IDD ELIMINATION IN QVEMO-KARTLI REGION

FINAL DRAFT REPORT

(RFA # B-GEO-2008-003)

Prepared by:
Nino Sekhniashvili, Tea Pkhakadze, Irina Madichi

Medinvest
Tbilisi 2008

Table of Contents

Abbreviations and Acronyms

DBS	Dried Blood Spots
GDP	Gross Domestic Product
GNI	Gross National Income
GoG	Government of Georgia
IDD	Iodine Deficiency Disorders
RFA	Request for Application
Tg	Thyroglobulin
TSH	Thyroid Stimulating Hormone
UI	Urinary Iodine
USI	Universal Salt Iodization
VRF	Vishnevskaya-Rostropovich Foundation
WHO	World Health Organization

Acknowledgments

The Medinvest project implementation team is grateful to the UNICEF Georgia office for giving us the opportunity to undertake this assignment. We are thankful to Dr. Tako Ugulava, UNICEF Georgia Health Project Officer for the guidance and insights offered throughout the project implementation.

We are thankful to Vishnevskaya-Rostropovich Foundation and especially to Mr. George Gvinepadze, the Executive Director of VRF and Mrs. Maka Gumberidze, Project Officer VRF, who provided us with invaluable data that informed the project with valuable inputs.

We would like to extend our thanks to all individuals who agreed to be surveyed and supported us with their advice and comments, and informed the report with their knowledge and valuable inputs.

Introduction and Responsibility

By agreement dated July 16, 2008, UNICEF Georgia office engaged MEDINVEST to implement the IDD Elimination Project in Qvemo-Kartli region of Georgia.

Although UNICEF commissioned this report, the UNICEF bears no responsibility for and is not in any way committed to the views and recommendations expressed herein; these are the sole responsibility of the authors.

Goals and Objectives of the Study

The **main goal of the "IDD elimination project in Qvemo-Kartli Region"** was to contribute to the prevention of IDD in Georgia through development and implementation of a comprehensive multi-component model for IDD control that addresses problems of the critical groups for IDD control (such as newborns, school-age children and pregnant women), is replicable/adaptable to the country context, and allows taking corrective measures for IDD elimination when necessary.

The project aimed at achieving the following two specific objectives:

Objective 1 – Development and implementation of the model for IDD control that ensures adequate monitoring of the specific intervention effects on the iodine status of the population through: collecting and analysis of available data on the iodine status of school-age children, neonates and pregnant women;

Objective 2 – Strengthened capacity of the stakeholders and policy makers in monitoring IDD elimination process through provision of evidence based information to the stakeholders and policy makers on the most effective mechanisms of IDD control and costs related to the implementation of these mechanisms.

Expected outcomes of the project implementation

The MEDINVEST was expected to:

- Design and implement the project to assess the impact of IDD elimination activities implemented in the country utilizing the IDD control impact indicators;
- propose the cost-effective IDD control model that is replicable throughout the country;
- produce comprehensive report covering all aspects stated above and deliver to UNICEF Georgia on or before January 1, 2009

Executive Summary

According to the agreement dated July 19, 2008 the MEDINVEST started implementation of IDD elimination project in Qvemo-Kartli region, aiming at designing of a comprehensive and replicable model for controlling IDD and implementation of this model in Qvemo-Kartli Region.

Methodology utilized during the project implementation rests on the available body of evidence related to the IDD control projects and programs carried out in Georgia and is a result of extensive literature review related to the most important contextual factors for IDD elimination, that were identified and researched during the project implementation: a) salt iodization programs implemented in Georgia and b) available data on iodine status of the Georgian population and particularly three most critical groups for IDD control – neonates, school-age children and women of reproductive age. Data obtained through the sentinel survey, carried out within the project implementation framework, was complemented with the analysis of data provided in the available reports.

The project was implemented during 22 weeks in three implementation phases: I - preparatory phase; II - survey implementation phase and III - evaluation and results dissemination phase. The phase I was devoted to the data collection for design of component A (neonates) of the IDD model as well as preparatory work for sentinel survey implementation. During phase II sentinel survey was carried out among the school-age children and pregnant women, for collection of data on iodine status among these two critical groups for IDD control and design of components B and C of the IDD control model; data entry and preparation of the database for analysis and phase III – to the analysis of survey results and finalizing design and costing of IDD control model, dissemination of results among stakeholders; elaboration of specific recommendations for policy makers and key stakeholders for replication of IDD controlling model in other parts of the country for IDD monitoring and final report writing.

