Elimination of lodine Deficiency Disorders

A manual for health workers





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Elimination of iodine deficiency disorders. A manual for health workers

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Preface

Iodine deficiency disorders (IDD) are the most important preventable cause of impaired development of the brain and subsequent mental retardation in the world. Millions are at risk, both globally and in the Eastern Mediterranean Region. Therefore, elimination of IDD as a public health problem is an important health and social goal.

Continuous monitoring and evaluation are an essential part of universal salt iodization (USI) and of any programme for the elimination of IDD. Adequate amounts of iodine must be shown to be reaching the target population, which requires selection of appropriate process and impact indicators. The iodine content of salt is an indicator of the salt iodization process while median urinary iodine concentration remains the principal impact indicator.

This publication presents an overview of IDD and provides detailed instructions for a wide range of health workers in the monitoring and evaluation of IDD control and prevention programmes. Health and nutrition programme staff working at the provincial, district and field levels in the public health sector will find it particularly useful. The manual may also be used by interested iodized salt producers and those involved in the formulation of health and nutrition policy and programmes.

This publication developed out of the training materials used in two regional training workshops on the monitoring and evaluation of national IDD control and prevention programmes that were organized in collaboration with the Regional Coordinator of the International Council for the Control of Iodine Deficiency Disorders (ICCIDD) in the Islamic Republic of Iran during 2001 and 2002. The workshops were part of an ongoing cooperative agreement between the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC), Atlanta, USA. The information contained in this manual is intended to help the countries of the Region to combat iodine deficiency disorders, thereby reaching the goal of sustainable elimination of iodine deficiency disorders.

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Introduction

Iodine, named after the Greek word for violet, was first observed as a violet vapour during the making of gunpowder at the beginning of the 19th century. Most of the Earth's iodine exists in the ocean: sea water, fish and vegetation. It was present during the primordial development of the earth, but large amounts were leached from the surface soil by glaciation, snow or rain and carried by wind, rivers and floods into the sea.

Iodine is found in the deep layers of soil and in oil wells and natural gas effluents. Water from such deep wells can be a major source for iodine. But the return of iodine to soil is slow and small in amount compared to the original loss, and subsequent repeated flooding ensures that iodine deficiency in the soil continues. There is no natural rectification, and iodine deficiency persists in the soil indefinitely. All crops grown in these soils will be iodine deficient. As a result, human and animal populations, which are totally dependent on food grown in such soil, become iodine deficient. This accounts for the occurrence of severe iodine deficiency in vast populations worldwide, especially those dependent on soil-grown food.

Iodine deficiency in affected populations will continue unless continuous supplementation is provided, the most cost-effective way being salt iodization. The term iodine deficiency disorders (IDD) refers to all the ill-effects of iodine deficiency in a population that can be prevented by ensuring that the population has an adequate intake of iodine. Some of the adverse effects due to iodine deficiency are listed in Table 1. The most notable effects are related to brain development and loss of intelligence in children.

Iodine is an essential dietary nutrient that helps the body to manufacture thyroxine, the hormone that regulates normal growth and development. The quantity of iodine required by an individual is minute, being 150–200 µg per day, or a teaspoonful during a lifetime! The recommended daily intake of iodine is shown in Table 2.

Apart from health consequences, iodine deficiency can result in socioeconomic decline in communities whose members are mentally slow, less vigorous and more difficult to educate and thus low in productivity. Livestock, too, need iodine. Iodine deficiency in livestock can cause reduced milk and meat yields and lower wool production from sheep. All this can be prevented;

	Table 1. The spectrum of iodine deficiency disorders			
Fetus	Abortions Stillbirths Congenital anomalies Increased perinatal mortality Endemic cretinism			
Neonate	Neonatal goitre Neonatal hypothyroidism Endemic mental retardation Increased susceptibility of the thyroid gland to nuclear radiation			
Child	Goitre Adolescent (subclinical) hypothyroidism Impaired mental function (low intelligence) Retarded physical development Increased susceptibility of the thyroid gland to nuclear radiation			
Adult	Goitre with its complications Hypothyroidism Impaired mental function Spontaneous hyperthyroidism in the elderly			

Adapted from references 1 and 2.

it is possible to eliminate IDD by simply ensuring a steady and continuous supply of iodine to the entire population.

Increased susceptibility of the thyroid gland to nuclear radiation

In an area where the extent of IDD is unknown, the problem should be assessed, followed by communication, political decision-planning and implementation of an elimination programme. Constant monitoring and evaluation are an essential part of any IDD elimination programme.

Figure 1 shows the infrastructure of a typical national IDD elimination programme.

Table 2. Recommended daily intake of iodine
90 µg for preschool children (0 to 59 months)
120 μg for schoolchildren (6 to 12 years)
150 μg for adults (above 12 years)
250 μg for pregnant and lactating women
· · · · · · · · · · · · · · · · · · ·

Adapted from references 1 and 2.

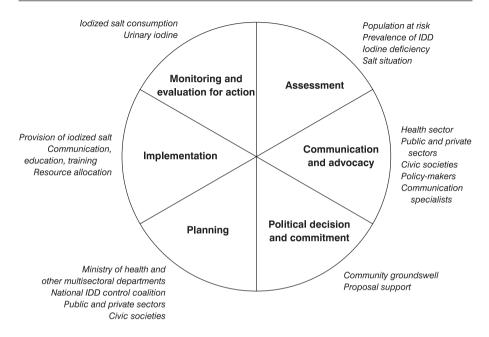


Figure 1. The integrated programme elements in a national IDD elimination programme

Iodine deficiency disorders in the Eastern Mediterranean Region

Despite the high prevalence of iodine deficiency disorders (IDD) in many countries of the UNICEF Middle East and North Africa Region and the WHO Eastern Mediterranean Region, iodine deficiency was not recognized as a serious public health problem until 1987. Goitre as an indication of iodine deficiency was regarded as being restricted to certain geographical areas and as such, not considered a public health issue affecting the majority of the populations.

