extent to which existing regulatory monitoring system monitors use of iodized salt in processed foods and how any requirements are enforced |
| PRODUCTION AND SUPPLY | • Assess knowledge and interpretation of large scale manufacturers of major processed foods contributing significantly to salt intake with wide market segment reach on existing requirements   
• Identify processed food items that are most important contributors to population salt intake (based on consumption surveys, HIEC’s, scanner data etc.)   
• Determine extent to which food processors verify the iodization and level of iodization of salt used   
• Model the potential contribution of iodized salt in processed foods to the iodine intake of the population |
| IMPLEMENTATION | • Assess and address reasons for non-use of iodized salt for food processing, especially where legislation exists   
• Raise awareness of existing data and evidence that use of iodized salt in processed foods does not cause organoleptic changes and that iodine is retained   
• Support changes as necessary to existing legislation to ensure clear requirements for use of iodized salt in food processing   
• Recommend adaptation of the existing regulatory monitoring system to facilitate enforcement of regulations on use of iodized salt in food processing |
1.6. WHAT INDICATOR(S) AND TOOLS SHOULD BE USED TO TRACK GLOBAL PERFORMANCE OF SALT IODIZATION PROGRAMS?

Julia Krasevec (UNICEF) presented an overview of UNICEF’s tracking of salt iodization coverage data and the criteria used for inclusion in UNICEF’s global databases (Figure 5). Historically, UNICEF has reported on the status of iodine control programs in UNICEF program countries through its annual State of the World’s Children reports (6). In these reports, there was a progression from mere mentioning iodine-related global goals in 1990 (24) to including country-level data on total goiter rates (TGR) (25) to reporting on the coverage of adequately iodized salt starting in 1998 (26). In 2000, UNICEF discontinued the inclusion of TGR and focused on the HHIS as WHO has the mandate and responsibility for tracking data on iodine status, using TGR and subsequently UIC. A 2014 review of previously reported coverage estimates identified that several results from 2011-2013 population-based surveys reporting only on the presence or absence of iodine had inadvertently been included in the database as estimates of adequately iodized salt. Given that these coverage estimates based on salt with any iodine are higher (upwards of 20 percentage points) than coverage estimates of adequately iodized salt, estimates of global and regional coverage of adequately iodized salt were overestimated for those years.

Another issue is that the tool used to assess the iodine content in salt and generate estimates of ‘adequately iodized salt’ has typically been the RTK, which is only appropriate to distinguish between the presence and absence of iodine in salt (see section 1.2). In the 2014 HHIS coverage database, 49 out of 53 (92 %) available recent national estimates were based on RTK, while quantitative tools represent the remainder. Coverage estimates on adequately iodized salt are among the 80 indicators that are updated annually in UNICEF’s global databases through reporting of survey data submitted by UNICEF field offices. Submitted data undergoes the ‘Country Reporting on Indicators for the Goals’ quality assurance process. In general, trend analyses are only constructed at regional or global levels if there are comparable data for the same set of countries across different time points with sufficient population coverage. Due to a lack of comparable data in the same set of countries, global and regional temporal trends for household coverage of adequately iodized salt have not been presented in UNICEF reports. In UNICEF country profiles that present data on HHIS coverage over time, notes are included to suggest that the data may not be comparable. The Iodine Global Network links the UNICEF data on HHIS coverage estimates with data on iodine status (MUIC) in its Global Iodine Scorecard (27).

**BOX 3:**
Criteria for UNICEF global nutrition indicators

UNICEF’s global indicators need to represent a) UNICEF program priority areas, b) an internationally standardized indicator, and c) agreed upon division of labor with WHO.

IODINE MEETING REPORT APRIL 2016
Subsequent discussions were guided by questions developed by the presenter. It was recommended by the group that global salt monitoring efforts should focus on reporting only the coverage of households with any iodine in salt, e.g. presence or absence of iodine in population-based surveys (as described in section 1.2) as a sign of the ‘reach’ of salt iodization programs. However, careful messaging should accompany the ensuing HHIS increases in country, regional and global coverage estimates. As described previously, the group recommended that RTKs should not be used as semi-quantitative tool, but rather only as a qualitative test. The group also discussed that since the type of salt may affect salt iodine distributions (Figure 3), comparisons on the proportion of adequately iodized salt used across countries and over time may be biased if different types of salt are in use. Similarly, sub-group comparisons of RTK-based estimates of adequately iodized salt within the same survey may be biased if subgroups consume different types of salt. However, more data is needed to substantiate these claims. When examining the reach of salt iodization programs, inequalities in coverage should be examined through stratified presentation of data by measures of socioeconomic status or other measures of deprivation.

As already covered in section 1.3, it was suggested that the feasibility of tracking average salt iodine content should be explored. In this regard, the potential usefulness of composite samples at the cluster level should be explored in operations research settings. Furthermore, data on the contribution of processed foods to iodine intakes should be explored; given that the measurement of iodine levels in foods samples is difficult, such data may have to stem from production levels. Data on the HHIS coverage and processed foods produced using iodized salt should then be interpreted in line with observed UIIC in the overall population and in population subgroups.

