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NATIONAL INSTITUTE OF HEALTH

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PILOT IMPLEMENTATION OF USI FORTIMAS METHODOLOGY FOR ASSESSMENT AND TRACKING EFFECTIVE COVERAGE OF THE NATIONAL SALT IODIZATION PROGRAM AND IODINE STATUS OF PREGNANT WOMEN IN THE REPUBLIC OF ARMENIA

TECHNICAL REPORT

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CONTENT

ABSTRACT

To enable public and private sector stakeholders of the national salt iodization program in Armenia to be able to confirm high population coverage of well iodized salt and the associated adequate iodine status of the population systematically and at a substantially lower cost than typical population-based representative surveys, the IGN supported the “pilot” implementation of the FORTIMAS (Fortification Monitoring and Surveillance) methodology, adapted to tracking “effective coverage” of iodized salt, in Armenia. Primary analysis of non-probabilistic data showed high (92%) household coverage of adequately iodized salt and optimum (175.3 µg/L) median urinary iodine concentration among 1st trimester pregnant women, across purposively selected sentinel sites. Secondary analysis of data on production, imports and distribution of iodized salt indicated consistently high expected and assessed population coverage of iodized salt during the past decade. The prevalence of neonatal TSH levels above 5 mUI/L (an indicator of iodine status among pregnant women) over past 12 years was less than 3% with a general trend of decreasing from 2.35% in 2017 to 1.39% in 2023.

The cost of implementation of the FORTIMAS approach as an initial round of “annual” iodized salt program monitoring and surveillance in Armenia, was only a fraction of that of a typical nationally representative salt iodization/population iodine status survey. Furthermore, because the overall framework of a potential “Armenia FORTIMAS System” has been developed under this project, it may be estimated that about 10 annual rounds of salt iodization program monitoring and surveillance may be carried out in Armenia into the future, at about the same cost as one nationally representative salt iodization program survey.

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Abbreviations and acronyms

In alphabetical order:

ASP – Avan Salt Plant
ANC - antenatal care
CJSC - closed joint-stock company
DHS Demographic and Health Survey
FSIB - Food Safety Inspection Body of the Republic of Armenia
ICCIDD International Council for Control of Iodine Deficiency Disorders
IDD – Iodine Deficiency Disorders
IGN – Iodine Global Network
MC – Medical Centre
MoH/RA - Ministry of Health of the Republic of Armenia
mUIC - median urinary iodine concentration
M&S - Monitoring and Surveillance
NCP - Neonatal Screening Program (at Arabkir MC)
NIH - National Institute of Health
NCDC - National Centre for Disease Control and Prevention
NWG - National Working Group
TSH – Thyroid-Stimulating Hormone
USI – Universal Salt Iodization
UNICEF - United Nations Children's Fund
WHO – World Health Organization

I. Introduction

Located in the South Caucasus, Armenia was historically affected by endemic goiter that was virtually eliminated in early 1970s as part of effective salt iodization strategy in the USSR. Iodine deficiency returned in 1991 when Armenia became independent after dissolution of the Soviet Union [1]. However, starting from 1999, production of iodized salt was resumed by sole national salt producer, Avan Salt Plant (ASP). By 1998, about 70% of households were using iodized salt. A Demographic and Health Survey (DHS) carried out in Armenia in 2000, found that although use of iodized salt at the household level had increased to 84% in the country overall with substantial variation by regions [2, 3]. In 2004, the government passed decree No. 353-N making production and importation of iodized salt mandatory as well as its use at household level and for food processing. More recently, in 2016, regulatory inspection and enforcement of the use of iodized salt in Armenia was established through a Joint Order (829-A and 74-A) of the Ministries of Health and Agriculture (currently, Economy) [4].

A national survey was conducted in Armenia in 2005 showing that 97.2% of households were using iodized salt while median urinary iodine concentration (UIC) among 8 to 10 years old children was slightly above 300μg/L, most likely due to a relatively high level (50 ± 10 mg/kg) of iodine content in salt [5]. Subsequently, this was reduced to 40 ± 15 mg/kg. The most recent survey (2016), confirmed that the country's population has adequate iodine nutrition with median UIC of 242μg/L in school-age children and 226 μg/L in pregnant women [6].

Armenia's 2016 STEPS Survey [7] found a mean salt intake of 9.8 g/day in adults (11 g/day for men and 8.4 g/day for women) based on sodium excretion measured in 24 hours urine samples. In a spin-off of the 2016 Iodine Survey, sodium was measured in spot urine samples of adult women and, based on urinary Na/Creatinine ratios, average sodium intake was calculated at 5.5 g/day, equivalent to salt consumption of 13.9 g/day. Finally, the Global Fortification Data Exchange [8] provides an estimate of salt intake for the country at 12.5 g/day. The modeling conducted in 2019 using IGN Guidance allowed to estimate the contribution of most important processed foods and household salt to iodine intake among the Armenian population. Mean per capita daily salt intake from household salt and major salt-containing foods is 10.6 g, of which 4.0 g originates from household salt, 4.3 g from bread and 2.3 g from all other key salt containing foods combined [9].

From a public health perspective, the WHO recommends that national surveys of household coverage of iodized salt and population iodine status be carried out every 3-5 years. However, the high cost of such surveys is a significant barrier to their regular implementation [10]. Experience has shown that it is unrealistic to expect ongoing external (or internal) funding every few years to support costly statistically representative national surveys of iodized salt coverage and/or population iodine status. Therefore, the Iodine Global Network[1] (IGN) has supported the adaptation of the FORTIMAS methodology as a much less costly salt iodization program monitoring and surveillance approach that countries could implement to track the status of their salt iodization programs, without much external funding support.

[1] - https://ign.org/; accessed 6 March 2024.

