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## Achieving Health Impact in Ethiopia through Salt Iodization: Progress to Date and GAIN's Role

### Executive Summary

Ethiopia is one of the target countries for the GAIN-UNICEF Universal Salt Iodization (USI) Partnership Project (2008-2015) because of its large population, high prevalence of iodine deficiency, and low household coverage of iodized salt.

While over 80% of Ethiopian households had access to iodized salt via Eritrean sea salt producers prior to 1998, the Eritrean-Ethiopian War resulted in political tensions and border closures for many products, including salt. This resulted in household coverage of iodized salt plummeting. Some surveys indicated household coverage to be as low as 4.7% in 2008 (NNP baseline survey, Ethiopian Public Health Institute 2008). In 2005, the Ethiopian Health and Nutrition Research Institute (EHNRI) -- now called the Ethiopian Public Health Institute (EPHI) -- estimated that over 83% of school children had mild to severe iodine deficiency, as measured by urinary iodine concentration (UIC). Goiter rates of 40% in children and 36% in mothers were also found, which are also indicative of severe iodine deficiency.

GAIN has been supporting the National Universal Salt Iodization (USI) Program in Ethiopia since 2009 through technical and financial assistance working with government, the salt industry, civil society, and consumers to increase the availability and access to adequately iodized salt. GAIN's role in partnership with the Federal Ministry of Health (FMoH); the Food, Medicine, and Health Care Administration and Control Authority (FMHACA); UNICEF; and the private sector has been critical in pushing forward the national USI program. GAIN has provided input and built capacity across the entire fortification impact model, from the foundation building, set-up and launch stages through to scale-up & delivery and demonstrating of impact (Figure 1).

Preliminary results of the 2014 National Micronutrient Survey report that coverage of iodized salt has increased significantly during the time of GAIN's engagement: 95.2% of households now have access to salt with some iodine and 42.7% of households have access to salt that is adequately iodized to national standards.

This increased coverage of iodized salt has improved children's iodine status, mental development, and physical growth. This has been demonstrated through a 2015 cluster randomized trial of children <36 months in 60 villages in Amhara, Ethiopia.<sup>1</sup> Children with iodized salt access had significantly higher scores at reassessment on three of the four Bayley-III subscales.<sup>2</sup> Also, the length-for-age was higher among children consuming iodized salt for those with high household assets, suggesting a positive link for stunting reduction. UIC was higher in children consuming iodized salt with an unschooled mother, unimproved water, and no recent illness. **These results further validate universal salt iodization to improve children's lives in Ethiopia and provide evidence that the USI program has success during the time of GAIN's engagement<sup>3</sup>.**

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<sup>1</sup> Bougma K, *et al.* 2015. Iodized salt improves child's iodine status, mental development, and physical growth in a cluster randomized trial in Ethiopia. *The FASEB Journal*. 29: 28.6.

<sup>2</sup> Standards of measurement used to assess the motor, language, and cognitive development of children aged 0-3.

<sup>3</sup> It is difficult to precisely quantify the degree to which this success is attributable to GAIN's efforts. However there is very strong evidence to indicate that GAIN's work in Ethiopia was critical to advancing the reforms necessary to move towards USI and has greatly improved the coverage and quality of iodized salt produced.

## GAIN's Approach in Ethiopia

GAIN used its National Fortification Impact Model, shown in Figure 1, in the Ethiopian salt iodization context. GAIN has played a key role in each of the model's elements.