With regard to the denominator used when determining HHIS coverage, the presenter explained

![Figure 5: Indicators tracked on iodine nutrition in the UNICEF State of the World’s Children databases (1990-2015)](image)

- Years when the global database included data points with cutoffs lower than 15 ppm iodine PPM=Parts per million
that UNICEF currently includes in its database households without salt in the denominator. However, the group suggested that it may be advantageous to exclude households without salt at the time of sampling from the denominator, and to therefore change the indicator used from ‘HHIS coverage’ to ‘percentage of available salt that is iodized.’ One major justification for this change is that salt iodization programs do not attempt to incite households that do not use table salt to start doing so; rather, these programs attempt to ensure that of the salt used, all of it is iodized. The presenter explained that UNICEF could consider changing the database if a recommendation were made to change the indicator to ‘percentage of available salt that is iodized.’ However, for this change to occur, UNICEF would require an official notification from global normative processes. Furthermore, even if such a change was to occur, it would still be useful to present in the database a variable for percentage of households without salt to better characterize the country context and to aid in the identification of subgroups that may be at increased risk for having low access to iodized salt, and as such poor iodine status.

In survey settings, questions should be developed and field tested to understand why no salt is available for testing in some households at the time of the survey, especially as the proportion of such households has been consistently large (≥ 20%) over time in a small number of countries. Such follow up questions would allow for additional analyses to understand whether these households are at an increased risk of IDD. Policymakers may choose to identify what proportion of salt could feasibly be iodized (‘fortifiable salt’; section 1.4), and to focus their salt iodization program on the proportion of ‘fortifiable’ salt in the country, rather than on all salt for human consumption. Participants suggested that UNICEF should continue reporting on HHIS coverage, while the IGN should maintain the data on iodine status and the Global Iodine Scorecard, which brings together the UIC database with the UNICEF-maintained HHIS data (27). It was also suggested that the IGN should develop and apply review criteria for the UIC database and that it does so in consultation with partners. In addition, there is a need to develop updated guidance for program managers on the monitoring of salt iodization programs (see section 2.5).

**KEY AGENDA MOVING FORWARD**

1. Modify and update the UNICEF global salt database on iodized salt to only present data on the presence or absence of iodine in salt, e.g. salt with any iodine.
2. Develop official recommendations on how to handle households without salt in the denominator of HHIS coverage estimates derived from survey settings. Such recommendations should be shared with the WHO/UNICEF Technical Expert Advisory Group on Nutrition Monitoring.
3. Develop and field test methodologies to inquire about the reasons of non-availability of table salt in population-based surveys and assess vulnerability of households without salt at the time of the survey.
4. Develop tools to assess the type of salt used (e.g. coarse, washed, or refined salt) and how these data would be analyzed, stratified and presented for different subgroups (by SES) to highlight salt preference disparities and potential inequities.
5. Recommend in selected upcoming micronutrient surveys the collection of biomarkers as well as food samples (including salt) to determine reach of fortified products and nutrient levels delivered.
DAY 2: IODINE STATUS

MONITORING AND DEVELOPMENT OF WHO/UNICEF/IGN MANUAL ON ‘ACHIEVING OPTIMAL IODINE NUTRITION: A MANUAL FOR HEALTH PROGRAMME MANAGERS’
2.1. WHAT IS A SUCCESSFUL PROGRAM TO ACHIEVE OPTIMAL IODINE NUTRITION?

Arnold Timmer (Global Alliance for Improved Nutrition) reviewed WHO recommended iodine intake levels and UIC ranges by age and population group (Table 3 and Figure 6) (13, 28). He explained that successful iodine nutrition programs minimize the proportion of the population with higher than necessary or excessive intakes, and maximize the proportion of the population with optimal iodine status, especially among vulnerable groups such as pregnant women and children < 2 years. As already explained in section 1.3, WHO has published guidance to set suitable salt iodization levels based on salt consumption practices (per capita intake of salt) of populations to meet the physiological requirements (29).

TABLE 3:
Recommended dietary intakes by iodine by age of population group (13, 28)

<table>
<thead>
<tr>
<th>AGE OR POPULATION GROUP</th>
<th>IOM</th>
<th>WHO</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EAR (μg/day)</td>
<td>AI OR RDA (μg/day)</td>
</tr>
<tr>
<td>Infants (0 - 12 months)</td>
<td>-</td>
<td>110-130†</td>
</tr>
<tr>
<td>Children (1 - 8 years)</td>
<td>65</td>
<td>90</td>
</tr>
<tr>
<td>Children (9-13 years)</td>
<td>73</td>
<td>120</td>
</tr>
<tr>
<td>Adults ≥ 14 years</td>
<td>95</td>
<td>150</td>
</tr>
<tr>
<td>Pregnant Women</td>
<td>160</td>
<td>220</td>
</tr>
<tr>
<td>Lactating Women</td>
<td>200</td>
<td>290</td>
</tr>
</tbody>
</table>

†Values are adequate intake.