To enable public and private sector stakeholders of the national salt iodization program in Armenia to be able to confirm high population coverage of well iodized salt and the associated adequate iodine status of the population systematically and at a substantially lower cost than typical population-based representative surveys, the IGN supported the “pilot” implementation of the FORTIMAS[2] (Fortification Monitoring and Surveillance) methodology, adapted to tracking “effective coverage” of iodized salt, in Armenia.

Objectives. The primary objective of this project was to assess the feasibility/acceptability of the recently developed IGN methodology for monitoring and surveillance (M&S) of national iodization programmes, using sentinel site data collection (referred to as USI FORTIMAS), that could be implemented as a less complex and costly data collection approach for assessing and tracking the national USI programmes in a timely manner. The secondary objective of the study was to update older population survey data (2016) in order to assess the current nutritional (iodine) status of the population and the coverage of adequately iodized salt, to help inform national USI implementation in Armenia.

Expected outcomes. There were two expected outcomes of the pilot:

- Findings and conclusions from national implementation of the new IGN methodology in Armenia are generalized and feasibility/acceptability of USI FORTIMAS is evaluated (including usability, clarity of instructions and examples, appropriateness of content, assessment of resources needed for implementation); and, ultimately, its regular implementation for the monitoring and surveillance of national iodization programmes is recommended.
- The national salt iodization strategy in Armenia is strengthened to achieve/sustain optimal iodine nutrition through salt iodization, using current data/information on the coverage of iodized salt and nutritional (iodine) status of the population.

2. Materials and Methods

Based on the FORTIMAS approach, this study included secondary analysis of data on domestic production and imports of iodized salt (to estimate the “expected” population coverage of **quality** iodized salt). Data/information was provided by Avan Salt Plant, and the relevant government authorities - the Ministry of Economy and the Food Safety Inspection Body (FSIB) of the Republic of Armenia. That information is then “triangulated” with findings of primary data on household coverage of adequately iodized (containing >15 mg/kg iodine [10]) and iodine status among 1st trimester pregnant women, collected using **sentinel site**[3] and purposive (non-probabilistic) data collection methods, as well as findings of annual trends in neonatal TSH levels provided by the Neonatal Screening Program (NSP) .

Indicators deemed needed and feasible, to assess and track quality, coverage, and impact of a national salt iodization program are summarized below in Table 1.

2- https://www.smarterfutures.net/fortimas; accessed 6 March 2024.

3 - “Sentinel site” refers to a community (a large town or a district) within a region, purposively selected, based on its “expected” rate of population coverage of (adequately) iodized salt, where household salt samples and urine samples of (1st trimester) pregnant women could be feasibly collected for testing to “confirm” adequate (or inadequate) rate of household coverage of adequately iodized salt and median urinary iodine concentration among pregnant women.

Table 1. Indicators as deemed needed and feasible, to assess and track quality, coverage, and impact of a national salt iodization program in the Republic of Armenia

Row	Indicator Category	Indicator (in rank order)		Data Type	Measure
1	Quality & Quantity of Iodized Salt	1	Annual quantity of domestic **quality** iodized salt	Program level	MT
		2	Annual quantity of imported **quality** iodized salt	Program level	MT
		4	Annual quantity of domestic and imported iodized salt marketed	Program level	MT
2	Coverage of Iodized Salt	1	Annual "expected" population **coverage** of **quality** iodized salt* (refer to **Table 3**)	Program level	%
		2-a	Prevalence of households that use (any) iodized salt	Population level	%
		2-b	Average iodine content of household iodized salt, in and across, all sentinel sites	Population level	mg/Kg (or ppm)
3	Impact	1-a	Median urinary iodine concentration (mUIC) (among 1st trimester pregnant women)	Population level	µg/L
4	Impact	1-b	Median neonatal TSH concentration <3mIU/L and/or <3% prevalence of elevated (>5mIU/L) neonatal TSH concentration[β]	Population level	

*Includes population coverage of total iodized salt available for household use as well as for domestic production of target processed food(s).
β - Applies in countries where (essentially) all newborns are screened/tested for congenital hypothyroidism

2.1 Indicators of the salt iodization process

Monitoring of iodized salt quality. The Laboratory Services Centre (LSC) of the FSIB routinely determines iodine levels in food-grade salt[4] collected by its inspectors from commercial markets and processed food production facilities, to identify food-grade salt with iodine concentration "outside standard" of 40 ± 15 mg/kg. For this study, data were extracted from FSIB form N1 (annex to Joint Order 829-A and 74-A, March 2016) for calendar years 2021 through 2023. From a total of 1,916 salt samples tested, 1,392 had been collected from selected retail outlets, food catering facilities, and processed food production businesses across Armenia. Another 524 samples were collected from imported batches of salt at border control points over the same three-year period. Quantitative data on iodine concentrations in a total of 185 such salt samples identified by the FSIB/in 2022 and 2023, were extracted from the FSIB/LSC records and categorized as "non-iodized" (<5mg/kg); "inadequately iodized" (5–14.9 mg/kg); "**adequately iodized**" (15–40

4 Using iodometric titration as the official laboratory method per GOST R 5157.

mg/kg); and "over-iodized" (>40mg/kg), based on their iodine levels, per international guidelines which also define household salt with iodine concentration ≥15 mg/kg as adequately iodized [10].

Monitoring of expected annual population coverage of iodized salt. The design of the non-probabilistic FORTIMAS data collection approach to assess the coverage of iodized salt and iodine status of 1st trimester pregnant women in Armenia included the calculation of expected annual population coverage of iodized salt in the country based on:

- Total annual quantity of iodized salt available in the country for use by households, commercial food catering businesses (e.g., public restaurants and canteens), and processed food production facilities (e.g., bakeries, snack food producers, etc.).
- Estimated average per capita salt consumption of 12.5 g/day[5].
- Annual population size of the country[6].
- Data on quantities of production and imports of adequately iodized salt were provided by the Avan Salt Plant and the Ministry of Economy of the Republic of Armenia, respectively.