The results of the IDD control model implementation indicated insufficient iodine intake among all researched groups.

Analysis of the data[1] on newborn TSH tests revealed that 7 out of 1,218 cases tested during September – November in Qvemo-Kartli region, **detected elevated TSH[2] and thus detected iodine deficiency among the neonates**. This number is rather high and calls for immediate attention, considering that in iodine sufficient countries, sporadic congenital hypothyroidism occurs in approximately one of 4,000 births.

Median urinary iodine concentration in school-aged children was 90µg/l. This rate is corresponding to the **Mild Iodine Deficiency** resulted from insufficient iodine intake and/or lack of awareness on the use of iodized salt.

Median urinary iodine concentration detected in the population of pregnant women (94µg/l) is far below the sufficient range[3]. Similarly to the school-age children, this could

[1] Data was kindly provided by the Vishnevskaya-Rostropovich Foundation
[2] Above 5mlU/l in whole blood
[3] median urinary iodine concentration in the pregnant women population should be within the range 150-249 µg /l

be explained by insufficient iodine intake or lack of knowledge on the proper storage and use of iodized salt.

Depending on the IDD elimination strategies that can be applied in the future, current problems related to the IDD elimination and sustainability of achieved results could be reduced or effectively addressed. During design of the corrective interventions, for addressing existing problems, several key factors that have most impact on the success of IDD elimination, should be taken into account. These factors are: a) quality of salt iodization consumed by the population and b) population's awareness on the use of iodized salt and importance of iodine.

In addition to the IDD control model design and implementation, the MEDINVEST team carried out costing of the control model to define the costs and resources to the IDD model replication in other parts of the country.

All costs related to the model implementation were grouped into the two sub-groups: a) fixed costs and b) variable costs. Survey sample size and thus, the number of tests to be performed was identified as the key cost variable that had the most impact on cost composition. However, due to the relatively similar population size in all regions of Georgia (except Tbilisi), it was assumed that the IDD model implementation costs would not have significant variations depending on the region of implementation. Details of the IDD costing are represented in the respective section of this report.

Background

Country Profile

Georgia is a country with an approximate area of 70 sq. km. situated in the central and western parts of Caucasus. The country borders Armenia, Azerbaijan, Russian Federation and Turkey. In 1991 Georgia adopted a declaration on independence and on July 1992, the country became the 179th Member of the United Nations.

In early 2004, after the "Rose Revolution" Georgia welcomed major changes in its political situation. In economic terms, Georgia is one of the poorest countries of the former Soviet Union. It has emerged from a worrying economic situation, thanks in particular to a debt relief agreement that enabled it to finance external trade. GDP has been increasing since 2000; growth of about 10% was achieved in 2004 and this rate was maintained in 2005 and 2006. Inflation is under control and the currency is stable. Georgia's main economic activities include: the cultivation of agricultural products, such as citrus fruits, tea, hazelnuts and grapes; mining of manganese and copper; and the production of alcoholic and non-alcoholic beverages, metals machinery and chemicals by a relatively small industrial sector.

Total population of the country is 4.65[4] million, and the sex ratio (men per hundred women) is 81. The proportion of population under the age of 15 years is 20.4% and the proportion of population above the age of 65 years is 14.15 %. Percent of population residing in the rural areas of the country is 48.8. The literacy rate is 100% for men and 98% for women.

The latest data on health and socioeconomic indicators are as listed below:

- Live births per 1,000 population – 10.7 (2005)
- Total fertility rate – 1.4 (2005)
- Live expectancy at birth – 73.1
- Infant mortality rate per 1,000 live births – 19.7 (2005)
- Maternal mortality rate per 100,000 live births – 45.3
- Total expenditure on health as a % of GDP (2005) – 5.8
- Gross National Income (GNI) per capita – 1040
- Adults (15+ years) literacy rate (%) – 100[5]

Epidemiology of IDD in Georgia

Iodine deficiency, through its effects on the developing brain, has condemned millions of people to a life of few prospects and continued underdevelopment. On a worldwide basis, iodine deficiency is the single, most important, preventable cause of brain damage.

Historically, iodine deficiency has been a serious problem in Georgia as the country's soil and water are poor by means of iodine content. Some regions are more affected than others, IDD[6] is endemic in Svaneti, Racha-Lechkhumi, Imereti, and in highland areas[7].