Abbreviations: AI, adequate intake; EAR, estimated average requirement; RDA, recommended dietary allowance; RNI, recommended nutrient intake; UL, tolerable upper intake level

However, recent consumption data for discretionary salt (cooking and table salt) plus salt present in processed foods and condiments are often unavailable and program managers often use UIC levels to adjust salt iodization levels. The speaker also emphasized that, while national level data are useful for global compilations and for trend analyses, subgroup analyses are imperative to better understand variations in iodine status by iodine content, as well as by demographic and socioeconomic variables. He also reminded the group that there is a WHO resolution which stipulates that every country should collect data on iodine status at least every three years. With the focus on achieving optimal iodine status (MUIC in the adequate range), the definition of ‘adequately iodized salt’ will therefore need to be context-specific, given that varying iodine content will be required in different settings to optimize iodine status.
The speaker explained that if salt iodization cannot ensure adequate iodine status among all vulnerable groups, then complementary interventions (for the delivery of iodine) should be considered. To illustrate, even in a well-functioning USI program, the physiological requirements of pregnant women may not be met especially if they enter pregnancy with sub-optimal stores. In such a case, iodine supplements may be required, either through single iodine or as part of a multiple micronutrient supplement (31). Such improvements in maternal iodine status may also benefit breastfeeding infants (32). For children 6-23 months, specialized fortified nutritional products such as micronutrient powders may also be considered. The speaker concluded that even though the coverage of supplementation programs and use of specialized products remains low in low- and middle-income settings, these complementary strategies should be considered as a component of IDD control strategies and supported where salt iodization cannot meet the nutritional needs of all target groups. In such settings it will be imperative to develop monitoring tools which assess the reach and contribution of these different interventions. The group reiterated that statements about program success should be based on analyses demonstrating optimal UIC among all target group as defined by age, physiologic status, geography, and socioeconomic status.
2.2. ONGOING RESEARCH ON IODINE STATUS ASSESSMENT AND FUTURE RESEARCH NEEDS

Michael Zimmermann and Maria Andersson (Swiss Federal Institute of Technology, ETH) presented findings from ongoing research on iodine nutrition. The first study presented was the Salt Iodization: Meeting the needs of Pregnancy, Lactation and Infancy (SIMPLIFY) study. Data have been collected from study sites in China, Croatia and the Philippines as part of a joint ETH/GAIN/UNICEF study to examine whether USI can meet the physiological dietary requirements of iodine in women of reproductive age, pregnant women, lactating women, and infants up to two years of age without causing excessive iodine intake in school-age children and non-pregnant, non-lactating women. Preliminary findings indicate that salt iodized at an average level of 25 μg/kg provides adequate iodine intake to the general population and meets the increased physiological iodine requirements in pregnant women, lactating women and breast-fed infants. The iodine intake was not excessive in school children and women of reproductive age, except for children in the Philippines. The results of the thyroid function parameters indicate normal thyroid function in all population groups. The results also suggest that a well-functioning USI program can supply adequate iodine via breast milk to breast fed infants, and similarly suggest sufficient iodine intake in 7-24 mo old toddlers. However, before these findings can be taken to suggest that the optimal iodine status is attributable, exclusively to iodized salt, other possible sources of dietary iodine must be evaluated.

A second study assessed the feasibility of thyroglobulin (Tg), a protein precursor of thyroid hormone which reflects iodine nutrition over a period of weeks/months, as a complementary indicator to UIC to monitor the iodine status of populations (33). A recent controlled intervention study in adults reported that thyroglobulin is a sensitive biomarker of even mild iodine deficiency (34). In a previous multicenter study supported by ETH/UNICEF/IGN, thyroglobulin was shown to be a sensitive indicator of low and excessive iodine intake among school-aged children and provided the basis for a revised range of MUIC for the classification of optimal iodine status and monitoring of iodized salt programs (15). In pregnancy, the current MUIC ranges recommended for the classification of optimal status (13) are supported by only limited evidence. The speakers presented evidence from different settings demonstrating that serum thyroglobulin increases with worsening iodine deficiency in pregnancy (35-37), and data from China indicates that serum thyroglobulin shows a U-shaped curve vs UIC in iodine sufficient Chinese pregnant women (38). Recently, a new low-cost enzyme-linked immunoassay has been developed for the assessment of thyroglobulin from dried serum and dried whole blood spots collected on a filter paper matrix and could enable more rapid assessment of iodine status for program monitoring (39).

A recently completed infant balance study has defined the required intake for iodine at this age (M. Andersson, personal communication) and current efforts are examining the most appropriate criteria to classify optimal iodine status among children 0-12 months based on UIC; other research questions remain for infants (Table 4). Finally, the researchers presented the results of a modelling exercise which examined the relationship between total goiter rate and iodine status (MUIC) from a number of national surveys (40) which was used to develop regression equations to estimate goiter rates based on latest national UIC estimates (J Gorstein, unpublished). The presenters opined that such models serve as a useful advocacy tool to show the remarkable progress that has been achieved globally on the reduction of clinical iodine deficiency at national levels. However, a focus on goiter in the routine global reporting on IDD has limited value because a focus on this clinical endpoint neglects the more widespread cognitive impairments as the primary health consequence of iodine deficiency.