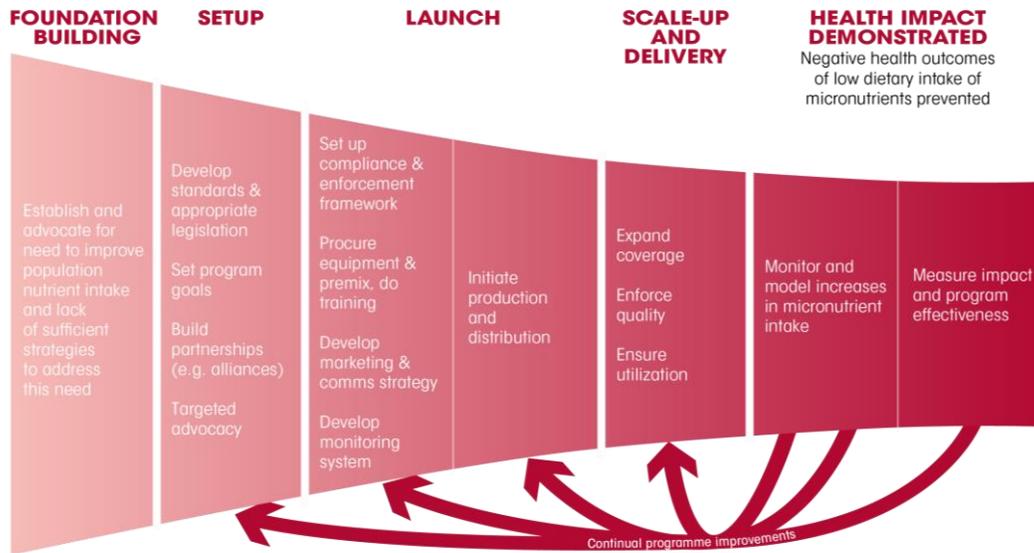


Figure 1: GAIN's National Fortification Impact Model

The following GAIN activities are categorized as per the columns in this impact model and are subsequently discussed in this paper. They are also summarized in Appendix 1:

- **Foundation Building & Setup:** advocating for mandatory salt iodization legislation and appropriate standards, which were passed in February 2011;
- **Launch:** Analyzing the potassium iodate (KIO<sub>3</sub>) supply chain and establishing a sustainable supply system with a cost recovery mechanism;
- **Scale-up & Delivery:**
  - Increasing the production capacity of salt producers via the provision of iodization equipment and training on use and maintenance;
  - Building both internal and external QA/QC and regulatory monitoring capacity; and
- **Health Impact:** Improving monitoring and evaluation processes for continued improvement, sustainability and demonstration of impact.

## Foundation Building & Setup: Mandatory Fortification Legislation & Standards

As a difficult, bureaucratic, and decentralized legislative and business environment, the passage of Ethiopia's mandatory salt iodization legislation was a major milestone that was unlikely to happen without the constant advocacy efforts by GAIN, UNICEF and partners. For several years, advocacy for salt iodization among producers and government officials had little impact. However, in 2008, GAIN's full time USI officer based in Ethiopia contributed to the dialogue as part of the National Iodine and USI Meetings where legislation was discussed weekly. In November 2008, these efforts resulted in a high level stakeholder

meeting with regional and federal Ministers, landowners, and salt producers, which catalyzed a dramatic shift in attitudes towards salt iodization. This attitude shift culminated in a consensus and MOU between GAIN, the FMOH, and other Federal and Regional stakeholders, which clarified responsibilities. GAIN's USI officer continued to liaise with stakeholders, identifying and working to remedy roadblocks that occurred.

Throughout 2009, GAIN identified key challenges and barriers to salt iodization, including poor coordination, technical and supply issues, and resistance from producers. GAIN worked in parallel to tackle these challenges via  $KIO_3$  donations, technical assistance, and advocacy to encourage industry acceptance. As part of its advocacy work, GAIN arranged meetings and gave presentations during board meetings of various salt producers' associations. This all resulted in a significant increase in the commitment and willingness of local salt committees and producers to iodize salt, as evidenced by their demand for iodization equipment and  $KIO_3$  as well as an increase in iodized salt production in many areas.

GAIN also worked with federal and regional Ministers and officials to develop a blueprint for sustainable development of salt iodization. GAIN specifically contributed to the identification of constraints and the provision of recommendations for the commencement of salt iodization and related quality control procedures. GAIN was an active member of the National Technical Committee (NTC) to draft the legislation and revised salt standards for iodized salt. The legislation was submitted to the Council of Ministers in early 2010 and, after gaining industry support, it was approved and immediately implemented in February 2011.

The success of this activity can be attributed to the timely advocacy and technical support GAIN and its USI partners provided during a very promising enabling environment, including a motivated Ethiopian Prime Minister and other high level officials who were very interested in addressing malnutrition and micronutrient deficiencies in the country.