[4] 2002 Census Georgia
[5] Source – European Health for All Database (HFA-DB) accessed on December 15, 2008

The 1996 survey commissioned by the UNICEF and conducted among 30,000 school-age children, found iodine deficiency of various degrees in 64% percent of the surveyed population. Prevalence of goiter across the country varied from 54 to 78 percent. The entire territory of Georgia was affected, not only the endemic regions of traditionally high IDD prevalence. In 1997, IDD recorded in medical institutions affected 45% of children examined in endemic areas, including 4.2 percent of children under five.[8] In 1998, IDD was identified in 49% of children under 16 years-of-age in endemic areas, including 4.3 percent under five.

Considering existing experiences in other countries, UNICEF-Georgia continuously advocated the universal salt iodization and strongly addressed this issue to the GoG. As a result following legislative changes were made for IDD elimination in country: two presidential decrees of July and October 1996, making an iodization of salt mandatory and establishing the IDD Coordination Council at the parliament; tax exemption policy for import of iodized salt in 1997, elaboration of national standards for iodized salt in 1998 and finally, the breakthrough law on "Prevention of iodine, other microelement and vitamin deficiencies", banning the import of non-iodized salt – passed in February 2005.

UNICEF has also provided the four salt testing laboratories to the state Sanitary Department of Georgia. In addition, UNICEF has financed participation of the representatives of the Georgian Government in the IDD Conference held in Munich in 1997, supported a multi disciplinary management course on IDD and salt iodization in Tbilisi, in June 1998. The National Communication Campaign on IDD has been carried out by the National IDD Committee in fall, 1998. According to the study, supported by the UNICEF and following awareness campaign, advocacy efforts have been shown to be successful in significantly increasing the IDD problem awareness.

In order to uncover existing barriers to Universal Salt Iodization (USI) and identify the ways for their elimination, UNICEF conducted the salt situation analysis in the country in April of 1999. Also, UNICEF-Georgia facilitated participation of the governmental officials[9] in the Salt Producers meeting held in Kiev. The Goal of this meeting was to identify the ways for the Universal Salt Iodization (of all food grade salt-table salt and for the food industry) by the year 2000. In 1999 the UNICEF-Georgia supported establishment of the regional IDD committees aiming at the capacity building of the local authorities involved in the monitoring and quality assurance of the Iodized Salt.

In November 2005, the GoG and UNICEF carried out a national survey for measuring impact of IDD elimination efforts and recent iodization legislation changes. The survey results were also used to determine whether Georgia met criteria for sustainable IDD elimination certification by the World Health Organization[10]. According to the survey results, in part because of the national IDD elimination efforts and the 2005 law, Georgia

[6] IDD – Iodine Deficiency Disorders
[7] Children and Women in Georgia: A Situational Analysis, UNICEF, 2003
[8] MoLHSA, 1997
[9] State Sanitary Surveillance Department
[10] This certification requires that >90% of households use adequately iodized salt (>15 ppm) and that <50% of the surveyed population should have UIE levels below 100 mcg/L, including less than 20% below 50 mcg/L.

has achieved Universal Salt Iodization and met the primary WHO criteria for IDD elimination[11].

Survey found dramatic improvements, both in the prevalence of low UIE[12] among Georgian children (80% in 1998 and 4.4% in 2005), as well as in the percentage of Georgian households using salt with adequate iodine (8% in 1999, 67% in 2003 and 90.6% in 2005). Only 4.4 percent of analyzed urinary samples had a low UIE and goiter prevalence among children decreased from 39% in 2003 to 32.4% in 2005.

In 2007, GoG failed to meet its commitments towards prevention of IDD, due to the overall reform of the Georgia's health care sector. In the fall of 2006, the GoG initiated the public health system reform. As the result of reform, the local Public Health Centers were abolished and the Public Health Department and the National Center for Disease Control merged into an Entity of Public Law – the National Center for Disease Control and Public Health. Government financing for public health programs has been drastically reduced and IDD prevention program, alongside with the many other PH programs was cancelled. Furthermore, 4 IDD regional centers were closed down[13] as well.

Currently, the only ongoing program related to IDD prevention in Georgia is *Newborn-Screening Project to Detect Congenital Hypothyroidism*, funded by Vishnevskaya-Rostropovich Foundation-Georgia. The project aims at prevention of the permanent health impairments of mental retardation and growth failure caused by late detection and late treatment of this disorder. Recognizing the importance of national screening for congenital hypothyroidism, the GoG has made a commitment to finance 50% of the project cost in 2009 and provide full financing starting from 2010.

Project Implementation

The project was implemented during 22 weeks by the three implementation phases: phase I – preparatory phase, phase II – survey implementation and data analysis and phase III - evaluation and result dissemination phase.