Even though national median UIC estimates can be used to classify population iodine status, they
TABLE 4:
Required research needs for iodine status assessments (29)

PRIORITY RESEARCH QUESTIONS

- Establish the iodine requirements during infancy (0-6 mo, 6-24 mo)
- Define/revise the median UIC range indicating optimal iodine status in non-pregnant women of reproductive age and pregnant women, and lactating women
- Evaluate breast milk iodine concentration as an indicator for iodine status in lactating women as well as predict iodine supply to breast-fed children
- Investigate the role of breast milk (infant formula) for optimal iodine status during weaning in populations following pediatric recommendations to limit salt consumption before 12 mo
- Investigate the role of iodine containing MNPs for optimal iodine nutrition during infancy
- Investigate the role of breast milk (infant formula) for optimal iodine status during weaning in populations following pediatric recommendations to limit salt consumption before 12 mo

do not allow for an assessment of the proportion of the population with sub-optimal iodine intakes (13). ETH researchers are developing a method to calculate habitual dietary iodine intakes based on replicate casual UIC measurements (to account for expected within person variability), which then enables assessment against EARs and, in turn, to estimate the prevalence of inadequate iodine intakes based on the EAR cut-point (41). This method is being further refined and may enable determination of proportion of the population with intakes above the tolerable upper intake level (UL) and proportion of the population with sub-optimal iodine intakes based on UIC collected in population-based surveys.

In ensuing discussions, there was consensus that the optimal range of iodine status based on MUIC among pregnant women needs to be re-examined in a multicenter study using thyroglobulin as a marker of thyroid function. In addition, there is a need to re-examine median UIC ranges among women of reproductive age and young children, owing to the limited evidence base supporting the current range. Ensuring optimal iodine status among this group is important to ensure adequate iodine status for fetal development once a woman gets pregnant. If the SIMPLIFY trial demonstrates that USI in fact achieves adequate iodine status among all target groups, then population surveys may no longer have to attempt to sample UIC among pregnant women, given that this target group needs to be oversampled to get adequate sample size, but which increases survey costs.

KEY AGENDA MOVING FORWARD

1. Implement the research priorities listed in Table 4. Attribute high priority to defining/revising the median UIC threshold indicating optimal iodine nutrition in non-pregnant women of reproductive age and pregnant women.

2. Examine the feasibility including thyroglobulin in existing enzyme-linked immunosorbent assay kits that could enable the simultaneous measurement of ferritin, soluble transferring receptor, retinol binding protein, and C-reactive protein (42).

3. Expand the work and validation of the EAR cut-point method to other population groups, including those from Latin America and Africa.
2.3. EMERGING ISSUES ON USE OF URINARY IODINE CONCENTRATIONS

Omar Dary (United States Agency for International Development) provided the background on the establishment of UIC cut-off points based on goiter prevalence levels in communities in Latin America (40, 43). These data underpinned the epidemiological criterion that a MUIC ≥100 μg/l was associated with a population without clinical goiter attributable to IDD (44). He then went on to provide an example from the Dominican Republic which indicates that while only 37% of HHIS is iodized, the MUIC among women is in the adequate range and even classified as excessive in urban areas (45). Supported by data indicating that bouillon cubes and powdered soups are frequently consumed and were prepared using iodized salt, the speaker suggested that these vehicles, rather than discretionary household salt, is the major source of iodine in the Dominican Republic. While UIC data from Dominican Republic appeared to be excessive (> 300 μg/l) for different age groups, the speaker described why its classification may be a misinterpretation, in part due to the fact that UIC, expressed as μg iodine per liter of urine from a single convenience sample will vary depending on urine output. He noted that the UIC cut-off points were based on school-aged children, who excrete approximately 1 litre per day, and as such the UIC approximates the urinary iodine excretion (UIE) which is determined over a 24 hour period. In turn, the misclassification of iodine status based on UIC could be reduced if UIE data are used, although this requires a full urine collection over a 24 hour period. The speaker then presented data indicating that iodized salt intake (and thus iodine intake) is proportional to energy intake using results from a study done in Mexico City. As expected, females consumed 0.74-0.80 of the levels consumed for males both for iodine and salt, and which coincides with the same proportion of energy intake between the two sexes. The speaker concluded that UIC is a practical but crude indicator of population iodine status, and its utility is restricted to the median value for populations. As highlighted in the previous session, he stressed that it is not appropriate to present proportions of cases above or below different cut-off points. He also described that UIC may be influenced by climatic conditions, physical exercise, gender, and body mass, given that these conditions influence hydration and in turn, urine volume and the potential usefulness of UIC.

In discussions, it was stated that calculating UIE based on UIC with predictive equations is a crude approximation only and that there are many unanswered questions. To better characterize iodine status among pregnant women, UIC and thyroglobulin data should be examined together.