Monitoring household coverage of adequately iodized salt. To estimate the overall household coverage of iodized salt in the country in 2023, 30 students from one secondary school in each of 7 sentinel sites (total -210 students) were selected to bring 30 – 40 g of table/kitchen salt from their homes (herein referred to as household salt). Three sentinel sites were located in the capital city Yerevan and 4 in each of the following regions: Armavir, Ararat, Kotayk and Shirak. Each student was provided a small zip-lock plastic bag labelled with the predesignated identification codes of the selected school (i.e., data collection point). Upon collection of the household salt samples, the relevant information was recorded in a special form, which together with salt samples, were transported to the Salt Testing Laboratory of the ASP for quantitative measurement of iodine content by iodometric titration (GOST R 51575). In addition, a copy of the household salt collection form was kept at the "FORTMAS Central Office" in the National Institute of Health in Yerevan.

Monitoring of use (coverage) of iodized salt in bakeries. Two typical[7] bakeries producing "ordinary" (European style) bread and lavash (Armenian flat bread) were selected within each of the 7 sentinel sites (14 bakeries total) and the catchment area of the selected schools. One sample of salt was collected from each of the bakeries and transported to the designated Laboratory Services Center (LSC) of the FSIB for subsequent iodine analysis using iodometric titration (GOST R 51575). Salt content in bread (finished product) was calculated from the baker's recipe (BR) dividing salt concentration in dough to the commonly applied index 1.25 [11, 12]. Using information on daily per capita consumption of bread, average salt content in bread and iodine content of iodized salt, the average daily iodine intake from iodized salt in commercially baked bread was estimated.

[5] Global Fortification Data Exchange (GFDx) - https://fortificationdata.org/country-fortification-dashboard/?alpha3_code=ARM&lang=en; accessed 10 March 2024.
[6] Source: https://www.macrotrends.net/global-metrics/countries/ARM/armenia/population; accessed 5 March 2024.
[7] - "Typical" refers to bakeries where most of the families within the catchment area of each sentinel school purchase bread and bread products (relatively large ones).

2.2. Indicators of impact (iodine status)

Urinary iodine concentration (UIC). On average, every month hundreds of pregnant women (PW) in their 1st trimester visit antenatal health centers (ANC) in Armenia. These visits are free of charge and include examination by the obstetrician and collection of blood and urine samples for routine laboratory analysis. As part of this project, the additional task of medical personnel in the selected sentinel ANC was to complete a brief form and aliquot a small volume of urine (about 5 ml) in a separate labeled vial, freeze and ship it to the National Institute of Health (NIH) in Yerevan.

To assess iodine status in 1st trimester PW, urine samples of 280 subjects were collected in 7 sentinel ANC: 105 samples from 3 clinics in Yerevan, 44 samples from each clinic in Armavir, Ararat and Kotayk regions, and 43 samples from clinic in Shirak region (Table 2). Once collection of urine samples was completed, they were transferred to the "I"MUNO" laboratory in Tbilisi, Georgia where they were assayed for iodine concentration, under supervision of Dr. Nelly Barnabishvili, by Sandell-Kolthoff method with spectrophotometric detection and expressed in µg/L (micrograms per liter).

Table 2. Number of pregnant women recruited for urinary iodine testing

Region	**1st trimester pregnant women (N)**
Yerevan	105
Armavir	44
Ararat	44
Kotayk	44
Shirak	43
Total	**280**

Neonatal thyroid stimulating hormone (TSH) levels. Adequate thyroid function is important during pregnancy as maternal thyroxin greatly influences neurodevelopment of the fetus. Neonatal hypothyroidism screening tests measure the serum level of TSH. Elevated TSH in a newborn may indicate congenital hypothyroidism, or it may be a transient elevation due to inadequate maternal iodine status during pregnancy. The prevalence of neonates with elevated TSH levels is therefore a valuable indicator of the severity of iodine deficiency in a given population. The increase in the number of neonates with moderately elevated TSH concentrations (above 5 mlU/l whole blood) is proportional to the degree of iodine deficiency during pregnancy. When a sensitive TSH assay is used on samples collected three to four days after birth, a <3% frequency of TSH values >5 mlU/l indicates iodine sufficiency in a population [10].

In 2005, the Ministry of Health of Armenia instituted a neonatal congenital hypothyroidism screening program. It was expanded by 2012 to include all maternity clinics and hospitals in the country, accounting for nearly 100% of births in the country. The Neonatal Hypothyroidism

Screening Program (NHSP) at Arabkir Medical Center (MC) measures neonatal TSH via dried blood-spot sample on filter paper obtained from heel-prick of newborns. Each card includes the name of the maternity clinic, the sex of the child, date of birth of the infant, date of screening of the infant, duration of pregnancy, birth weight, and address of the mother. The samples are obtained by maternity ward clinicians throughout the country and sent to the central laboratory at Arabkir MC where they are analyzed for TSH level via fluoroimmunometry using DELFIA Neonatal TSH kit [13].

From 2017 through 2023, 255,108 neonatal TSH screening tests were performed by Arabkir Medical Center. Records with TSH values greater than 15mIU/L were removed. Tests in which the blood spot was not obtained between 2 and 5 days of life were also excluded, as were records of potentially premature infants (defined as less than 2500g at birth, or less than 37-week gestation, or where either the birth weight or gestational age were missing) [13]. After eliminating these influences on neonatal TSH level, an accurate and reliable dataset of 185,989 (from 2017 through 2023) was used to determine the mean and median neonatal TSH levels as indirect annual assessment of iodine status of pregnant women in Armenia (**Table 3**).