Phase I – preparatory phase – was devoted to the data collection for design of component A (neonates) of the IDD model; preparatory work for sentinel survey implementation among school-age children and pregnant women. Duration of the phase I was six weeks.

The following is the list of activities implemented during this phase:

1. Design of the multi-component model for IDD control through:
   - 1.1. Identification of available sources and collection of necessary data for development and costing of component – A (neonates).
   - 1.2. Preparatory work for the implementation of the sentinel survey to collect the data on iodine status among the school-age children and pregnant women (components B and C);

[11] *"Elimination of Iodine Deficiency in Republic of Georgia: Overview of 2005 National Survey"*- WHO, UNICEF, 2005
[12] below 100 mcg/L
[13] In 1998, centers were established in Kutaisi, Batumi, Zugdidi and Telavi.

- Development of survey methodology;
- Identification of survey groups;
- Development of framework for data analysis;

Phase II – survey implementation – was implemented during 12 weeks and included: collection of data on iodine status among the school-age children and pregnant women (components B and C), data entry and preparation of the database for analysis:

The following activities have been implemented during this phase:

2.1. Collection of test samples among the survey target groups;
2.2. Collection of demographic information from the surveyed population;
2.3. Computerization of the obtained data;

Phase III – evaluation and result dissemination phase – was devoted to the, analysis of survey results and finalizing design and costing of IDD control model, dissemination of results among stakeholders; elaboration of specific recommendations for policy makers and key stakeholders for replication of IDD controlling model in other parts of the country for IDD monitoring and final report writing. The phase III was implemented over the period of four weeks.

During the phase III project implementation team:

3.1. Analysis of survey results;
3.2. Costing of services and activities related to the implementation of components B and C;
3.3. Finalization of IDD control model design;
3.4. Based on the evaluation of results produced by the project elaboration of evidence based recommendations for the stakeholders;
3.5. Results dissemination workshop for sharing project implementation results with the stakeholders and policy makers;
3.6. Incorporation of the feedback obtained from the stakeholders and policy makers through the result dissemination workshop into the final report on project implementation;
3.7. Considering the feedback obtained from stakeholders and policy makers, produce final specific recommendations for replication of the model in other parts of the country;

IDD Model Design and Survey Methodology

IDD Model Design

Methodology utilized for the project implementation aimed at design and implementation of multi-component IDD control model for adequate monitoring of the results of IDD elimination efforts among **three main target groups for IDD surveillance – neonates, school-age children and pregnant women**.

The general approach for development and implementation of IDD control model was based on vision of eventually linking the model with the State regulated statutory system and development of platform for the model replication in other parts of the country. In order to achieve stated objective the project planned to obtain the evidence and experience through model implementation in Qvemo-Kartli region and provide evidence-based recommendations to the key decision makers.

The model design considered a) development of the custom-tailored component for each critical group – neonates, school-age children and pregnant women and b) costing of the IDD control model.

In general, implementation of this project was the first attempt to develop the relatively inexpensive, universal tool for addressing needs of the most critical groups of IDD surveillance and most importantly, address the needs of pregnant women, **the only group in Georgia that has never been researched.**

According to the methodology utilized for model implementation available data was used for development of component – A (newborns). In our case the data was kindly provided by the ***Vishnevskaya – Rostropovich Foundation Georgia****,* that is implementing *"Newborn-Screening Project to Detect Congenital Hypothyroidism"*.

For design and development of the components B and C (school-age children, pregnant women) data was obtained through the sentinel survey carried out among the relevant groups in Qvemo-Kartli region.

The overall rationale behind the project implementation methodology was to produce results that would inform about the general trends of IDD elimination in country and the iodine status of the main groups of the population. I was assumed that information about the current iodine status, costs and benefits of efficient IDD control would greatly contribute into capacity strengthening of country's policy makers for informed decision-making to address existing problems in IDD control.

Survey Methodology

According to the RFA requirements the data among the school-age children and pregnant women was obtained through the **Sentinel survey**.

According to the survey methodology and based on the type of the population targeted by the survey, the sentinel sites were established in public schools and women's consultation. Selection of the sentinel sites was carried out based on the specific criteria elaborated by the project implementation team.

Sampling period

The survey was undertaken between September and November 2008. Preparatory work for survey implementation started in the second half of July and was carried out within 6 weeks.

Collection of testing samples for pregnant women began on 1st of September and ended by the end of November, a period not exceeding 12 weeks.