**KEY AGENDA MOVING FORWARD**

1. Carry out studies under different ecological conditions and members of the family comparing UIE and UIC.

2. Re-examine the utility of creatinine to estimate 24-h iodine excretion of spot UIC samples.
2.4. STATISTICAL ISSUES FOR ANALYSIS OF IODINE SURVEYS

Bradley Woodruff (GroundWork) described that UIC is unlike any other biomarker of micronutrient status. Because UIC values are typically generated from a single casual sample, they are highly variable and do not reflect an individual’s habitual iodine intake. As a result, a single value cannot identify individuals with deficiency. Furthermore, UIC values from single spot samples are not normally distributed and therefore require non-parametric methods to determine sample size requirements, generate measures of precision around single point estimates or when comparing populations or sub-groups. Given the characteristics of the distributions, MUIC is useful to classify the iodine status of entire populations, and criteria have been developed based on the MUIC to designate deficiency, optimal status and excessive intake. Variability in UIC can be reduced by collecting repeat samples and compensating for within-individual variations in intake, but repeat collection of samples is often challenging in surveys. As described in section 2.2, methods are being developed to use duplicate urine specimens on a subset of survey participants to reduce the variance in distributions in order to obtain estimates of the prevalence of inadequate intake. Ideally, this work can produce correction factors that can subsequently be applied to other datasets where single UIC measurements (as well as weight measurements, required to estimate urine outputs) are available. In cross-sectional surveys, UIC distributions are generally right skewed (Figure 7) (46), and transformation techniques are required to allow the use of standard parametric techniques for continuous data. However, such transformations may create certain complexities (Table 5).

FIGURE 7:
Distribution of urinary iodine concentrations among non-pregnant women in 2013 Sierra Leone Micronutrient Survey (46)
Preliminary evidence indicates that among iodine sufficient populations, square root transformations may produce good results (Figure 8). For iodine deficient populations, other transformations may be necessary. However, it remains possible that for some datasets, no transformations will yield a normal distribution of UIC values, in which case non-parametric tests have to be employed. The presenter discussed methods to test for the statistical significance of differences between medians in different subgroups. Even though UIC data are subject to sampling errors, current recommended procedures for the analysis and presentation of UIC survey results do not comment on measures of precision for the median (13). The examination of measures of precision is important to determine whether planned subgroup analyses will provide informative results and whether survey medians are statistically different from one another and from recommended WHO cut points. The speaker illustrated the importance of providing precision estimates in the interpretation of MUIC data from non-pregnant women from the 2013 Sierra Leone Micronutrient survey (Figure 9) (46). To determine the statistical significance of the difference between a survey median and relevant cut points, “bootstrapping” or other methods to generate confidence intervals around the median are needed. To conduct sample size calculations for non-parametric distributions, it has been suggested to employ calculations based on parametric distributions which can be adjusted with appropriate factors (47). However, more work is needed to determine optimal methods for UIC surveys. To simplify non-parametric sample size calculations, analysts have chosen to classify survey subjects as below or above relevant cut points and then to apply sample size formula used to estimate proportions (48).

**TABLE 5:**

Key Issues in the design and analysis of UIC data for population surveys

<table>
<thead>
<tr>
<th>PROBLEM</th>
<th>PROPOSED SOLUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>May not work for some survey datasets</td>
<td>n/a</td>
</tr>
<tr>
<td>Requires more sophisticated analysis</td>
<td>- Must transform UIC values</td>
</tr>
<tr>
<td></td>
<td>- Must un-transform point estimates and confidence intervals</td>
</tr>
<tr>
<td></td>
<td>- Results may not be as intuitive as untransformed analyses</td>
</tr>
<tr>
<td>More difficult to calculate required minimum</td>
<td>- Must predict what method of transformation will be needed</td>
</tr>
<tr>
<td>sample size</td>
<td>- Must transform all assumptions using predicted method</td>
</tr>
<tr>
<td></td>
<td>(Predicted mean, Confidence intervals for desired precision,</td>
</tr>
<tr>
<td></td>
<td>Minimum difference between groups)</td>
</tr>
<tr>
<td>Still requires techniques for analyzing</td>
<td>n/a</td>
</tr>
<tr>
<td>continuous data</td>
<td></td>
</tr>
</tbody>
</table>

(continued)
FIGURE 8:
Distribution of square root of urinary iodine concentrations among non-pregnant women in 2013 Sierra Leone Micronutrient Survey (46)
In ensuing discussions, the importance of developing methods to construct 95% confidence intervals around UIC medians was highlighted. Bootstrapping methods may be the promising tool to obtain such measures of uncertainty in the case of UIC surveys. For the design of informative yet efficient UIC-based surveys and planned subgroup analyses, new sample size calculations need to be developed, as current guidance is not adequate (13, 48). Relevant guidance should be included in upcoming revisions of the WHO/UNICEF/IGN manual on ‘Achieving Optimal Iodine Nutrition: A Manual for Health Programme Managers’, the WHO/CDC/MI/UNICEF ‘Micronutrient Survey Manual on Indicators and Methods for Cross-Sectional Surveys of Vitamin and Mineral Status of Populations’, and other relevant documents. Furthermore, syntax for the most commonly used statistical software packages should be made available to program managers for sample size calculations and the analysis of UIC data. Participants recommended the creation of a technical working group to complete the required statistical work.