Table 3. Neonatal TSH screening data from 2017 to 2023.

Year	**Total number of screening tests**	**Number of screening tests used for analysis**	**Mean TSH level** (mIU/L)	**Median TSH level** (mIU/L)
2017	37,722	26,653	1,755	1,380
2918	36,464	25,833	1,777	1,380
2019	35,981	26,051	1,580	1,150
2020	36,477	27,035	1,506	1,120
2021	36,217	26,939	1,465	1,090
2022	35,597	26,516	1,458	1,080
2023	36,650	26,962	1,482	1.160

3. Results and discussion

3.1. Salt situation in Armenia

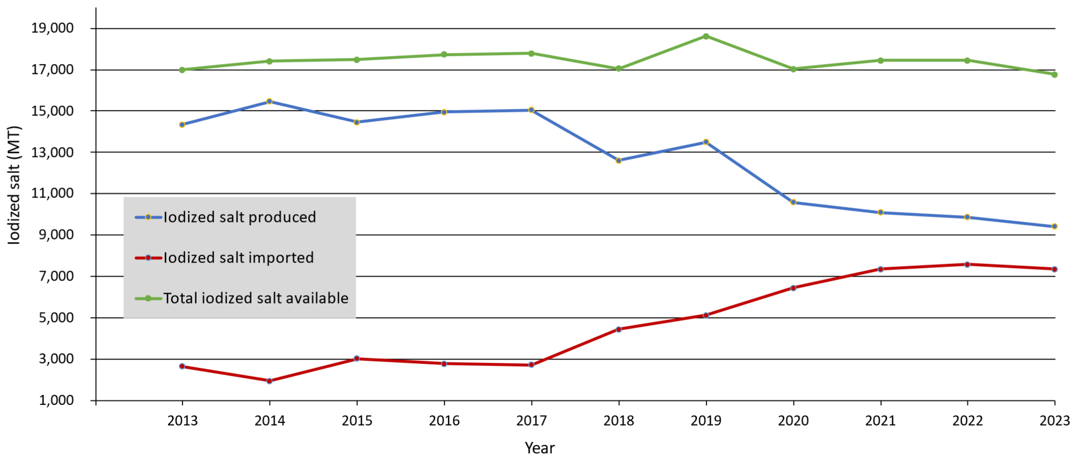
The Avan Salt Plant (ASP) was the primary supplier of edible salt in Armenia prior to 2018 (Annex 1). Thereafter a decreasing share of domestically produced iodized salt has been offset by increased iodized salt imports (Table 4, Figure 1). Besides fine (free flowing) iodized salt, ASP produced around 6,000 tons of lump rock salt (5-10 kg blocks) annually for animal consumption, out of which ≈1,400 tons were further ground as non-iodized salt for processed foods (mainly of artisanal soft cheese) that are exempt of requirement to use iodized salt. According to data from the Ministry of Economy, the total amount of imported iodized salt (mainly from Iran) increased from 4,400 tons in 2018 to 7,500 tons in 2023 (Figure 1). Export of salt from Armenia is small (less than 200 tons annually), and iodized salt constitutes up to 25% of that amount [4, 9].

Table 4. Annual volumes of salt supply in Armenia, 2019-2023 (production, imports, and exports)

INICATOR	Supply volumes (MT) by years				
	2019	**2020**	**2021**	**2022**	**2023**
a. Total amount of salt produced in the country	24,975.2	28,158.2	32,685.7	22,888.0	20,387.9
b. Amount of **iodized** food-grade salt produced in the country	13,487.3	10,578.8	10,085.4	9,873.2	9,415.3
c. Amount of **iodized** food-grade salt imported into the country	5,124.6	6,450.2	7,356.9	7,578.5	7,347.8
d. Amount of iodized food-grade salt exported from the country	73.7	3.6	11.4	15.8	12.6
e. Amount of iodized food-grade salt supplied to the population	**18,538.2**	**17,025.4**	**17,430.9**	**17,435.9**	**16,750.5**
f. Amounts of **non-iodized** "extra" food- grade salt supplied by ASP	**396.4**	**576.2**	**513.8**	**703.1**	**696.5**
g. **Total amount of food-grade salt, iodized and non-iodized, consumed**	**18,934.6**	**17,601.6**	**17,944.7**	**18,139.0**	**17,447.0**

a, c, d – data from Ministry of Economy; b, f – data from Avan Salt Plant;
e – supply according to the formula (e = b + c – d); and total g = e + f

Figure 1. Trends in annual quantities of domestic vs. imported vs. total iodized* salt available in Armenia from 2013 to 2023.



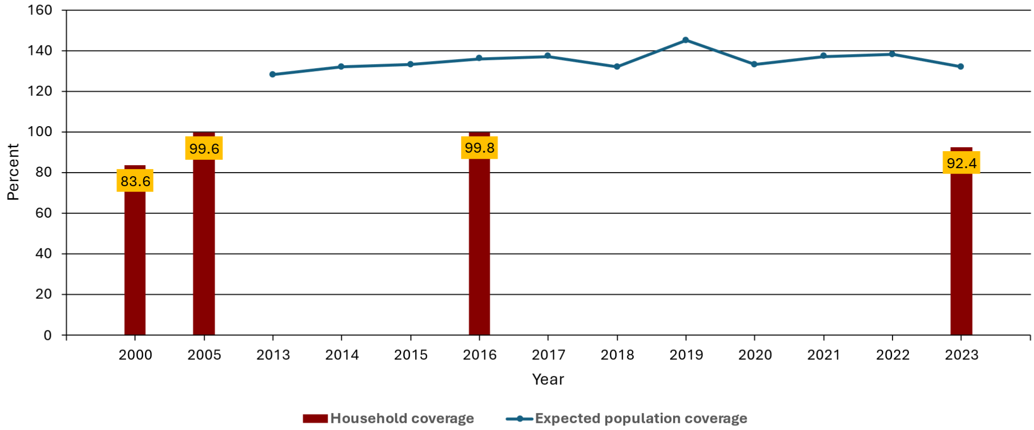
*Based on reported data from Avan Salt Plant and Armenia Ministry of Economy, on quantities of domestically produced and imported iodized salt, respectively.