A review of the prevalence of iodine deficiency disorders and the control and prevention in the countries of the Eastern Mediterranean Region was conducted in 1987. The review revealed that IDD was a serious public health problem in 15 of the countries of the Region and required urgent control and prevention measures. Between 1988 and 1990, WHO Regional Office for the Eastern Mediterranean organized training workshops and developed technical publications in order to assist countries in understanding the problem and in the formulation of appropriate intervention measures. The public health implication of IDD was also brought to the attention of the health ministers in the WHO Regional Committee for the Eastern Mediterranean, which resulted in resolutions EM/RC37/R.9 and EM/RC49/R.12, calling for Member States to take active steps towards the control, prevention and eventual elimination of IDD as a public health problem. With the active support and involvement of UNICEF and the International Council for the Control of Iodine Deficiency Disorders (ICCIDD), Micronutrient Initiative of Canada and other partner organizations. WHO has continued to support countries in their efforts to deal with IDD through technical workshops, training courses and programme assessments.

The Islamic Republic of Iran and the Syrian Arab Republic were the first countries to start iodizing salt, a practice which gradually spread to most of the countries of the Middle East and North Africa and Eastern Mediterranean regions. In 1995, the Regional Iodized Salt Producers Association (RISPA) was established to bring about improved coordination between the salt producers, the health sector and consumers. By 2000, eight countries had reached the goal of universal salt iodization (USI), where a minimum of 90% households consumed adequately iodized salt. By 2006, three countries had declared the elimination of iodine deficiency disorders as a public health problem and have sought a confirmation of this status from the international partner organizations.

The most recent information on the status of the control of IDD in countries of the Middle East, North Africa and Eastern Mediterranean is summarized in Table 3. Table 4 shows full IDD status in the countries of the regions.

Table 3. Summary of IDD control status

Status	Country
IDD eliminated	Islamic Republic of Iran, Tunisia
IDD almost controlled	Algeria, Jordan, Lebanon, Syrian Arab Republic,
USI begun; data are needed	Sudan, Egypt, Libyan Arab Jamahiriya, Oman, Morocco, Yemen
Mild IDD or data unavailable	Bahrain, Kuwait, Palestine, Qatar, United Arab Emirates
Severe IDD, difficult to study or lack of progress	Afghanistan, Iraq, Pakistan

Adapted from reference [1].

Table 4. IDD status in countries of the Middle East and North Africa and Eastern Mediterranean regions

Country	Households using iodized salt (%)	Total goitre rate (%)	Median urinary iodine (g/l)	Salt legislation	IDD monitoring	IDD status
Algeria	69	8 (1993)	347 (1996)	Yes	NA	Unknown
Egypt	78	11–35 (1993–98)	184 (2006)	Yes	No	Mild to moderate
Iran, Islamic Republic of	94	9 (2001)	176 (2001)	Yes	Yes	IDD-free
Iraq	40	NA	NA	Yes	No	Severe
Jordan	98 (2004)	32 (2000)	250 (2004)	Yes	Yes	IDD-free
Lebanon	92	26 (1997)	94 (1997)	Yes	Just for level of iodine in salt	Mild to moderate
Libyan Arab Jamahiriya	90	NA	NA	Yes	NA	Mild to moderate
Morocco	59	22 (1993)	86 (1998)	Yes	No	Moderate
Oman	61	NA				
Palestine	64	NA	NA	Yes	Yes	Mild to moderate
Sudan	1	13–87 (1997)	NA	Yes	No	Mild to moderate
Syrian Arab Republic	79	NA	116 (2006)	Yes	Yes	Mild to moderate
Tunisia	97	NA	158 (1995)	Yes	NA	IDD-free
Yemen	30	17 (2000)	173 (2000)	Yes	NA	Mild to moderate

Source: The state of the world's children 2007. New York, UNICEF, 2007.

NA: no data

Assessment of iodine deficiency disorders

Planning and implementing a survey

Objectives of IDD investigation

- To assess the prevalence of IDD and ascertain the extent and severity of the problem from a health point of view.
- To identify high-risk areas for early intervention.
- To monitor and evaluate IDD control programmes and surveillance longitudinally to assess the impact of ongoing programmes.

IDD assessment indicators (what to measure)

An indicator is something that is measurable and draws attention to a certain condition. An indicator not only helps describe a situation that exists, but also track changes in the situation over time. When selecting indicators the following factors must be considered:

- social acceptance of the assessment technique (accessibility)
- technical feasibility
- cost
- performance
- availability of reference data.

For each stage of an IDD control programme different indicators must be carefully selected. Though many indicators have been used in the past (Table 5), many are not applicable for prevalence studies.

Total goitre rate can be assessed using thyroid examination or ultrasonography. The latter has high precision for assessing goitre volume and it is especially applicable in areas of low goitre rate or where USI is implemented and reduced goitre rate is expected. Data are quantitative, reproducible and reliable. However, ultrasonography is expensive, needs expert personnel and there are no references for normal thyroid size.

The most appropriate biochemical indicator is the urinary iodine level. Serum thyroid-stimulating hormone and thyroglobulin levels are used in special situations. Therefore, for a prevalence study before iodine supplementation it

Table 5. Indicators of IDD status					
Туре	lodine supplementation	lodine supplementation			
	Before	After			
Main	Goitre size Urinary iodine level	lodized salt consumption Urinary iodine level Programmatic indicators			
Other	Cretinism Neonatal thyroid-stimulating hormone level Thyroid function tests and thyroglobulin	Goitre size Neonatal thyroid-stimulating hormone level			

is recommended to assess both the total goitre rate, by palpation, and median urinary iodine excretion in the studied population. In a population which receives iodine supplementation, percentage of iodized salt consumption by the household and median urinary iodine excretion are the indicators of choice.

Techniques for measurement of indicators (how to measure)

Thyroid examination is performed by inspection and palpation

- Advantages
 - low cost
 - feasible in schoolchildren
 - easy assessment and training
- Disadvantages
 - low precision.

Table 6 shows the simplified classification for the assessment of goitre grade recommended by WHO/UNICEF/ICCIDD.