**KEY AGENDA MOVING FORWARD**

1. Include guidance in relevant program notes to emphasize that the proportion of the population below the recommended UIC for a given target group cannot be used to quantify the proportion of the population with iodine deficiency. If the survey sample’s median falls statistically significantly below the recommended UIC for a given target group, then the population (as a whole) should be classified as deficient.

2. Develop and validate techniques to estimate precision and 95% confidence intervals around MUICs.

3. Calculate minimum sample size requirements to estimate MUIC both for national level data and for sub-group analyses.

4. Develop statistical methods to compare MUIC levels against cutoff levels and between subgroups and make syntax available for common statistical software programs available to program managers.
2.5. DEVELOPMENT OF WHO/UNICEF/IGN MANUAL ON ‘ACHIEVING OPTIMAL IODINE NUTRITION: A MANUAL FOR HEALTH PROGRAMME MANAGERS’

Lisa Rogers (World Health Organization) provided background information on previous interagency collaborations to develop global manuals and guidelines on iodine programs and presented the suggested outline and proposed timeline for the development of a revised WHO/UNICEF/IGN manual on ‘Achieving Optimal Iodine Nutrition: A Manual for Health Programme Managers.’ The presenter reviewed the previous manuals developed by WHO and supported by other agencies (Table 6). In accordance with the framework of the WHO Strategy on Research for Health (50), the revised manual will be organized into five general chapters (Table 7). Since the manual is targeted to program managers, it will place particular focus on implementation and monitoring & evaluation. The speaker presented broad headlines for each of the five chapters and suggested timelines for the completion of the manual.

**TABLE 6:**
World Health Organization guidance documents on iodine nutrition

<table>
<thead>
<tr>
<th>TITLE</th>
<th>AGENCIES</th>
<th>REFERENCE</th>
<th>YEAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>A practical guide to the correction of iodine deficiency</td>
<td>WHO, UNICEF, ICCIDD</td>
<td>(52)</td>
<td>1990</td>
</tr>
<tr>
<td>Technical manual no. 3</td>
<td><a href="http://apps.who.int/iris/bitstream/10665/39840/1/9070785056_eng.pdf">http://apps.who.int/iris/bitstream/10665/39840/1/9070785056_eng.pdf</a></td>
<td></td>
<td></td>
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<tr>
<td>Global prevalence of iodine deficiency disorders</td>
<td>WHO</td>
<td>(53)</td>
<td>1993</td>
</tr>
<tr>
<td>Recommended iodine levels in salt and guidelines for monitoring their adequacy and effectiveness</td>
<td>WHO, UNICEF, ICCIDD</td>
<td>(55)</td>
<td>1996</td>
</tr>
<tr>
<td>Progress towards the elimination of iodine deficiency disorders</td>
<td>WHO, UNICEF, ICCIDD</td>
<td>(56)</td>
<td>1999</td>
</tr>
<tr>
<td><a href="http://apps.who.int/iris/bitstream/10665/61278/1/WHO_NHD_01.1.pdf">http://apps.who.int/iris/bitstream/10665/61278/1/WHO_NHD_01.1.pdf</a></td>
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<td><a href="http://apps.who.int/iris/bitstream/10665/43781/1/9789241595827_eng.pdf">http://apps.who.int/iris/bitstream/10665/43781/1/9789241595827_eng.pdf</a></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Fortification of food-grade salt with iodine for the prevention and control of iodine deficiency disorders.</td>
<td>WHO</td>
<td>(29)</td>
<td>2014</td>
</tr>
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</table>
TABLE 7:
Framework of the WHO Strategy on Research for Health

| Step 1: Magnitude and distribution of iodine deficiency disorders as a public health problem |
| Step 2: Biological, contextual, social, economic determinants of iodine deficiency *(role of iodine in health and disease)* |
| Step 3: Interventions to prevent and control iodine deficiency |
| Step 4: Implementation of iodine deficiency prevention and control programmes |
| Step 5: Monitoring and evaluation of iodine deficiency prevention and control programmes |
| Fast evolving areas and current knowledge gaps |
| References/Links |

In ensuing discussions, it was mentioned that for the different interventions available to control IDD (Step 3), the focus is on salt iodization, while much less information is available on other IDD control interventions. The chapter may therefore have to be divided into a part on salt iodization and a second part summarizing all available information on other IDD control strategies. It was also decided that given the wealth of new information discussed during the current meeting, and the need to further refine many of the concepts, it would be most prudent to delay the production of the Manual at this time. Instead, the meeting participants recommended that a more informal Program Note should be developed which describes changes that can already be made to salt iodization programs. This Program Note may follow the format produced by the Home Fortification Technical Advisory Group (51) and does not require WHO endorsement. It was suggested that a meeting, perhaps in conjunction with the MN Forum in October, 2016 could be held with program managers to present the Note. In parallel, the participants agreed to develop a clear research agenda to fill critical evidence gaps. The outputs of this research would help to inform the background needs required for the preparation of the WHO/UNICEF/IGN Manual. In parallel, WHO should initiate the scoping required for a systematic review of indicators of iodine status. WHO will seek recommendations on suitable participants for the review group. Lastly, WHO may consider a formal recommendation not to use the proportion of the population with UIC < 100 μg/l as the proportion of the population with iodine deficiency (see section 2.4).
KEY AGENDA MOVING FORWARD