The annual amounts of salt consumed in the country in most recent years have averaged around 18,000 tons, almost entirely in iodized form. However, it is estimated that a small share (up to 4%) of edible salt used in households and by food processors may be non-iodized.

3.2. Expected annual rate of population coverage of iodized salt in Armenia

While the decrease of iodized salt domestic production has been offset by its increased imports, the annual rate of expected population coverage of iodized salt has remained stable over the same time period (Figure 2). It should be noted that the consistently higher than 100% "expected" population coverage of iodized salt in Armenia over time may, in part, be due to an actual higher per capita intake of salt than 12.5 g/day or some inaccuracies in annual iodized salt production and imports data, as well as unknown levels of losses of salt.

Figure 2. Trends in annual rates of expected population coverage* vs. assessed household coverage** of iodized salt in Armenia: 2000 through 2023.



*Based on data from Avan Salt Plan and Armenia Ministry of Economy on annual quantities of production and imports of iodized salt 2013 - 2023.
**Based on findings of national surveys implemented in Armenia in 2000, 2005 and 2016, and FORTIMAS sentinel site data in 2023.

3.3. Household coverage of iodized salt in the country

Household salt samples (210 in total) were tested for iodine content within 8 to 14 days of collection. As shown in Table 5, 12 salt samples (5.6%) were non-iodized, and out of those, 11 were from Shirak region (city of Gumry). However, only 1 of the 199 household salt samples from the other 6 sentinel sites was found to contain no iodine. Further assessment of the source of non-iodized salt marketed in Gumry city may be warranted.

Table 5. Ranges of iodine level in household salt in Armenia in 2023.

Salt iodine level (mg/kg)	Salt samples (N)	Prevalence (%)
0.0	12	5.7
10 – 14.9	4	2.0
$\geq$15	194	92.4
Total samples tested	210	100.0

Excluding those 12 salt samples, only 2% of all the remaining household salt samples from the 7 sentinel sites contained <15 mg/kg iodine, while over 92% were found to be adequately iodized (containing >15 mg/kg iodine) (Table 5). Furthermore, among the 198 salt samples found to be iodized, a mean iodine concentration of 32.8 mg/kg was within the national standard of 40 ± 15 mg/kg.

Using the categories of salt falling "within" vs. "outside" the national iodization standard (from 25 to 55 mg/kg), nearly 23% of the household salt samples from the sentinel sites fell "outside standard" (Table 6). Furthermore, among the "outside standard" salt samples, only 1% contained >55 mg/kg iodine, while about 17% contained <25 mg/kg iodine. In comparison, a recent analysis of data on iodine content of salt samples collected from various market sources in Armenia and tested by the FSIB in 2023, found that the iodine content of about 31% of those salt samples fell "outside standard" [14].

Table 6. The proportion of household salt samples with iodine content "outside standard" *. Armenia, 2023.

Salt iodine level	Salt samples (N)	Prevalence (%)
Outside standard	48	22.9
Within standard	162	77.1
Total samples tested	210	100.0

*Defined as salt with 25 to 55 mg/kg iodine content.

Given the findings of complementary information that indicate consistently high <u>expected population</u> coverage of iodized salt, and <u>assessed household</u> coverage via statistically representative surveys, during the past decade (Figure 2), finding of about 92% household coverage of adequately iodized salt in Armenia in 2023, using the FORTIMAS methodology, appears to be quite reliable. The learning is particularly important because the cost of this approach as an initial round of "annual" iodized salt program monitoring and surveillance in Armenia, was only a fraction of that of a typical nationally representative salt iodization/population iodine status survey. Furthermore, because the overall framework of a potential "Armenia FORTIMAS System" has been developed under this project, it may be estimated that about 10 annual rounds of salt iodization program monitoring and surveillance may be carried out in the country in the future, at about the same cost as one nationally representative salt iodization program survey.

3.4. Assessment of the use of iodized salt in commercial bakeries

In 2022, people in Armenia consumed a total of 8.09 kg bread per month or 266 g per day [15]. The consumption of "ordinary" breads, including popular premium wheat breads, "naan", white or brown loafs, baguettes, etc. was 6.99 kg/month and lavash (Armenian flat bread) - 1.1 kg/month. The ratio of consumption of these two main categories of bread (86.4% and 13.6%) allowed for calculation of weighted average of iodized salt content of 1.4 g in 100g of bread. Based on daily consumption of bread in Armenia (266 g/day) and the average concentration of salt in bread (1.4%), the average daily salt intake from bread is 3.72 g or about 37.2% of the total average daily consumption of salt by the population of the country.

Iodine content in salt samples collected in 14 bakeries from the seven sentinel sites are presented in Table 7. Only one out of 14 sentinel bakeries used non-iodized salt while the other 13 used adequately iodized salt with iodine content within the range of the national standard (25 - 55 mg/kg). Median iodine content of bakery salt was 37.0 mg/kg (95% CI 33.82 ÷ 42.18).

Table 7. Iodine levels in salt used for bread baking in sentinel bakeries.