Although it was planned to start collection of test samples among the school-age children at the same time, collection was postponed due to the political developments in the country[14] that caused one month delay of beginning of school calendar year. Thus, collection of the samples started on October 1 and lasted 10 weeks.

All collected samples were delivered to Tbilisi to the laboratories of the National Center of Nutrition and Medinvest.

Selection of indicators

In response to the technical requirements of the original RFA[15] the project was focused on **Impact Indicators** to monitor and evaluate impact of IDD elimination efforts on the iodine status of target population and assess magnitude of IDD as a public health problem. According to the WHO recommendations[16], the four main indicators of impact are used for assessing the impact of IDD elimination on the population: urinary iodine (UI), assessment of thyroid size (by palpation or ultrasound research), thyroid stimulating hormone (TSH) and thyroglobulin (Tg).

The recommended impact indicators were carefully reviewed to select the most appropriate indicator for the study implementation.

Thyroid Size – assessment of thyroid size by palpation is the time-honored method, however, because of the lack of sensitivity to acute changes in iodine intake, this method is of limited usefulness in assessing the impact of programs once salt iodization has commenced.

Thyroid Stimulating Hormone (THS) – The pituitary secretes TSH in response to circulating levels of T_4 concentrations are low, and falls when they are high. Iodine deficiency lowers circulating T_4 and raises the serum TSH, so iodine-deficient populations generally have higher serum TSH concentrations than do iodine-sufficient groups.

However, the difference is not significant and serious overlap occurs between individual TSH values. Therefore, the blood TSH concentration in school-age children and adults is not a practical marker for iodine deficiency, and its routine use among the school-age children and adults is not recommended[11].

Thyroglobulin (Tg) – is a thyroid protein that is precursor in the synthesis of thyroid hormone, and small amounts of Tg can be detected in the blood of all healthy individuals. The thyroid hyperplasia and goiter characteristic of iodine deficiency increases serum Tg levels, and in this setting serum Tg reflects iodine nutrition over a period of months or years. This contrasts to urinary iodine concentration, which assesses more immediate iodine intake. A serum Tg monitoring has recently been adapted for use on dried whole blood spots (DBS). Measurement of DBS Tg in school-age children is a sensitive indicator of iodine status in a population and can be used to monitor improving thyroid function after iodine repletion. DBS Tg correlates well with other indicators for monitoring iodine status in population – urinary iodine and thyroid size. It can be used in

[14] Due to the august Russian aggression against Georgia, all public schools of Georgia started new calendar year in from the month of October.
[15] RFA - No: B-Geo-2008-03
[16] World Health Organization, 2007 - *Assessment of iodine deficiency disorders and monitoring their elimination. "A guide for Programme Managers, third edition"*

conjunction with urinary iodine to measure recent iodine intake, and thyroid volume to assess long-term anatomic response[11].

Urinary Iodine – the measurement of the iodine concentration in urine is the recommended way to assess the current iodine status of population. Most of the iodine ingested is excreted in the urine, resulting in urinary iodine concentration being a good indicator of iodine intake. At the individual level, the excretion of iodine varies throughout the day due to hydration and iodine intake, therefore a single casual specimen is not useful in determining the iodine intake of an individual. As the population level, the median UI concentration will be representative of the population's recent iodine intake. For assessing the iodine status of a population, the collection of urine specimens from individuals over a 24-hour period is not necessary. Also unnecessary is relating iodine excretion to creatinine levels.

Considering context of study implementation, biological features, implementation feasibility and cost-effectiveness of all recommended impact indicators, **the urinary iodine was selected as a primary indicator for study implementation.** This indicator is reflective of the current intake of iodine in diet, and thus was completely addressing project implementation needs and enabling project implementation team to assess of the iodine status of the target population in Qvemo-Kartli region of Georgia.

The median value for the sampled population is the most commonly assessed indicator. Urinary iodine values from populations are usually not normally distributed. **Therefore, the median rather than the mean should be used as the measure of central tendency.** Likewise, percentiles rather than standard deviations should be used as measures of spread[17].

In children and non-pregnant women, median urinary iodine concentrations of between 100 µg/l and 299 µg /l define a population which has no iodine deficiency[18]. In addition, not more than 20% of samples should be below 50µg/l. In non-pregnant, non-lactating women, a urinary iodine concentration of 100µg/l corresponds roughly to a daily iodine intake of about 150 µg under steady-state conditions.

During pregnancy, median urinary iodine concentrations of between 150µg/l and 249µg/l define a population which has no iodine deficiency.