Table 6. Classification of goitre by palpation Grade 0 No palpable or visible goitre. Grade 1 A mass in the neck that is consistent with an enlarged thyroid that is palpable but not visible and each lobe of thyroid has a volume greater than the terminal phalanges of the thumbs of the person examined, when the neck is in the normal position. It moves upward in the neck as the subject swallows. Nodular alteration(s) can occur even when the thyroid is not visibly enlarged. Grade 2 A swelling in the neck that is visible when the neck is in a normal position and is consistent with an enlarged thyroid when the neck is palpated.

Adapted from references [1] and [2].

and gottle prevalence		
Total goitre rate (%)	Severity of IDD*	
5–19.9	Mild	
20-29.9	Moderate	
≥30	Severe	

Table 7. The relationship between the severity of IDD and goitre prevalence

The relationship between the severity of IDD and the prevalence of goitre is shown in Table 7.

Method

The examiner faces the subject and looks for visible thyroid enlargement. The subject then looks up, extending the neck and making any thyroid enlargement more visible. The examiner palpates the thyroid by standing behind the subject, sliding his/her fingers along each side of the trachea (windpipe) between the thyroid cartilage (Adam's apple) and the top of the sternum. The size and consistency of the thyroid is carefully noted. The thyroid moves upward when the subject swallows, which can sometimes define its size. The thyroid gland whose lateral lobes have a volume greater than the terminal phalanges of the thumbs of the person examined is considered goitrous.

With small goitres, palpation becomes more difficult, because it is difficult to palpate the difference between a small goitre and no goitre. In grade 2 goitre there is agreement in almost all cases. However, there can be a variation of about 40% between grade 0 and grade 1. The only way to improve this measurement is by active training and retraining of people who carry out these studies. For a good assessment, a process of validation is necessary (ultrasonography and/or other surveys). Repeating surveys at different times and comparing the results with ultrasonography has shown that assessment with palpation is not very precise; it only indicates that a problem exists, without clarifying its extent.

Although it is necessary to emphasize that palpation is used only where no prior intervention has been in place and/or urinary iodine assessment is not available, the results can be used as basic data for further studies on goitre or any iodine deficiency disorders and their correlations in the future.

^{*} Prior to implementation of iodide supplementation programme.

Urinary iodine

Most iodine absorbed in the body eventually appears in the urine; therefore, urinary iodine is a good marker of recent dietary iodine intake. In individuals, urinary iodine excretion can vary somewhat from day to day and even within a given day, but this variation tends to cancel out across populations. Samples are easy to obtain, and the analytical techniques to measure the iodine content are not too difficult. Table 8 shows equipment and supplies needed for collection of samples.

To identify the problem, the median urinary iodine excretion of the population and the prevalence of cases with urinary iodine below 50 μ g/l are good indicators. Median values should be used rather than the mean, as urinary iodine values from populations are not normally distributed.

In populations with longstanding iodine deficiency and rapid increase in iodine intake, it is recommended that median values for urinary iodine should not exceed 200 μ g/l, in order to avoid the risk of iodine-induced hyperthyroidism, which can occur during the first few years following the introduction of iodized salt. Beyond this period of time, median values up to 300 μ g/l have not demonstrated side effects.

Table 9 shows the relationship between the urinary iodine level and the severity of IDD in a given population.

Table 8. Field equipment and supplies needed for assessment of iodine control of urine and salt

Item to be collected/tested	Equipment and supplies needed
Urinary iodine	Disposable cups for collecting specimens Screw-capped tubes for urine storage and transportation Disposable pipettes for transferring urine from cup to tube Tube labels Cardboard with styrofoam-insert boxes Mailing/shipping labels Permanent ink pens for labels Sealable plastic bags
lodized salt	Rapid test kits (available from UNICEF); one vial can test approximately 50 salt samples Tube, bags or packages for salt samples to be sent to a central laboratory for salt iodine titration analysis

Adapted from reference [3].

Since casual specimens are used, it is desirable to sample enough subjects from a given population to allow for difficult degrees of subject hydration and other biological variation. In general, 30 urine determinations from a defined sampling group are sufficient.

Selection of survey subjects (whom to measure)

Criteria for target group selection:

- vulnerability
 - extent of exposure
 - severity of consequences
 - responsiveness to interventions
- representativeness
- accessibility.

Usefulness for surveillance of multiple micronutrient and other health problems

Taking all these factors into account, schoolchildren are considered to be the most suitable group for IDD surveillance because of their combined high vulnerability, easy access and usefulness for a range of surveillance activities. Affected children develop an enlarged thyroid in response to iodine deficiency and can be readily examined in large numbers in school settings. At the same time, other health concerns in this age group, including helminthic infections, anaemia and behavioural factors affecting health, can be assessed and educational interventions implemented. A major concern arising in school-based surveys is that children not attending school are not represented, which possibly leads to biased prevalence estimates. If school enrolments or attendance are low, school-aged children can be surveyed during household surveys.

Table 9. Relationship between severity of IDD and median urinary iodine level

Urinary iodine (μg/l)	Severity of IDD
50–99	Mild
20–49	Moderate
<20	Severe

Circumstances when schoolchildren may not be appropriate

Occasionally, school-based cluster surveys may not be appropriate, for example when school attendance is low or schoolchildren are not representative of the general population (for example, because of the existence of school feeding schemes or low enrolment of girls in schools). Alternatives are to survey adult women or school-aged children in households.

Organization of survey

Surveys for endemic goitre can be conducted most rapidly if forms are readily available for recording the necessary data for each individual examined

Name, age, sex, locality and years of residence in that locality are generally included with a space for indicating a previous place of residence when applicable. The date should always be indicated, and there should be space for the examiner's initials, an important consideration when several people are engaged in a survey.

It is essential to record information such as the size and type of locality, its altitude and its type of water supply. When a school is examined, it should be noted whether it is public or private, urban or rural. In localities containing distinct racial groups, it may be of interest to tabulate any racial variations in prevalence, which may be due to differences in response to environmental influences. In this case, an indication of race must be recorded on each form.

Survey methodology

The recommended approach is multi stage "probability proportionate to size" (PPS) cluster sampling, a methodology widely used for health indicators. The usual sampling unit is either communities or schools. Each unit is one cluster in a defined geographical area.

Sample size varies based on: homogeneity of area and apparent severity (prevalence).