1. Develop a Programming Note with key recommendations that can be shared with program managers.

2. Pilot test corrective approaches suggested in the Programming Note and conduct additional research where required.

3. Form a working group to advance the development of the Programming Note, address current knowledge gaps for the Programming Note.

4. Start the scoping for the systematic review of indicators of iodine status.
## ANNEX A: PARTICIPANT LIST

<table>
<thead>
<tr>
<th>Organization</th>
<th>Person</th>
<th>Position</th>
<th>Affiliation</th>
<th>Address</th>
<th>Email</th>
</tr>
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<tbody>
<tr>
<td>Bill &amp; Melinda Gates Foundation</td>
<td>Senoe Torgerson</td>
<td>Program Officer</td>
<td>Nutrition</td>
<td>Seattle, WA, US</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bill &amp; Melinda Gates Foundation</td>
<td>Greg Garrett</td>
<td>Director, Food Fortification</td>
<td>GAIN – Global Alliance for Improved Nutrition</td>
<td>Rue de Vermont 37-39, PO Box 55</td>
</tr>
<tr>
<td>Centers for Disease Control</td>
<td>Rafael Flores</td>
<td>Team Lead, IMMPaCt Program</td>
<td>Nutrition Branch, Division of Nutrition, Physical Activity and Obesity (DNPAO)</td>
<td>U.S. Centers for Disease Control and Prevention (CDC)</td>
<td>4770 Buford Hwy, MS F-77, Atlanta, GA 30341</td>
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<tr>
<td></td>
<td>Rafael Flores</td>
<td>Team Lead, IMMPaCt Program</td>
<td>Centers for Disease Control</td>
<td>Atlanta, GA, US</td>
<td></td>
</tr>
<tr>
<td>ETH Zürich</td>
<td>Maria Andersson (by videoconference)</td>
<td>Senior Scientist</td>
<td>Department of Health Sciences and Technology</td>
<td>Swiss Federal Institute of Technology</td>
<td>Schmelzbergstrasse 7</td>
</tr>
<tr>
<td></td>
<td>Michael Zimmermann (by videoconference)</td>
<td>Professor</td>
<td>Department of Health Sciences and Technology</td>
<td>Swiss Federal Institute of Technology</td>
<td>Schmelzbergstrasse 7</td>
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<tr>
<td></td>
<td>GroundWork</td>
<td>Fabian Rohner (by videoconference)</td>
<td>Nutrition and Public Health Expert</td>
<td>GroundWork</td>
<td>Ouagadougou, Burkina Faso</td>
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<tr>
<td></td>
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<td></td>
<td>Bradley Woodruff</td>
<td>Epidemiology and Public Health Expert</td>
<td>GroundWork Atlanta, GA, US</td>
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<tr>
<td>Iodine Global Network</td>
<td>Jonathan Gorstein</td>
<td>Executive Director</td>
<td>Iodine Global Network</td>
<td>Seattle, WA, US</td>
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</tr>
<tr>
<td>JBPHN LLC</td>
<td>Jack Bagriansky</td>
<td>Independent Consultant</td>
<td>JBPHN LLC</td>
<td>606 Park Lane</td>
<td>Decatur, GA. 30033</td>
</tr>
</tbody>
</table>
ANNEX A: PARTICIPANT LIST

Julia Krasevec
Statistics and Monitoring Specialist (Nutrition), Data and Analytics Section, Division of Data, Research and Policy
3 UN Plaza
New York, NY 10017, US

Richard Kumapley
Consultant, Micronutrients Nutrition Section, UNICEF
3 UN Plaza
New York, NY 10017, US

Roland Kupka
Senior Adviser, Micronutrients Nutrition Section, UNICEF
3 UN Plaza
New York, NY 10017, US

Ruth Situma
Nutrition Specialist, Micronutrients Nutrition Section, UNICEF
3 UN Plaza
New York, NY 10017, US

USAID
Omar Dary
Health Science Specialist (Nutrition)
Bureau of Global Health, USAID
1300 Pennsylvania Ave. NW, CP3, Room 10010A
Washington DC 20523, US

World Health Organization
Lisa Rogers
Technical Officer, Evidence and Programme Guidance
World Health Organization
Avenue Appia 20,
1211 Geneva 27, Switzerland
TECHNICAL WORKING GROUP MEETING ON RESEARCH PRIORITIES FOR THE MONITORING OF SALT IODIZATION PROGRAMS AND DETERMINATION OF POPULATION IODINE STATUS