The upper limit of the recommended range for these populations reflects concern about the risk of hyperthyroidism when high levels are introduced to a previously endemic population.

Urinary iodine concentration is currently the most practical biochemical marker for iodine nutrition when carried out with appropriate technology and sampling[17].

Sample population

The sentinel survey was targeted at the school–age children of 6-12 years, both male and female and pregnant women aged 15-44 years attending antenatal clinics during the study period.

[17] World Health Organization, 2007 - *Assessment of iodine deficiency disorders and monitoring their elimination. "A guide for Programme Managers, third edition"*
[18] By definition, when the median is 100 µg/l, at least 50% of the samples will be lower than 100 µg/l

Site Selection Criteria

The logic of sentinel site selection was dictated by the type of survey target groups. Since, the data was to be obtained on iodine status of the school–age children and pregnant women, therefore, the women's consultations and public schools were identified as the sentinel sites.

The following inclusion criteria were elaborated for selection of sentinel site to obtain data on iodine status of pregnant women:

- The site provides health care services to relatively large number of individuals per month, so that an adequate sample size can be obtained in the predetermined period and thus, the sites that consistently (for 3 years) fail to produce the minimum number of clients were excluded from further participation in the survey;
- The site provides services to the selected sentinel population (antenatal care services);
- Urine samples are drawn from patients/clients as part of routine services provided at the site;
- Site staff are competent and willing to participate in sentinel surveillance;
- Sites from where the transportation of specimen to the testing laboratory in Tbilisi was feasible.

Based on these criteria, the women's consultation # 2 in Rustavi was selected as the survey sentinel site. During selection of this site the following aspects were taken into account: the facility a) has the highest catching area in the region, b) is quite popular among the local population due to the quality services provided and c) facility is used as the referral site for the whole region.

For carrying out survey among the school – age children, the public schools with the highest enrollment rate were identified as the potential sentinel sites.

The inclusion criteria for schools were as follows:

- Public (secondary) schools;
- Schools attended by the students 6-12 years of age (this age group corresponds to 1-7 grades of the public secondary schools);
- Schools with the highest enrollment rate in the region;

As result of selection, sentinel sites were established at the three public schools of Rustavi. Considering that the total number of schools in Rustavi is 30, results of the survey would represent 10% of schools in the city, which seemed to be sufficient number.

Inclusion/Eligibility criteria for sampling

Following inclusion criteria was elaborated for selection of women:

- The pregnant women willing to participate in the survey;
- The woman aged 15-49;
- The pregnancy is confirmed by a health care provider on site;
- The pregnant women attending the women's consultation during the survey period;

Inclusion criteria for children:

- School-age children (6-12 years of age);
- Students attending 1-7 grates in selected schools;

Sample size

Taking into consideration the number of population targeted by the survey, an estimate IDD prevalence in survey target population in Qvemo-Kartli region, the precision of relative error considered acceptable (5%) and the level of confidence (95%) desired, the minimum sample size of 361 for pregnant women and 378 for school-age children was deemed adequate.

Sampling scheme

For selection of pregnant women the consecutive sampling was used, consisting of sampling of every pregnant women attending sentinel site, that met inclusion criteria until the required sample size was obtained or the sampling period was over.

The school students were selected among the 1-7 grade students (6-12 years of age). Sampling group in each site consisted of 126 students.

Specimen and data collection

All women, regardless of eligibility, were offered the opportunity to be screened and treated for IDD as part of routine antenatal care.

Incoming women during the survey period were first screened to ensure that the eligibility criteria were met. For those women who were eligible, initial demographic information was recorded in the data collection form. The demographic data for each eligible woman included – age, pregnancy period and contact information.

Total number of urine samples obtained from each grade of each school was 18. Therefore, total number of samples obtained for each grade was 54 and the collected samples were evenly representing all students between 6-12 years of age.

Laboratory methods

All urine tests were conducted using Ammonium Persulfate Method (Ammonium Persulfate digestion with spectrophotometric detection of Sandell-Kolthoff reaction).

Quality assurance

The following measures were adopted to ensuring accurate, reliable and reproducible results:

- Engagement of qualified and experienced laboratory technicians who were currently practicing at the laboratories;
- Appropriate transportation and storage of samples;
- Retesting of all samples with doubtful results;
- Strict adherence to the Standard Operating Procedures and protocols;

Survey management

Survey Management was provided by the Medinvest survey implementation team, led by the Senior Technical Expert. The survey implementation team was meeting regularly on a bi-weekly basis to discuss survey implementation progress and take major decisions on the implementation process.