Sample size *n* can be estimated through following equation:

$$n = \frac{z^2 p(1-p) \text{DEFF}}{d^2}$$

where z = 1.96, p is the estimate of extended proportion (prevalence), d is the level of absolute precision (the width of the confidence interval) and DEFF is the estimated design effect.

The sample is divided into 30 clusters in order to ensure a valid prevalence estimate. Schools are selected on the basis of enrolment or random samples. Within each cluster a specified number of children are selected by systematic random sampling.

In areas where prevalence of goitre is unknown, it is recommended to use 40 children per cluster for a total of 1200 children (30 cluster \times 40 children per cluster), to establish whether IDD is present. This is calculated on the basis of 95% confidence interval with a width d of $\pm 5\%$ and design effect (DEFF) of 3, which with p of 0.5 (or 50%) gives sample size of 1153; and 1200 is taken for ease of calculation. With DEFF of 2 the sample size is decreased to 769, and 26 samples per cluster would be enough. One should remember that the more the clusters differ from one another, the larger the DEFF; therefore, if the proportion of a condition is similar in each cluster, the DEFF will be around 1.3.

To assess the degree of severity, the sample size has to be increased to 70 children per cluster.

Data collection

A clear procedure should be identified to process the collected data:

- checking the completeness and accuracy of the data gathered
- numbering data collecting forms or questionnaires at the time of examination/interview
- identifying the person responsible for data storage
- deciding how and where data should be stored storage should be organized so that record forms are logically placed in a numbered or data sequence
- deciding whether the data will be processed or tabulated in the field or whether they are to be transported back to the main base for this exercise
- standardizing enumerators and examiners for data collection.

This should be done through training both the examiners and enumerators before the survey and doing a validation text and then comparing the results of their test with a key experienced person.

Data analysis

Making a plan for data analysis and interpretation including provisions for:

- systematic quality control of data
- processing of data
- data analysis.

Such a plan helps the researcher to make sure that, at the end of the study:

- all the information needed has indeed been collected, and in an appropriate way (standardized)
- there are no unnecessary data collected that will never be analysed
- this plan for data analysis must be prepared before the data are collected in the field.

Systematic quality control of the data

- Checking the data in the field to ensure that all the information has been properly collected and recorded.
- Rechecking information for completeness and internal consistency before and during processing.
- Inconsistency, due to a mistake in recording; the answer may be possible to correct by checking it with the researcher.
- Inconsistency—not clear as to who is responsible; it may be possible to return to the respondent and ask for clarification.

Summarizing the raw research data

The raw research data should be summarized in an efficient way to facilitate data analysis. If the study is small, you may tally, by hand, all answers on a data master sheet. Master sheets help you to make tables, which describe the study population more easily than do the original questionnaires (see Annex 1, Form 1).

Data analysis

Commonly used computer programmes that are helpful in the analysis of data are EpiInfo (www.cdc.gov/epiinfo), SAS (www.sas.com) and SPSS (www.spss.com).

The data must be sorted in relation to the objectives of the study and the variables in order to allow further processing and analysis. Remember that study has to provide answers to the problem we are investigating. Imagine that we have conducted a study among school-aged children 8–10 years of age in order to find out who has goitre, how goitre affects their school achievement, and how iodized salt could help to reduce goitre. First of all we use the data collected to describe the population in more detail. This can be done in simple tables, which may record absolute or relative frequency distribution of the study group according to their age, sex, goitre grades, etc.

The following is an example of a survey and analysis of the findings. Table 10 shows the frequency of the study population regarding sex, age and degree of goitre.

Comparison of different groups of subjects for the same variable by cross-tabulation is more interesting than simple counts of total study population. In this example we compare goitrous and non-goitrous children for the same variable—in this case, school achievement (Table 11). Note that children without goitre have more "good" and acceptable" scores than those with grade 1 goitre. Cross-tabulation may show an association and thus a possible casual relationship between goitre and other variables. In our example, school

Table 10. Absolute and relative frequency of study participants (example)

, , , , , , , , , , , , , , , , , , ,		. ,
Variable	Number	%
Sex		
Male	260	52
Female	240	48
Age		
8	150	30
9	170	34
10	180	36
Goitre		
0	300	60
1	150	30
2	50	10
Total	500	100

grade (example)					
	School achievement				
Goitre	Good	Acceptable	Bad	Total	
0	200	80	20	300	
1	70	60	20	150	
2	10	20	20	50	
Total	280	160	60	500	

Table 11. Relationship between school achievement and goitre grade (example)

n = 500; DF = 4; $\chi^2 = 38.5$; p < 0.001

achievement would be the dependent variable; goitre would be the independent variable or risk factor.

Table 12 demonstrates the relationship between goitre and iodized salt consumption. In this example goitre would be the dependent variable; iodized salt consumption would be the independent variable.

It is extremely important to decide, before you start collecting the data, exactly what tables you will need in order to look for possible explanations for the problem you have defined. This will prevent you from collecting too little or too much data in the field. It will also save much of your time in the data processing stage.

A schedule or work plan for the analysis of data should include:

- the preparation of dummy tables for the description of the population and for the establishment of relationships between variables
- the sequence of tables to be analysed (what should be analysed first?)
- specification of the staff required for the analysis
- a decision on how the data are to be analysed (by hand, by computer, etc.)

Table 12. Relationship between goitre grade and iodized salt consumption (example)

	Goitre				
lodized salt	1	2	3	Total	
Yes	260	30	10	300	
No	40	120	40	200	
Total	300	160	50	500	

n = 500; DF = 2; $\chi^2 = 222.2$; p < 0.0001

- an estimate of the time the analysis is likely to take, and which aspects might take longer than others
- an estimate of the total costs of the analysis.

In conclusion

Data analysis usually involves an amount of calculation and/or statistical procedures. Statistical procedures allow the data, in particular in quantitative studies, to be summarized and interpreted. In quantitative studies it is advisable to consult a person with statistical knowledge from the start, in order that:

- a correct sampling method be selected
- decisions on coding are made that will facilitate data processing and analysis
- a clear understanding and agreement be reached on the planned data analysis and interpretation, including agreement on the tables to be prepared and the testing of relationship between certain variables. For this purpose, dummy tables have to be prepared.