Sentinel site (administrative territory – district or marz)	Code of sentinel school	Code of Sentinel bakery	Bakery salt iodine content, mg/kg
1. Yerevan, community Nor Nork	1.	1a.	39.1
		1b.	37.0
2. Yerevan, community Erebuni	2.	2a.	31.7
		2b.	31.7
3. Yerevan, community Malatia-Sebastia	3.	3a.	43.3
		3b.	37.0
4. Armavir marz, city of Echmiadzin	4.	4a.	29.6
		4b.	45.4
5. Kotayk marz, city of Abovyan	5.	5a.	34.9
		5b.	34.9
6. Shirak marz, city of Gyumri	6.	6a.	43.3
		6b.	0 (no iodine)
7. Ararat marz, city of Ararat	7.	7a.	32.7
		7b.	53.9

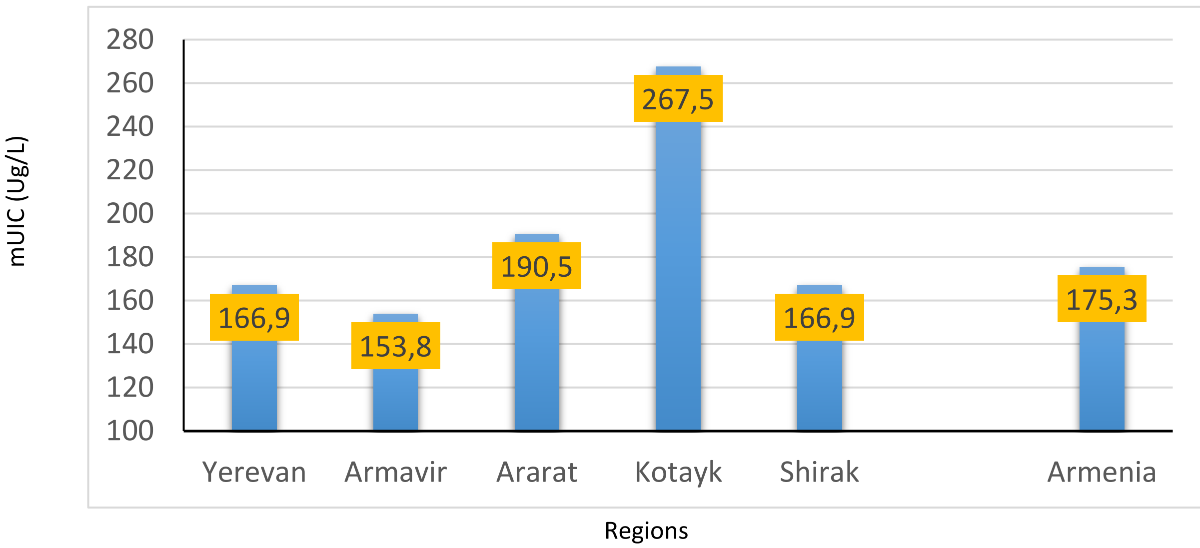
Mean 38.0 ± 6.86; Median - 37.0 mg/kg

The results of this study confirm that bread products commonly consumed in Armenia remain the major source of salt in the diet and on average provide 61.2% of Recommended Nutrient Intake for iodine.

3.5. Median urinary iodine concentration (mUIC) among 1st trimester pregnant women.

Urinary iodine concentration (UIC) is the main impact indicator reflecting iodine status of the surveyed population. Based on such analysis of urine samples of 280 1st trimester subjects, median UIC (mUIC) among pregnant women nationwide was 175.3 µg/L (range 26.8 – 600.4 µg/L) (Figure 3), confirming adequate iodine status (mUIC within the 150-250 µg/L range) in the population group most sensitive to insufficient iodine intake [10].

Figure 3. Median UIC in pregnant women nationally and by regions of Armenia

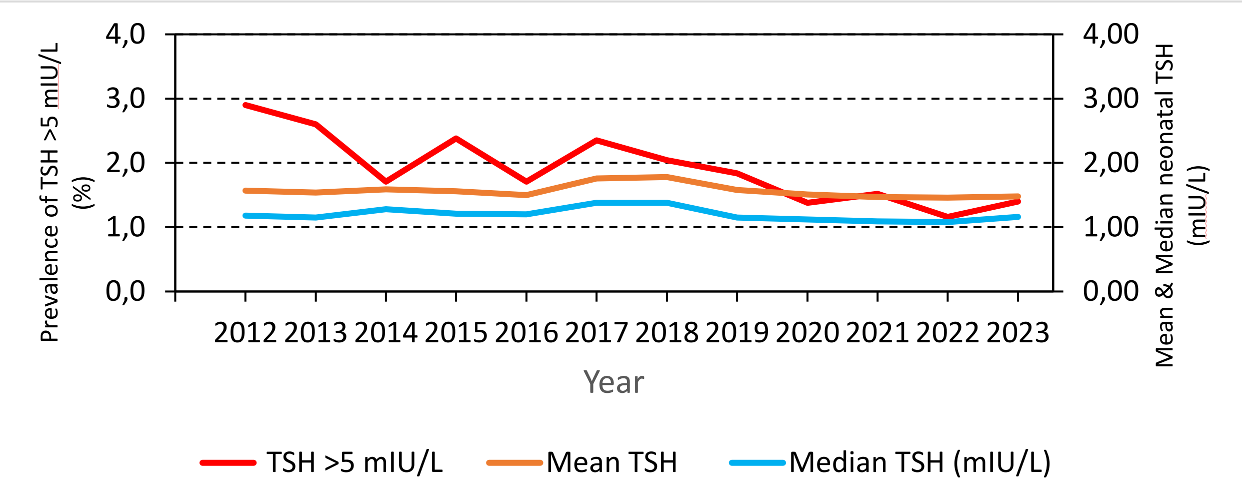


Median UIC across the selected regions of Armenia (data from 3 sentinel sites in Yerevan were pooled) are presented in Figure 3 to illustrate the generally adequate iodine status among 1st trimester pregnant women across the country. The differences in mUIC levels between the regions are likely due to random fluctuations in urinary iodine excretion manifested by insufficient samples sizes to estimate mUIC at the sub-geographic level.