Data management

Data forms were checked for completeness, obvious errors and inconsistencies to identify any data quality errors. Data was entered and analyzed in MS Excel computer software. Specific measures were taken to ensure that data entry was accurate. Validation of entered data was done using double data entry. Frequency tables were generated for all variables in order to further examine whether there were any unusual entries.

Study Limitations

In general, the limitation of sentinel surveillance is the fact that surveyed population may not be representative of the whole population in the region. Women attending women's consultations during pregnancy may not be representative of pregnant women in general population since the latter include those who are not referring to the medical facilities at all.

Sentinel sites were purposely selected on the basis of specific criteria and therefore may not be representative of all health facilities or educational institutions (public schools). However, considering the main goal of the study to assess the existing TREND in IDD elimination and produce recommendations for implementing corrective measures for ensuring IDD control among the population, the results produced by the study seem to be sufficient for analyzing existing situation and elaborating precise recommendations.

Results

The analysis of data obtained during IDD control model implementation indicated insufficient iodine intake among all researched groups.

Newborns

Assessment of IDD and iodine status among the newborns was carried out through the analysis of data provided by the Vishnevskaya-Rostropovich Foundation. According to this data, during the period September – November, in total 1,218 TSH tests were conducted among the newborns from Qvemo-Kartli region within the ***"Newborn-Screening Project to Detect Congenital Hypothyroidism"***. In 7 cases out 1,218 – evaluated TSH was detected, reflecting existence of the iodine deficiency among the screened newborns. Considering that in iodine sufficient countries, sporadic congenital hypothyroidism occurs in approximately one of 4,000 births, existing rate in Georgia is obviously high and calls to immediate attention.

School-age population

Median urinary iodine concentration in the sample of 378 school-aged children was equal to 90µg/l. This rate is corresponding to the **Mild Iodine Deficiency** that might be a result of insufficient iodine intake or the inadequate iodization of salt consumed by target group (see table 3).

Table 1 – Summary results on urinary iodine data for sample of school-age children

Number	378
Median	**90**
20th percentile (P20)	76.4
80th percentile (P80)	301.8
Distribution	
0-49	0.53%
50-99µg/l	70.63%
100-149µg/l	28.84%
150-199µg/l	0.00%

Pregnant women

Median urinary iodine concentration detected in the sample of pregnant women was – 94µg/l which is far below of the sufficient range (see table 4). Similarly to the school-age children, this finding also could be explained as the result of insufficient iodine intake and/or inadequate iodization of the consumed salt.

Details of analysis of a sample of pregnant women are represented in the table 2

Table 2 – summary results of urinary iodine data for sample of pregnant women

Number	361
Median	**94**
20th percentile (P20)	83
80th percentile (P80)	106.2
Distribution	
0-49	0.8%
50-100µg/l	68.4%
100-149µg/l	30.7%
150-199µg/l	0.00%
200-249µg/l	0.00%
250-349µg/l	0.00%

Table 3 - Epidemiological criteria for assessing iodine nutrition based on median urinary iodine concentrations of school-age children (>6 years)[19,20]

MEDIAN URINARY IODINE	IODINE INTAKE	IODINE STATUS
≤ 20	Insufficient	Severe iodine deficiency
20-49	Insufficient	Moderate iodine deficiency
50-99	Insufficient	Mild iodine deficiency
100-199	Adequate	Adequate iodine nutrition
200-299	Above requirements	Likely to provide adequate intake for pregnant/lactating women, but may pose a slight risk of more than adequate intake in the overall population
≥ 300	Excessive	Risk of adverse health consequences (iodine-induced hyperthyroidism, autoimmune thyroid diseases)

Table 4 – Epidemiological criteria for assessing iodine nutrition based on median or range in urinary iodine concentrations of pregnant women[21,21]

POPULATION GROUP	MEDIAN URINARY IODINE CONCENTRATION (µg/l)	IODINE INTAKE
Pregnant Women	< 150	Insufficient
	150 -249	Adequate
	250 – 499	Above requirements
	≥ 500	Excessive[22]

IDD control model costing

During the costing of IDD model implementation it was assumed that sufficient time for implementation of all activities for IDD model implementation equals to 7 moths, out of which two weeks will be devoted to the survey preparatory work, 6 moths – to the survey implementation and the remaining two weeks to the data analysis, report writing and result dissemination.