In general, a researcher carrying out a quantitative study should have or may have to obtain some statistical knowledge in order to fully comprehend the whole process of data analysis and interpretation.

Interpreting and presenting results

Many IDD parameters are not normally distributed. Rather, the results may be highly skewed in one direction. For example, the distributions of the urinary iodine and thyroid size values are typically skewed to the right (positively skewed). The upper tail of the distribution is longer than the lower tail. In such cases, the use of means and standard deviations to summarize the data is inappropriate, and nonparametric methods should be used to summarize and compare distributions. One way to measure the spread of a distribution that is not normally distributed is to take certain percentiles. The value of the 20th and 80th percentiles (first and fourth quintiles) would be suitable, and would give a sense of the shape of the distribution of values. However, it is usual in giving the results of IDD surveys to use cut-off points to delineate the lower tail of the distribution. For example, in a frequency distribution of urinary iodine values, it is helpful to indicate the numbers and proportion below set values (typically 100, 50 and 20 µg/l). After iodine prophylaxis has been introduced, it may also be helpful to indicate the proportion of values above a particularly high level (e.g. 500 µg/l). Individual spot urinary iodine

values reflect recent dietary intake of iodine and are likely to vary greatly over time.

Note that in carrying out a survey, only a sample of individuals is examined, not the entire population. There will therefore inevitably be a degree of sampling error in the results obtained. This can be decreased—but not eliminated—by increasing the sample size, although this will cost more. The use of confidence intervals gives an idea as to the range in which the true population value is likely to lie. Confidence intervals of 95% can be calculated for a median, and should be quoted alongside the value itself. In compiling overall results of IDD surveys, for example at the national level, it is important not to simply take averages of subnational data. By so doing, the overall result obtained may be biased. Instead, the following guidelines are useful.

Results from prevalence surveys in different regions should be weighted according to population size before combining them. For example, goitre prevalence data should be adjusted by the size of the total study population. The total enrolment of all schools in the region or the total population of the region should be used to make this adjustment.

Urinary iodine values and thyroid volumes from ultrasound should be treated in a similar way. (These are both numerical variables, unlike presence or absence of goitre, which is a categorical variable.)

Results from sentinel surveillance data are not representative of national data, and therefore should not be presented as such; instead the median of medians from each sentinel district should be presented as the overall median urinary iodine from *x* sentinel districts.

Salt situation analysis

At the outset, a situation analysis should be made of salt in a country, starting from production and/or importation and then through distribution channels until it reaches the household (Figure 2). A salt situation analysis helps understand a country's salt system and identify where monitoring may be needed. Loss of iodine at any point in the salt distribution may limit the success of an enrichment programme. This analysis should include a list of major producers or importers, production/import/export statistics, salt purity, packaging, transport and storage, retail prices and the proportion of households with iodized salt. These data needs to be updated periodically according to the country situation, perhaps annually or biannually. Essentially the analysis should cover the following major areas.

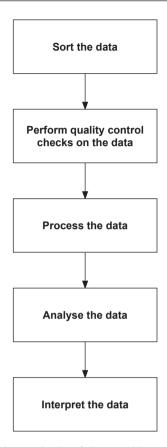


Figure 2. Steps in the analysis of data and interpretation of results

Production and importation

- List the major salt producers/importers in the country.
- Tabulate information on the quantity of salt imported or produced, status
 of processing and iodization facilities, quality assurance mechanisms,
 packaging procedures, overall salt purity and level of iodization, and cost
 considerations.
- Obtain procurement costs for potassium iodide (KI) and potassium iodate (KIO₃) (KIO₃ being the preferred compound).
- Describe the capacity of the current producers (or importers) to meet national needs for iodized salt and the input necessary to ensure this capacity.

• Overall status of annual salt production, importation/exportation and refining in the country could be presented in the following format.

Wholesale/retail/distribution practices

- Follow the distribution of salt from the point of production or importation to the point at which it is available to consumers.
- Provide information on traders and transport (including cooperatives or transport associations); major warehouse and storage practices; packaging or repacking issues; and retail outlet practices (storage and sales).
- Describe pricing issues, including government incentive and subsidy programmes, constraints to free-market pricing and marketing activities, both private and public.

Salt consumption

- Describe salt consumption patterns, including a general estimate of daily
 per capita consumption; consumer preferences for different types of salt;
 cultural practices with respect to purchase of salt; and factors affecting
 the stability of iodine in household salt.
- Review previous consumer education efforts and the capacity of the government and the private sector to influence consumer purchase of iodized salt

Legislation and political climate

- Review the current legislation and regulations affecting salt iodization.
- List the agencies responsible for enforcing regulations and procedures used to ensure corrective action is taken.
- Describe the political climate in which monitoring activities are being developed, including past advocacy efforts; the level of commitment within various sectors and by various senior political leaders; and the support of key influential groups, such as medical associations and consumer groups.

The methodology and specific objectives for a salt situation analysis will depend upon the status of the iodization programme in the country. Various stages of planning and implementing salt iodization programmes can be characterized as follows:

- non-existent
- exists but needs substantial modification.

Table 13 Recommended	action for	· different salt	indization	situations
Table 13 Necollillellueu	action for	unicient San	. IUUIZaliUII	Situations

Status of salt iodization programme	Recommended action
Non-existent	Analysis should include a survey of the extent and severity of IDD by region, analysis of salt production and distribution patterns and identification of the best point for iodization. Based on these data an implementation programme can be developed.
Exists but needs substantial modification	Salt importation, production, distribution and consumption patterns should be reviewed to identify the bottlenecks that hamper successful implementation of the salt iodization programme. Analysis should include review of the effective support measures such as quality control, social marketing, industry incentives, legislation and enforcement.
Exists but needs strengthening	Analysis should include an overview of current salt iodization procedures and the population reached, including those areas where iodization is not an integral part of salt production/distribution, and discussion of factors inhibiting sustained universal salt iodization.
Exists and is effective	Analysis should include discussion of the key elements leading to success, estimate of programme costs and staff patterns, and possible points of stress for long-term sustainability, including monitoring.

Adapted from reference [4].

- exists but needs strengthening
- exists and is effective.

The steps to be taken for these different situations are summarized in Table 13.