Thursday, 17 December, 2015

Coffee and light refreshments available from 8:00 am

Chair: Roland Kupka

8:30 am - 9:00 am: Meeting introduction (20 min presentation, 10 min question)
Presenter: Roland Kupka

Session goals:
• Explain the purpose and mechanics of the meeting

Domain 1: Salt monitoring

9:00 am - 9:30 am: Topic 1: What is a successful salt iodization program? (15 min presentation; 15 min discussion)
Presenter: Ruth Situma

Session goals:
• Establish a common basis on what it means to have a successful salt iodization

9:30 am - 10:30 am: Topic 2: What is the performance of Rapid Test Kits? (20 min presentation; 40 min discussion)
Presenter: Jonathan Gorstein

Session goals:
• Examine the performance of RTK as a semi-quantitative tool to measure salt iodine levels and what alternatives are available
• Identify potential research priorities

10:30 am – 10:45 am: Break

10:45 am - 12:00 pm: Topic 3: What is the best metric to determine the adequacy of iodine content in salt? (30 min presentation; 45 min discussion)
Presenter: Omar Dary

Session goals:
• Examine the potential promise of composite samples to determine the adequacy of iodine levels in salt for household surveys and at factory level (internal and external regulatory monitoring)
• Identify potential knowledge gaps related to the use of composite samples and how to address them
12:00 pm – 1:00 pm: Topic 4: Do Fortification Assessment Coverage Tool surveys hold promise to replace current population-based designs to measure coverage of adequately iodized salt at household levels? (20 min presentation, 40 min discussion) Presenter: Greg Garrett
Session goals:
• Examine the current design and application of FACT surveys
• Identify potential knowledge gaps and formulate related research priorities

1:00-2:00 pm: Lunch (provided)

Chair: Omar Dary

2:00 pm – 3:00 pm: Topic 5: What monitoring tools are needed to quantify the consumption of iodized salt through processed foods and condiments? (20 min presentation, 40 min discussion) Presenter: Jonathan Gorstein
Session goals:
• Examine the current status on monitoring tools for iodized salt contained in processed foods and condiments
• Identify potential knowledge gaps and formulate related research priorities

3:00 pm - 3.15 pm: Break

3:15 pm - 4:45 pm: Topic 6: What indicator(s) and tools should be used to track global performance of salt iodization programs? (25 min presentation, 65 min discussion) Presenters: Julia Krasevec and Jonathan Gorstein
Session goals:
• Present challenges related to the global database on tracking of salt iodization (and, when indicated on iodine status)
• Identify the future characteristics of the global database on tracking of salt iodization (and, when indicated on iodine status)

4:45 pm – 5:00 pm: Wrap up
Presenter: Roland Kupka
Session goals:
• Present and achieve consensus on action points
Friday, 18 December, 2015  
Domain 2: Iodine Status Monitoring  
Chair: Rafael Flores  

8:30 am - 9:00 am: Topic 1: What is a successful program to achieve optimal iodine nutrition? (20 min presentation, 10 min discussion)  
Presenter: Arnold Timmer  
Session goals:  
• Establish a common basis on what it means to have a successful iodine deficiency control program  

9:00 am – 10:00 am: Topic 2: Ongoing research on iodine status assessment and future research needs (20 min presentation, 40 min discussion)  
Presenters: Michael Zimmermann and Maria Andersson  
Session goals:  
• Present currently ongoing research efforts  
• Identify priority epidemiological research questions  

10:00 am – 11:00 am: Topic 3: Emerging issues on use of urinary iodine concentrations (20 min presentation, 40 min discussion)  
Presenter: Omar Dary  
Session goals:  
• Identify current limitations related to the use of spot samples to measure urinary iodine concentrations  
• Formulate required assessments to improve the measurement of population iodine status  

11:00 am – 11:30 am: Coffee break  

11:30 am – 12:30 pm: Topic 4: Statistical issues for analysis of iodine surveys (20 min presentation, 40 min discussion)  
Presenter: Bradley Woodruff  
Session goals:  
• Identify current statistical challenges in the design and analysis of iodine surveys  
• Formulate research agenda to improve the efficiency and quality of iodine surveys  

12:30 pm - 1:30 pm: Lunch (provided)
Chair: Greg Garrett

    Presenter: Lisa Rogers
Session goals:
    • Examine the draft Table of Contents
    • Identify new work that needs to be completed before updated book can be published
    • Articulate a timeline for the development of the guidelines

3:00 pm – 3:30 pm: Wrap-up of Meeting
    Presenter: Roland Kupka
Session goals:
    • Present and achieve consensus on action points
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33. Ma ZF, Skeaff SA. Thyroglobulin as a biomarker of iodine deficiency: a review. Thyroid 2014;24(8):1195-209


55. World Health Organization, ICCIDD, UNICEF. Recommended iodine levels in salt and guidelines for monitoring their adequacy and effectiveness. Geneva; 1996.


ACKNOWLEDGEMENTS

The organizers thank the United States Agency for International Development and the Bill & Melinda Gates Foundation for providing financial support for this work.