### **Launch: $KIO_3$ Needs Identified and Cost Recovery Mechanism Established**

In 2010, GAIN led an extensive analysis of the  $KIO_3$  supply chain in Ethiopia and the quality of stock present throughout the country, consulting with key stakeholders throughout the process. This analysis resulted in finding nearly 12.6 MT of  $KIO_3$  that had been previously donated for iodization efforts sitting expired in warehouses throughout the country. The expired stock amounted to nearly \$700,000<sup>4</sup> in losses, prompting the government to recognize this opportunity to work with GAIN to create a more sustainable mechanism for  $KIO_3$  procurement to balance the risk of stock-outs with that of expiration.

GAIN assessed information on the national iodized salt demand and iodization capacity at production facilities throughout the country to determine the total annual need for  $KIO_3$ . GAIN identified that the government had plans to procure an amount of  $KIO_3$  that far exceeded the current production needs and worked with the government to modify its procurement request, saving money and the potential for future wastage in the process. GAIN designed a supply system and then worked with the government's Pharmaceutical Fund and Supply Agency (PFSA) to establish the system, a revolving fund for sustainable purchase and a fee schedule for salt producers to purchase  $KIO_3$  in amounts relative to their production capacity and quotas. The revolving fund began in July 2012 with an initial donation of 22 MT (13.9 MT from the GAIN Premix Facility). GAIN also led on all logistics and negotiated the recovery of an additional 6 MT, reprocessed from the 12.6 MT of expired stock by Calibre Chemicals in 2013.

As of 2015, the revolving fund and cost recovery mechanism are working well. A total of 54 MT of  $KIO_3$  has been successfully procured by PFSA without external resources in addition to the seed stock. PFSA is committed to having enough in stock to cover the national needs for 8 months of production. A request for the fourth round of procurement (totaling 40 MT) has been received by the FMOH from PFSA, providing evidence that the cost recovery mechanism has remained free of donor support since the initial  $KIO_3$

<sup>4</sup> The average cost of  $KIO_3$  was US\$ 55/kg.

provision and the supply of  $KIO_3$  has stabilized within the country. The Ethiopian government has opened a dedicated bank account for  $KIO_3$  payments and salt producers have fully complied with prepaying for their allocated  $KIO_3$  prior to delivery. No  $KIO_3$  is known to have expired since the establishment of the GAIN-designed procurement and distribution system.

The success of this activity can be fully attributed to GAIN’s technical expertise in high quality  $KIO_3$  procurement, distribution and financing mechanisms. GAIN was able to leverage its GAIN Premix Facility and its past experience in implementing similar successful revolving fund models in Tanzania and Ghana that pooled procurement quantities and worked with local distribution agencies to ensure even the smallest producers had access to affordable  $KIO_3$  and other fortification premixes.

### Scale up & Delivery: Industry Production Rapidly Increased and Internal QA/QC Improved

Ethiopia’s salt iodization capacity during 2011 was only able to meet 15% of the national requirement. This was corroborated by the 2011 DHS which indicated that 15.4% of households were using salt with some amount of iodine. GAIN worked with development partners, government, and industry to advocate for a strategy to increase iodization to 84% of national needs by 2015.

GAIN was instrumental in the provision and installation of iodization equipment and its related procurement and customs clearing processes. From 2011 to 2015, GAIN procured several quality-assured salt iodization machines (including 6 Davey machines with 10MT/hour capacity), generators, and materials to repair existing machines that had previously been left idle. Upon installation, training was provided to salt producers on iodization processes, machine handling, and maintenance. The Davey iodization machines were installed in early 2015 and are expected to increase the production of adequately iodized salt by 24%.<sup>5</sup>

GAIN also led efforts to improve the QA/QC and laboratory capacity of salt producers. Training was provided to salt producers on quality monitoring and quantitative iodine analysis. Salt producers were trained on three different validated methods for iodine measurement: titration, analysis via WYD devices, and analysis via Bioanalyt iCheck® devices. Recommendations for the appropriate use of each type of method were provided along with the laboratory equipment and analysis devices according to the needs and constraints presented in the Ethiopian context, summarized in Table 1.