Control of iodine deficiency disorders

Communication, planning, political decision, implementation, monitoring and evaluation are the major components of control programmes for iodine deficiency.

Communication

A fundamental lesson learned over the past few decades in national endeavours to eliminate IDD was that a communications strategy must be an essential component of the endeavour from the very beginning. The absence of planned communications has been a significant factor in the waning support and sagging political will for work.

The principle reason for not overcoming IDD is that the ideas were not communicated to those who controlled the capacity to act, whether in government or the private sector. Moreover, information about the science and technology available was not communicated to those who could act upon it. Any attempts made to share the information were often cautious and restricted.

Communications between professional circles were restrained. The idea that representatives of medicine, health, education, agriculture, industry, communications, management and mining could share information and plans for national benefit and progress has only recently been considered and acted upon.

Iodizing salt as a way to overcome iodine deficiency disorders goes beyond food technology and supply. A key ingredient for success in any such programme is to create demand: demand on the part of the partners to participate and fulfil their role and demand by consumers to use the product. Demand and improved practices on the part of all project participants require the implementation of a strategic communications and marketing programme, which should describe the way to develop and coordinate the key roles of communications and marketing and the vision and process to complete this task.

The absence of adequate communications is directly responsible for setbacks in the elimination programmes in a number of countries. In order to sustain political commitment, community interest must be sustained and progress measured and sustained. Posting an idea on the airwaves is not a good way of communication. Social communication is far more successful.

Lessons learnt

In the planning of communications it is necessary to understand that to possess information is power. Lack of information is a facet of underdevelopment. Sometimes there is a reluctance to share information since it means sharing power.

Communication is still confused with media transmission of information, public education campaigns and project support activities. All of these are useful methods of supporting a project with materials and visual aids to describe something beneficial we are about to do for people. Communication includes and uses all of those tactics in a strategic comprehensive plan to inform the public of the problems and dangers; of the prospects for progress; of action to be taken; of the methods of measuring progress. It requires communication horizontally between and among professional groups, government agencies, private industry and communicators. It requires interpersonal communication between each of these and other officials in the process. It requires vertical communication from people to programme managers through knowledge, attitude and practice studies and demand for good health and good products as well as vertical communications between ministries and the private sector to satisfy public demand.

Assessment of the national magnitude of an IDD problem should include assessment of resources available to address the problem.

Communications are integral to all action: to ensure understanding of the problem; to understand the role of each agency; to understand the need for consultant quality control and assurance procedures, processes and products; and to sustain the need for financial and other support once a programme has begun.

Ignorance of the magnitude of a problem on the part of a government is a serious issue arising from poor communication between officials and those who have the knowledge and information. Essential health information is made needlessly complicated and even elusive and obscure due to poor communication.

Professional communicators are required for the work from the beginning of the situation analysis through the application of the intervention and to the monitoring of results. Public officials and scientists may not be fully comfortable working with communicators, especially in the public sector.

But evidence has shown the value of any collaboration once the roles are understood and mutual professional respect is attained.

Professional communicators can best assist in stating the objectives of communication and selecting the strategy, developing and field-testing the messages, developing training techniques and testing them, redesigning if necessary, and monitoring.

A communication plan and strategy for any national endeavour should begin with the recognition that the success of the venture is not dependent upon the ministry of health alone. Success requires full participation of multiple organizations both from the public and private sectors. Various governmental departments including health, education, industry, finance, mining, planning, agriculture and commerce, which require executive, legislature and judiciary support are involved. In the private sector the salt industry, packaging industry, communication outlets and media must be taken into account. Traditional forms of communication should also be enlisted. Religious leaders should be approached and invited to collaborate.

Communication planning

In any communication plan the following topics should be taken into account:

- Objective: What do you want to achieve from the communication activities?
- Audience: Whom are you addressing?
- Key messages: What do you want your audience to be informed of and act upon?
- Implementation strategies: How do you plan to transfer the key messages?
- Intervention: How will you intervene/implement the intervention?
- Monitoring and evaluation of the communication plan which will cover:
 - content analysis of news stories and coverage
 - frequency of news coverage or events
 - increase in public awareness
 - policy change
 - consumer demand.
- Crisis management: What should be done if something goes wrong?
- Indicators: What events show that you are on track and on schedule?

Resources, budget, people and equipment: What can be afforded?

In the final analysis of the plan, five major questions should be answered, though in different ways.

Organization and management: How is communication to be managed?

The following points define the organization and management of any communication project.

- State who will handle the marketing work; is it the government or private sector or is any other agency to be hired?
- Define the key roles to be developed and coordinated. Will the government, centrally, coordinate and develop these roles, or is this the responsibility of the private sector or the combined effort of both? The vision and process used to complete the task should also be defined.
- Outline the organization framework for communications and marketing.
- Define the party to be held responsible in case of any adverse effect, such as an increase in salt consumption per household, occurring.

Some part of the work may be allocated to the private sector (salt iodization); for the rest, the government or other party responsible for the IDD programme would be responsible for communication; the communication plan must contain agreements between the major players with respect to allocation of duties.

Programme communication among the partners should also be taken into account. Notification, by circulars, of new decisions, developments and reviews must be clear. Laws related to iodization level, labelling, etc., should be communicated to all salt producers to ensure their compliance. The kind of documentation and the responsible organization/ministry to circulate these documents among partners must be defined.

Audience segmentation: Who is the audience?

It is important to know who the audience is in order to choose the appropriate way to transfer information. This will include market analysis. The iodization programme naturally targets the entire population, especially children and pregnant women. The present status of the programme should be defined as should the goals and the expectations after the programme is in place or has become sustainable. Consumer preferences should also be considered.

The communication/advocacy activities among partners of the programme (private sector, governmental sector, public health groups, consumer groups, scientists, etc.) should be defined. Consumer groups and potential beneficiaries should be defined. Consumer behaviour should also be addressed. The consumer should be able to differentiate between iodized and non-iodized salt. Information transfer must not encourage increased salt consumed daily, based on the belief that it benefits the body. Ways to monitor key behaviour and attitudes need to be identified and monitored over time.