3.6. Neonatal TSH concentration

Another impact indicator of universal salt iodization – less than 3% prevalence of elevated (over 5 mUI/L) neonatal TSH concentration [10] also points to sustained adequate iodine nutrition of Armenia population. Over the past 12 years the prevalence of elevated TSH level was less than 3% with a general trend of decreasing from 2.35% in 2017 to 1.39% in 2023, while the mean and median TSH levels remained stable between 1.00 and 2.00 mIU/L (Figure 4).

Figure 4. Annual trends in prevalence of elevated (>5mIU/L) neonatal TSH concentration and mean vs. median neonatal TSH concentration in Armenia (2012 – 2023).



4. Conclusions and Recommendations

Recognizing the profound interest and need of the health authorities, management and partners of the national salt iodization program in Armenia to confirm high population coverage of well iodized salt and the associated adequate iodine status of the population systematically and at a substantially lower cost, than typical population-based representative surveys, the IGN supported the "pilot" implementation of the FORTIMAS (Fortification Monitoring and Surveillance) methodology, adapted to track the coverage and impact of the national salt iodization program in Armenia.

The project was implemented with active and essential engagement of public and private sector stakeholders (main partners) of the salt iodization programme in the country, such as Ministry of Economy, Food Safety Inspection Body (FSIB), Neonatal Screening Program and Avan Salt Plant (ASP). Facilitating its successful implementation, the FSIB provided quantitative data on iodine levels in salt samples from all supply chains monitored by the agency; initiated relevant revision of its reporting tool (Form N 1 in Joint Order 829-A and 74-A of 2016), requested technical assistance from the USI FORTIMAS Office of the NIH toward development of its "risk-based audit plans" for future salt inspections, including more focus towards monitoring of salt used in food industry with special focus on bakeries because of bread being a major staple food in the country.

The Ministry of Economy initiated review of its data collection forms to provide disaggregated data on total annual volumes of domestically produced and imported iodized and non-iodized dietary salt. Given the above efforts, it should be assumed that the FORTIMAS approach has apparently helped the partners to better appreciate how their data and information relate to public health and nutrition in the country.

The ASP, a strong historical partner of the national USI program, further exhibited its partnership by offering its laboratory and technical capacity by testing iodine content of household salt samples collected through the schools across the seven sentinel sites.

Findings from primary analysis of non-probabilistic data showed high (92%) household coverage of iodized salt and adequate (175.3 μg/L) median UIC among 1st trimester pregnant women, across purposively selected sentinel sites. Secondary analysis of data on production and imports of iodized salt also indicated consistently high expected and assessed population coverage of iodized salt during the past decade. The prevalence of neonatal TSH levels above 5 mUI/L (an indicator of iodine status among pregnant women) over the past 12 years was less than 3% with a general trend of decreasing from 2.35% in 2017 to 1.39% in 2023. It is obvious, that sustained adequacy of iodine status in a population is achieved as the population in Armenia is able to consume quality "dietary iodized salt", i.e., household iodized salt and iodized salt containing processed foods.

The cost of implementation of the FORTIMAS approach as an initial round of "annual" iodized salt program monitoring and surveillance in Armenia was only a fraction of that of a typical nationally representative salt iodization/population iodine status survey. Furthermore, because the overall framework of a potential "Armenia FORTIMAS System" has been developed under this project, it may be estimated that about 10 annual rounds of salt iodization program monitoring and surveillance may be carried out in Armenia into the future, at about the same cost as one nationally representative salt iodization program survey.

In general, the pilot implementation of the FORTIMAS approach allowed for an "overall" assessment of the status of the national salt iodization program in Armenia where the last national population iodine status survey was carried out in 2016. The exercise helped to positively assess the feasibility and utility of the FORTIMAS methodology as a much less costly approach that Armenia should continue implementing to track the status of the national salt iodization program without much external funding support.

In this study, urine samples were transferred to Tbilisi, Georgia where their iodine concentrations were assayed by the "I"MUNO" laboratory under supervision of Dr. Nelly Barnabishvili., who demonstrated extremely kind and professional attitude towards this important part of the project in Armenia. The transportation of samples to Tbilisi however added to complexity and the cost of the activity. In addition, the procedures of transportation, including customs clearance were "not easy" to overcome. Expecting regular implementation of the activity, there must be a feasible solution for this challenge. A feasibility study for creation of a national laboratory for regular UI determination was planned in 2005 and the need to strengthen the system for assessment of iodine nutrition was recalled in the government decree No 40 of 2014. However, a specialized laboratory to carry out regular UI assays is still absent.

In a view of potential introduction and, possibly, regular implementation of USI FORTIMAS methodology in Armenia, it is strongly recommended, that the Ministry of Health in cooperation with the main government stakeholders – FSIB and Ministry of Economy re-establish, support and coordinate the work of an Intersectoral (Multidisciplinary) Working Group (IWG) to ensure on-going, systematic and regular collection, analysis and interpretation of secondary, as well as primary, data to assess the status of the USI program over time (preferably on annual basis), as exemplified by this pilot project. The repeat annual collection and analysis of data on the indicators summarized in this report should be quite feasible because data on annual quantities of domestic and imported iodized salt, FSIB quality monitoring, and neonatal TSH are available through the relevant organizations in the country.