**Table 1: Quantitative iodine measurement methods, usage, and constraints.**

Method	Expertise Required	Infrastructure Required	Costs Required	Recommended Usage
<b>Titration</b>	Basic laboratory skills	Basic laboratory facilities	Inexpensive upfront investment, costs decrease as the number of samples increases	Analysis at a fixed location with frequent sampling
<b>WYD Device</b>	Basic laboratory skills	Basic laboratory facilities needed for reagent preparation, unit can then be used in the field	Inexpensive upfront investment, costs decrease as the number of samples increases	Comparable to titration but slightly more user- and field-friendly and with a slightly lower precision
<b>Bioanalyt iCheck®</b>	None	No laboratory or reagents necessary, very user-friendly	High initial capital investment for unit, moderate fixed cost per sample analysis.	Analysis in the field where there is poor infrastructure and a lack of availability of reagents and laboratories

<sup>5</sup> 6 Davey machines X 10 MT X 8 hours per day X 22 days per month X 8 months (excluding the hot months of May-August when salt is not produced) = 84,480 MT. The annual national requirement is 350,000 MT per annum.

GAIN developed and deployed a QA/QC manual, which included standard operating procedures, protocols for sampling frequency and testing methods, and steps to remedy under-iodized salt. A follow up training in December 2014 was attended by 23 individuals from 7 factories/salt associations. Participants developed workplans for scaling up production and improving iodization quality by July 2015 and signed MOUs with GAIN to solidify their commitment.

This activity's success was evidenced by preliminary results of the 2014 National Micronutrient Survey, which estimated that 95.2% of households had access to iodized salt, exceeding the goal of 84%.<sup>6</sup> As the main drivers of fortification in Ethiopia at the time, a clear linkage can be made between the activities undertaken by GAIN at the industry level and the rapid increase in iodized salt coverage in only 3 years.

### Scale up & Delivery: Government-Level Regulatory Monitoring Systems Built

After several years of stagnated progress on salt iodization, the 2011 signing of mandatory legislation, the reactivation of the national USI coordination and technical committee and ongoing inputs from GAIN and partners reprioritized focus on the regulation and enforcement of salt iodization. FMHACA was assigned responsibility to enforce the new legislation and put robust licensing, monitoring, and enforcement measures in place. GAIN conducted a comprehensive review of regulatory monitoring activities and worked with FMHACA, the FMoH, and EPRI to create sustainable and effective implementation systems for the legislation and its regulatory mechanisms.

Identifying regulatory capacity gaps, GAIN recruited for a secondment of a quality management systems expert to assess regulatory systems and make recommendations for strengthening. FMHACA adopted many of these recommendations and worked to regulate iodized salt at critical control points along the process. One such recommendation was to establish checkpoints on the main road leading from salt production sites to the central part of the country to ensure all salt leaving production facilities was adequately iodized. Limited road and transportation networks around the major salt production sites allowed this method to work relatively well. GAIN also provided 47 WYD devices and 8 new Bioanalyt iCheck<sup>®</sup> devices for robust quantitative iodine analysis. FMHACA inspectors were trained on titration methods as well as methods using WYD and iCheck<sup>®</sup> devices along with their calibration through a series of training workshops.

In April 2014, GAIN – with FMHACA and government regulatory bodies involved in salt iodization – created an action plan. GAIN conducted a detailed assessment of FMHACA and jointly prioritized key activities for improving enforcement capacity. FMHACA allocated national budget amounts accordingly to these priorities and government bodies signed an MOU with GAIN to solidify their commitment. In April 2015, GAIN again met with FMHACA to review progress and continue to identify areas for improvement. GAIN proposed a two-staged approach to monitoring. Until adequate iodization capacity is built, FMHACA will assume a capacity building role, monitoring and providing feedback on how to improve production and internal QA/QC processes. In this way relationships between producers and FMHACA can be improved before penalizing action is taken during stage two, once the private sector has gained enough capacity to iodize. GAIN also made recommendations and is working to implement improvements including the following:

- Developing a set of documentation and reporting tools for use during FMHACA inspections to improve the flow of data to increase accountability;
- Identifying critical control points to simplify FMHACA's monitoring and minimize the number of inspection visits; and
- Registering salt producers to track production capacity, iodization progress, and inspection visits.