The insight and perception of politicians is important in converting a programme into one that is self-financing. Information should hence be transferred to them in such a way as to assure their support.

Communication plan: How will you reach your audiences?

Define the way information will be disseminated and what type of demand you want to create to ensure the sustainability and public health impact of the programme.

Describe the process of strategy development and stakeholder consensus about the communication and marketing programme by defining the people responsible for transfer of this information to the consumers, their training and support, and the types of communication products and processes.

Outline the communication activities necessary among salt iodization partners in order to ensure the support of the programme.

Demand generation: What do you want your audience to do?

Your expectations from consumers will be outlined here.

Barriers: What are the barriers that could hinder the programme?

Barriers that could hinder achieving the goals set by an IDD control programme, such as cost, barriers in using iodized salt, consumer behaviour, adverse events (iodine-induced hyperthyroidism in long-standing goitres), lack of consumption of iodized salt, price, availability, taste and at times dietary beliefs, should be mentioned.

The manager should enlist help from scientists, international organizations and local authorities to deal with adverse events. For example, in well executed IDD control programmes iodine-induced thyrotoxicosis is rare, and if it occurs

it is transient and subsides two years after implementation. These facts should be communicated to the people and stakeholders of the programme.

Communication not only puts people in touch with each other, but builds partnerships of trust, which ensures sharing of essential information

Planning

In most populations, the introduction and use of iodized salt will be the primary intervention for eliminating IDD. For universal (nationwide) salt iodization (USI) to be effective, the salt reaching households must have adequate iodine, and the entire population must consume the salt. In some populations other strategies may be needed, such as use of iodized capsules or fortification of other food items

In developing a successful and sustainable salt iodization programme, a government must create an environment that facilitates the transition to production and importation of only iodized salt for human and animal consumption. The government must work in collaboration with the private sector to establish working relationships among businesses (producers and importers), government agencies, and nongovernmental groups. The coalition requires political establishment from the leadership of public, private and civic origins and must be given a mandate to see to it that the national goal is achieved and sustained. For this to happen effectively, the coalition should have the mandate to demand information—from monitoring, for example—and to issue directives for addressing imperfections as they occur.

This collaboration can be expanded to other fortification efforts as appropriate. This collaborative effort should address a number of issues, including the following.

Supervision of legislation that will enable only salt with a specified amount of iodine content (set out in regulations) to be imported or produced (at least for households), thereby guaranteeing that only this salt is available in the marketplace.

Regulatory mechanisms phased in over time, to ensure that the appropriate level of iodine in the form of iodate/iodide is added, labelling and packaging procedures are carried out correctly, warehouse storage procedures are followed, and monitoring and enforcement activities are understood by and acceptable to all involved.

Incentives provided to importers and producers, such as supplies, equipment, technical support, training, product endorsement and cooperative marketing, as well as tax, capitalization and other more direct financial incentives, in order to facilitate compliance.

One of the most frequently asked questions on IDD elimination is why has it not yet been accomplished, despite its being easy to do. The reasons simply stated are:

- weak or absent political commitment to undertake the task
- those that could act were not informed of the problem and the means of prevention
- iodine deficiency never ranked high on the national public health agenda in most countries, because health authorities failed to comprehend the multisectoral, multiprofessional dimensions of prevention
- lack of scientific leadership and appropriate monitoring system.

It is important to keep in mind that national advocacy planning is required to combine political commitment, scientific support, communications strategy and creation of public demand into a cohesive whole; this approach is largely responsible for a successful national political commitment.

Efforts to draw attention to IDD as a problem with significant ramifications have serious competition for attention, with other issues being more easily understood. Governments undertake most public health measures with support from UN agencies. This has had some success, but actions have been limited because the key partners in any successful national endeavour were not the principal targets of the advocacy work.

A national IDD control committee should be appointed with the political authority to carry out the programme. The government should nominate the chair of this committee. The membership must reflect the various government departments involved and also the private sector. Universities must be also considered for academic and research input. The responsibility of the committee is to see to it that the IDD control programme is being developed; it ensures that progress is continuous by reviewing and acting upon information from progress reports.

National advocacy meetings are vehicles to enhance the communications between groups that use different languages to communicate: the scientific

community, the commercial community and the government. The planning of such meetings requires knowledge of the political situation in each case and of how processes are undertaken. The planning of each venture demands careful selection of participants in order to assure appropriate and attendance of groups having the knowledge, groups that can apply the knowledge, and groups which can assure that knowledge is shared with those that need it. Planning demands balance between individuals that have been prominent in IDD work, those in other professions, those in government services, those in profit-making businesses, those in political life and the general public.

The planning needs to specify objectives for the correction of iodine deficiency, alternative or multiple strategies for achieving these objectives, and priorities in the light of the mutual assessment carried out during the first step in the cycle. Human and technical resources and funding requirements all must be addressed. The planning should also take into account the routes to be taken when the programme is well established. When the objectives are achieved the most important matter will be the sustainability of the programme to maintain these achievements.

The technology will be determined by the assessment of the IDD endemic. Priority is given to areas and regions with moderate or severe IDD in order to focus resources and technology.

The method to be used for elimination of IDD, both in the short term and the long term, must also be decided at this stage.

Planning must also include ways to sustain the goals set when they are reached. To this end, circulation of information coming through monitoring and evaluation will be useful. Another important issue for the national plan to control IDD is how to gather this information, who is responsible for gathering the information and to whom must it be circulated

Political decisions

A national IDD elimination programme must operate in a supportive political climate with advocacy efforts creating awareness that all populations, urban and rural, rich and poor, are likely to be affected by IDD.

Politicians and policy-makers must understand the impact of iodine deficiency on the next generation, and the adverse consequences for national development if iodized salt is not widely available and used exclusively. This understanding must go beyond recognizing goitre as the only manifestation of

deficiency, but also to include awareness of the impact of any iodine deficiency on the developing brain. The potential economic impact of an iodized salt programme for livestock should also be emphasized, such as increased yield of meat, milk and wool, as well as improved reproduction.

Political decisions are critical to the authority of a national committee and the allocation of sufficient funds and resources for a national programme. Political decisions depend on the perception by politicians that the issue of IDD is a significant one to the community.