5. References

1. Delange F.M., Robertson A., McLoughney E., Gerasimov G, WHO Regional Office for Europe. et al. (1998) . Elimination of iodine deficiency disorders (IDD) in Central and Eastern Europe, the Commonwealth of Independent States, and the Baltic States: proceedings of a conference held in Munich, Germany, 3-6 September 1997 / edited by F. Delange et al/. World Health Organization. https://iris.who.int/handle/10665/83307

2. Ministry of Health of Armenia, National Statistical Service of RA. Gerasimov G. Report on results of a national representative survey of iodine nutrition and implementation of universal salt iodization program in Armenia. Yerevan: UNICEF, 2005.

3. Van der Haar F., Gerasimov G., Tyler V.Q. et al. Universal salt iodization in the Central and Eastern Europe, Commonwealth of Independent States (CEE/CIS) Region during the decade 2000–09. Food and Nutrition Bulletin, vol. 32, no. 4 (Suppl.), 2011, 124 p.

4. Technical report on assessment of implementation status of various components of the National IDD elimination programme in Armenia, 2018/H.Aslanyan, National Institute of Health, MoH, RA, 2018. Pages 33 (http://nih.am/assets/pdf/atvk/bc433e24a855285689843f2c11b2b57d.pdf) (bc433e24a855285689843f2c11b2b57d.pdf)

5. Report on results of national representative survey of iodine nutrition and implementation of universal salt iodization program in Armenia. UNICEF and Ministry of Health of Armenia, Yerevan, 2005

6. Hutchings N, Aghajanova E, et al. Constituent analysis of iodine intake in Armenia. Public Health Nutr.: 2018, N 21(16), p. 2982-2988 https://www.ncbi.nlm.nih.gov/pubmed/30189914.

7. "ARMENIA STEPS Survey, 2016-2017. Fact Sheet":

https://www.who.int/ncds/surveillance/steps/Armenia_2016_STEPS_FS.pdf
8. Global Fortification Data Exchange (GFDx) https://fortificationdata.org/country-fortification-dashboard/?alpha3_code=ARM&lang=en.
9. Aslanyan H. Assessment of the actual or potential contribution of industrially processed food salt to population iodine intake (Final National Report: Republic of Armenia), 2020, National Institute of Health, MoH, RA, 2020, 26 p.
10. Assessment of iodine deficiency disorders and monitoring their elimination: a guide for programme managers. – 3rd ed. WHO, 2008.
11. Al-Jawaldeh A., Al-Khamaiseh M. Assessment of salt concentration in bread commonly consumed in the Eastern Mediterranean Region, EMHJ, 2018, v. 24, No. 1, 18-24. https://www.researchgate.net/publication/324233423
12. Quilez J., Salas-Salvado J. Salt in bread in Europe: potential benefits of reduction. Nutrition Reviews, 2012, 70(11):666-78. https://www.researchgate.net/publication/ 232740468.
20. Global Fortification Data Exchange (GFDx) https://fortificationdata.org/country-fortification-dashboard/?alpha3_code=ARM&lang=en.
13. Hutchings N, Tovmasyan I, Hovsepyan M, Qefoyan M, Baghdasaryan S, Bilezikian J. Neonatal thyrotropin (TSH) screening as a tool for monitoring iodine nutrition in Armenia European Journal of Clinical Nutrition 2018 https://doi.org/10.1038/s41430-018-0298-4
14. Aslanyan, H. Ts. ; Vardanyan, G. G. ; Gevorgyan, A. K., Parvanta, I., Sargsyan, E. A. Rationale for the Importance of Revising the Strategy for Monitoring the Use of Iodised Salt in Armenia, Vol. 64 (2024), N1, p 68-76. https://arar.sci.am/dlibra/publication/401113/edition/371204/content
15. SOCIAL SNAPSHOT AND POVERTY IN ARMENIA. Statistical and analytical report, based on the findings of 2018, 2019, 2020, 2021, 2022 Household's Integrated Living Conditions Survey, ARMSTAT, https://www.armstat.am/am/?nid=82&id=2095; https://www.arm-stat.am/en/?nid=207

Annex 1.

Production and import of iodized and non-iodized food-grade salt in Armenia, 2013-2018

Salt source and type	Production/supply in MT: by years					
	2013	*2014*	*2015*	*2016*	*2017*	*2018*
Salt produced by ASP, total	**30786**	**29792**	**27392**	**32249**	**32550**	**22583**
A1. «Extra» iodized, including:	**14347**	**15389**	**14372**	**14821**	**14799**	**12415**
- packed, 1 kg brick-shaped in poly-propylene packages;	12092	12735	11953	11786	11982	9885
- packed in 25 kg polyethylene bags;	2255	2654	2419	3035	2817	2530
A2. «Extra» non-iodized, manufact. (25 kg polyethylene bags);	-	67,2	90,6	131,3	144,4	203,6
A3. 2nd grade rock salt, grinding N 2, **iodized**, 0,9 kg polypropylene packages:	295	294	306	303	252	199
A4. 2nd grade rock salt, grinding N 2, **non-iodized**, for manufacturing purposes:	-	-	-	76	93	125
B. "Technical" Grinding N3 (in industry, for melting road ice, for cleaning boiler filters, etc.):	9 786	7 227	6 602	11 394	12 358	5 963
C. Fodder rock salt (used in animal husbandry), including:	6 358	6 815	6 021	5 524	4 905	3 677
selective rock salt	5 905	6 375	5 606	5 211	4 634	3 576
D. Imported iodized salt (in brackets – non-iodized)	2638 (n/a)	1952 (n/a)	3021 (0)	2771 (90 MT)	2732	4433
E. The total volume of iodized salt produced and imported **(E = A1+ A3+D**)	**17280**	**17635**	**17699**	**17895**	**17783**	**17047**