All costs related to the IDD model implementation could be grouped in two sub-groups: a) fixed costs – the costs that will remain unchangeable for any region/part of the country, as these costs are mainly related to the project management, technical assistance, administration, operations and etc. and b) variable costs that might vary depending on the survey sample size i.e. the number of tests that have to be performed during the project implementation. The key variable cost of IDD model implementation is imposed by the number of tests that have to be performed during the study. However, considering that the population size is relatively similar in all regions of Georgia (except for Tbilisi), it can be

[19] Applies to adults, but not to pregnant and lactating women

[20] World Health Organization, 2007 - *Assessment of iodine deficiency disorders and monitoring their elimination. "A guide for Programme Managers, third edition"*

[21] For lactating women and children < 2 years of age a median urinary iodine concentration of 100 mg/l can be used to define adequate iodine intake, but no other categories of iodine intake are defined. Although, lactating women have the same requirement as pregnant women, the median urinary iodine is lower because iodine is excreted in breast milk.

[22] Term "excessive" means in excess of the amount required to prevent and control iodine deficiency

assumed that overall cost for the project implementation will not vary significantly from region to region.

The results of costing of IDD control model implementation is following:

Fixed costs equal to 77,483 GEL and the variable costs to – 19,655 GEL. Therefore, in total approximately 97,138 GEL is required for implementation of IDD control model which equals to $58,872[23].

Table 5 Results of IDD Control Model Costing

Fixed Costs				
Management, Administration, TA				50,533
Operational Costs				23,450
Result Dissemination				3,500
Total Fixed Costs				**77,483**

Variable Costs				
Direct Labor Costs and Goods				**19,655**

Total Cost	**97,138**

Conclusions and recommendations

Conclusions

The conclusions and recommendations presented in this section were based on the results of the project implementation and key findings of the sentinel survey.

The key findings of project implementation indicated insufficient iodine intake among all researched groups, however the effect of IDD elimination efforts made in the country is obvious, since there were no severe cases detected during the study.

Median urinary iodine in school-aged children indicated **Mild Iodine Deficiency** that most likely results from insufficient iodine intake. **Median urinary iodine concentration detected in the sample of pregnant women was below the sufficient range[24],** which also could be explained as the result of **insufficient iodine intake and/or lack of knowledge on the use of iodized salt**.

Analysis of the data[25] on newborn TSH tests carried out within the **"Newborn-Screening Project to Detect Congenital Hypothyroidism"**, implemented by the VRF, showed that 7 out of 1,218 cases tested during September – November in Qvemo-Kartli region, **revealed elevated TSH[26] corresponding to the existence of iodine deficiency among the neonates**. This number is rather high and calls to immediate attention, considering that in iodine sufficient countries, sporadic congenital hypothyroidism occurs in approximately one of 4,000 births.

[23] Exchange rate - $ 1 US – 1.65 GEL
[24] Median urinary iodine concentration in the pregnant women population should be within the range 150-249 mg/l
[25] Data was kindly provided by the Vishnevskaya-Rostropovich Foundation
[26] Above 5mlU/l in whole blood

There are several important factors that have the most impact on the IDD elimination. These factors are:

- Quality of salt iodization consumed by the population;
- Population's awareness on the IMPORTANCE of iodine and USE of iodized salt.

Considering these factors the only logical explanations could be that the population consumes inadequately iodized salt and/or there's a lack of awareness in population on the use of iodized salt and importance of iodine.

Recommendations

For addressing existing problems, it is recommended to devote significant efforts in various parts/regions of the country to planning and implementation of following corrective measures for ensuring sustainability of IDD elimination achievements:

1. Implement the IDD control multi-component model in other regions of the country. The main purpose of model implementation is to:
    a. assure the elimination of IDD is being sustained in a given region; or
    b. detect existing problems related to the IDD elimination in the region and contribute to the evidence based policy making process for planning and implementation of relevant interventions.
2. It is recommended to implement IDD control model in every three-five years in the high risk areas for IDD (such as Svaneti, Racha-Lechkhumi, Imereti and other highland areas of Georgia);
3. Ensure availability of financing for IDD model implementation in the regions of Georgia, through securing budget allocations in the relevant budgets (State, regional, municipal and etc.);
4. For ensuring consumption of adequately iodized salt by the population, carry out salt iodization survey in the IDD model implementation area/region;
5. Based on the findings of IDD model implementation and salt iodization survey, plan and implement IEC campaign among the population to increase population's awareness on IDD related problems. Include information on the importance of iodine and the use of iodized salt, within educational curricula.