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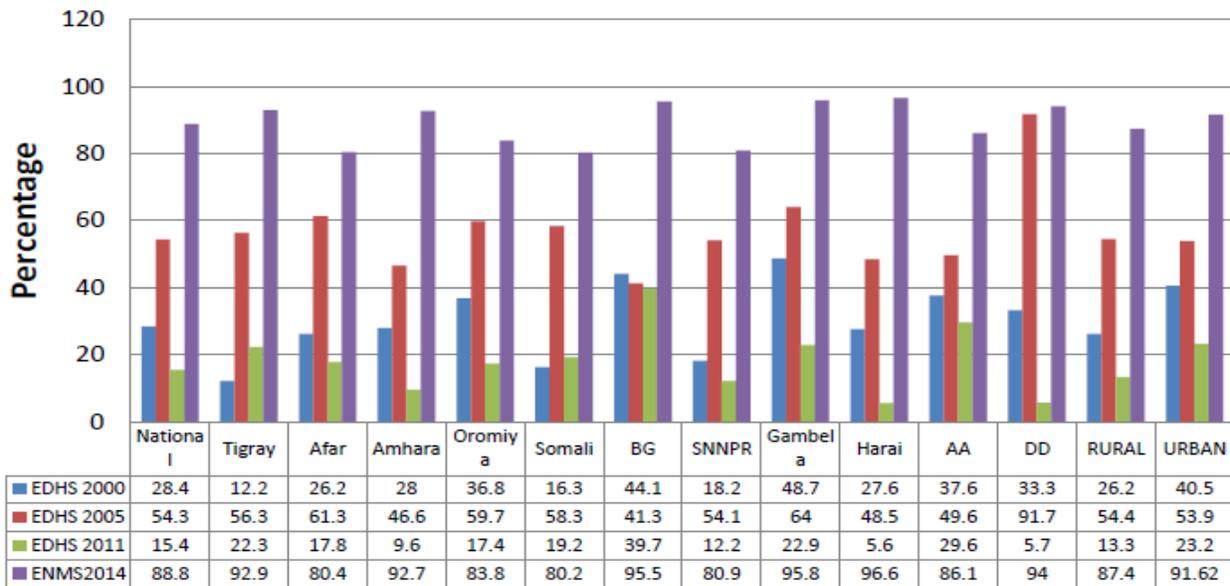
<sup>6</sup> Much of this increase is due to extensive use of manual knapsack sprayers at production sites, which produce inconsistently iodized salt. GAIN continues to work with industry to ensure they switch to more better methods using iodization machines.

While there is still much work to be done to build FMHACA’s regulatory monitoring capacity, clear successes can be attributable to GAIN’s work in this area, evidenced by the increase in adequately iodized salt from 15.4%<sup>7</sup> at the project’s baseline in 2009 to 42.7% as of 2014.

**Health Impact: Monitoring & Evaluation Processes Implemented and Impact Assessed**

GAIN provided consultative advice to the CDC and has supported Ethiopian medical and nutrition research institutes, such as EPHI to develop and undertake national surveys to monitor the impact of the national USI program. This has included inputs to questionnaires used to measure the coverage and quality of iodized salt at baseline (2008-2009) and endline (2014-2015). A summary of the key findings of various surveys on household access to iodized salt is indicated in Figure 2.

**Figure 2: Household iodated salt coverage from 2000 to 2014 in Ethiopia, by region.**



GAIN has worked closely with the CDC and EPHI to incorporate the iodine module into the National Nutrition Survey. The iodine module analyzes household salt samples using qualitative and quantitative tools at national and regional levels; determines UIE levels among women and school age children; and ascertains the knowledge, actions, and practices of consumers related to iodine deficiency and salt iodization. This module was first implemented in 2014 and will continue to be a part of national surveys to continue to monitor progress and identify gaps in coverage and quality. The 2014 survey is in the final stages, collecting household samples as well as biomarkers on urinary iodine concentration levels. GAIN also advised the research institutes on best practices for M&E based on its experience implementing its novel Fortification Assessment Coverage Tool (FACT), which encompasses elements of consumption, geography, and risk analysis to determine the effective reach and scale of iodized salt.

GAIN is currently working with EPHI and FMHACA to create responsive iodized salt tracking systems through inspections, market surveillance, and cross-sectional assessments so that bottlenecks can be identified and remedied efficiently in the interim periods between national surveys. The post market survey by FMHACA,

<sup>7</sup> From 2011 DHS Survey – 15.4% is for salt with any amount of iodine, but also taken as a maximum estimate of adequately iodized salt, rather than the adequately iodized salt estimate from the 2005 DHS, which used a different methodology.

currently underway, is expected to identify the types of salt that are most widely consumed and how well they meet national iodization standards.

The outcomes related to GAIN's work have been further validated through an independent cluster randomized trial undertaken in association with McGill University. Following mandatory fortification legislation, iodized salt was accessed early into the markets of half of the 60 study villages. Comparing with control villages, those children <36 months who had access to iodized salt had significantly higher UIE levels, cognitive and mental development levels, and physical growth.

GAIN will use these results as well as the data from the national micronutrient survey and FMHACA's monitoring to improve USI program design moving forward. GAIN's focus will be on improving the quality of iodized salt and ensuring long-term sustainability through strong and clear institutional structures, roles and responsibilities of USI and iodine nutrition in Ethiopia.

## Appendix 1: Summary Table of GAIN's Activities and Evidence of their Impact

Milestones	GAIN Intervention	Results	Evidence and Documentation
<b>Mandatory Fortification Legislation Enacted &amp; Appropriate Standard</b>	<ul style="list-style-type: none"> <li>• Contribution to legislation dialogue</li> <li>• Regulatory and industry landscape analysis</li> <li>• Advocacy by presenting in national TC meetings</li> <li>• Engagement &amp; support to the NTC</li> </ul>	<ul style="list-style-type: none"> <li>• Mandatory legislation adopted, February 2011</li> <li>• Improved industry acceptance</li> <li>• Sustainable development of salt iodization blueprint</li> </ul>	<ul style="list-style-type: none"> <li>• Legislative instruments in place</li> <li>• Minutes at FMOH meetings on iodine in 2008/2009/2010 outlining attendees and corresponding regulations</li> <li>• Speeches and presentations given to stakeholders</li> </ul>
<b>KIO<sub>3</sub> Needs Identified and Cost Recovery Mechanism Established</b>	<ul style="list-style-type: none"> <li>• KIO<sub>3</sub> needs, supply, and cost analysis</li> <li>• Design of KIO<sub>3</sub> procurement and cost recovery system</li> <li>• Advocacy with stakeholders for utilization</li> </ul>	<ul style="list-style-type: none"> <li>• Government purchase orders revised to reflect true needs</li> <li>• Expired KIO<sub>3</sub> reprocessed</li> <li>• Recommendations for cost recovery mechanism implemented</li> </ul>	<ul style="list-style-type: none"> <li>• Documented expiration of KIO<sub>3</sub> stock in country (email exchanges with FMOH)</li> <li>• Documented KIO<sub>3</sub> purchase history</li> <li>• Industry utilization reports and reports from FMOH</li> </ul>
<b>Industry Production Rapidly Increased and Internal QA/QC Improved</b>	<ul style="list-style-type: none"> <li>• Assessment, design, &amp; implementation of QA/QC systems</li> <li>• Iodization and laboratory equipment provided with training</li> </ul>	<ul style="list-style-type: none"> <li>• Increased coverage (4.2% to 95.2% with some iodine) and quality (15.4% to 42.7% adequately iodized) of iodized salt</li> <li>• Staff trained on use and maintenance of iodization and laboratory equipment</li> </ul>	<ul style="list-style-type: none"> <li>• Training reports</li> <li>• Case studies demonstrating examples of outcomes after QA/QC support</li> </ul>
<b>Government Level Regulatory Monitoring Systems Built</b>	<ul style="list-style-type: none"> <li>• Assessment, design, &amp; implementation of regulatory systems and capacity improvements</li> <li>• Laboratory equipment provided with training</li> </ul>	<ul style="list-style-type: none"> <li>• Increased monitoring and enforcement of iodized salt</li> <li>• Regulatory inspectors trained on laboratory techniques</li> </ul>	<ul style="list-style-type: none"> <li>• Training reports</li> <li>• Government stated commitment/MOUs for strengthening enforcement</li> </ul>
<b>Monitoring and Evaluation Processes Implemented and Impact Assessed</b>	<ul style="list-style-type: none"> <li>• M&amp;E process development and advising for national survey design</li> <li>• Gap assessment for next steps and identifying bottlenecks</li> </ul>	<ul style="list-style-type: none"> <li>• Iodine modules adapted for National Nutrition Survey</li> <li>• Impact validated via independent randomly controlled cluster trial</li> </ul>	<ul style="list-style-type: none"> <li>• Baseline and endline methodologies and data</li> <li>• Evidence of government commitment/MOUs with FMOH and FMHACA for continued monitoring and improvement</li> <li>• Peer-reviewed RCT demonstrating impact of salt iodization</li> </ul>