Effective political decisions are also important in the case of receiving international aid, since the international agencies, in general, follow the health and social planning priorities set by the governments. Aid agencies can allocate resources for national IDD control programme only if governments give priority to such programmes.

In gaining political support it is important to conduct an economic analysis. In economic analysis the first step is to estimate the cost of the intervention that is being used for control or prevention. In order to control IDD, iodine would be supplemented either by an iodized salt programme or an iodized oil programme. The iodized salt programme has capital costs at the beginning of the programme, as well as annual operating costs. The iodized oil programme has no capital costs, and the operating costs are incurred every five years. The second step is to re-emphasize the notable effects of iodine deficiency on brain development of the children and the role of IDD elimination in cognitive function of young generation, and the development of given country in accordance with new millennium goals. The third step is to estimate the losses due to IDD and the costs of the disease and treatment. A major expense is the cost of diagnosing the etiology of goitre. A high percentage of these goitres are due to iodine deficiency in iodine deficient areas. At times the thyroid gland will become so big that it requires surgery; another financial burden cost added to previous ones. In addition the duration that a person is bedridden or hospitalized, and working days thus lost, should be added to the above figures.

Therefore, one main objective in the economic evaluation of IDD control programmes is to calculate the costs of the salt programme and iodized oil programme for a given year. The next step is the identification, measurement and evaluation of the consequences of the prevention programme adopted. Hence consequences related to preventing IDD can be classified as follows:

- those related to changes in the physical, social or emotional functioning health effects
- those related to the change in resource use—costs averted and productivity gains
- those related to the change in the quality of life of patients and their families

The averted costs to the government health care system are in the form of reduced treatment costs associated with the prevention of IDD. The productivity gains are measured by the human capital approach, in which the health care programmes are viewed as an investment in people. This investment enables people to be more productive and to increase their material well-being. The increase in productivity associated with better health status, therefore, is a kind of benefit.

The full consequences of IDD go far beyond the cost averted and work time lost, which cannot fully be assessed monetarily and are the only ones that enter the cost-benefit analysis.

As a whole, the costs of diagnosis and treatment of goitre due to IDD are almost negligible. Endemic cretinism will disappear, and a rise in IQ will be seen. Neurological, mental, auditory and speech capabilities and also skeletal growth will improve, resulting in increased work ability, reduced costs due to reduced absence from work, reduced grade repetition at school and higher achievement by students. The benefits are not restricted to human beings alone. In livestock these improvements can be seen as increases in the number of live births, higher birth weights, fewer deformities and thicker wool coats in sheep; higher output of meat and other animal products, and a higher animal work output.

It is of great importance to recognize the need for re-advocacy of political decision on a periodic basis, as decision makers are exposed to many problems and solutions and they may be replaced, therefore, the drive for IDD may decrease

lodine supplementation

The objective of any iodine supplementation programme is to correct iodine deficiency as quickly, effectively and economically as possible. In concept, both the problem and its solution are straightforward—people are iodine deficient and need to receive more iodine. The challenge today is to

determine how the available knowledge can be applied towards establishing systems that can deliver iodine to the entire population on a continuous and self-sustaining manner.

Salt is the most ideal vehicle for iodization. Prompt implementation of salt iodization is easy in some countries where there is controlled access to high quality salt and a receptive government. It may be tortuous in others, as at least several years may be required to overcome logistical, political and economic constraints. In such countries an aggressive drive for salt iodization should be pursued, but at the same time alternative measures for prompt and temporary correction of iodine deficiency had been employed. Iodized oil, bread and water, iodine drops or tablets and fortification of other foods have been used in various circumstances, of which iodized oil is the most acceptable, practical and economical vehicle in very special conditions that need early control of IDD [5, 6].

Precautions for iodization. Iodine deficiency is associated with the development of thyroid function abnormalities and all can be prevented safely by iodized salt consumption. The effect of iodine on the thyroid gland is complex. The relation between iodine intake and risk of thyroid diseases is U-shaped meaning that both low and high iodine intake may be associated with increased risk of thyroid function abnormalities. It is stated that normal adults can tolerate up to about 1000 μg iodine/day without any side effects. However this upper limit of normal is much lower in a population that has been exposed to iodine deficiency in the past. The optimal level of iodine intake to prevent any thyroid disease may be a relatively narrow range around the recommended daily intake at 150 μg .

The possible side effects of iodine excess are goitre and iodine-induced hypothyroidism, iodine-induced hyperthyroidism, and iodine-induced thyroiditis.

It must be borne in mind that in a well executed IDD elimination programme, side-effects will not occur. Iodine-induced hyperthyroidism and other adverse effects can be almost entirely avoided by adequate and sustained quality assurance and monitoring of iodine provision that should also confirm adequate iodine intake. Careful management of any prophylactic health programme is the key to its ultimate success, and the IDD elimination programme is no exception.

Universal salt iodization (USI)

In 1990, 71 heads of state came together at the World Summit for Children in New York in order to discuss and set health and social development goals that could be achieved by the turn of the century. The virtual elimination of IDD was one of those.

Salt iodization was identified as the main intervention to deliver iodine on a continuous and self-sustaining basis and in a suitable amount. When salt becomes the major vehicle for providing iodine to the whole population, USI or universal salt iodization has been achieved. USI involves the iodization of all human and livestock salt, even the salt used in the food industry. Adequate iodization of salt will deliver the recommended amounts of iodine to the population on a continuous and self-sustaining basis. WHO/UNICEF/ICCIDD approved a cut-off point of 20–40 ppm for iodine in salt for USI.

It should be noted that as salt consumption decreases, it is essential that all salt consumed by a household be adequately iodized.

The iodization process

The production of common salt is one of the most ancient and widely distributed industries worldwide. Salt is produced by mining solid rock deposits or by the evaporation of seawater, lakes or underground brines. The salt is then ground to a powder or refined before being packed and offered for sale. The purity of salt varies over a wide range depending upon the source, method of manufacture and refining techniques employed. In developed countries and some developing countries, salt is refined in modern automated plants. In other countries, salt production is essentially a cottage scale operation, resulting in a great number of small-scale producers.

The process of iodization consists of mixing salt with a determined quantity of a compound of iodine, usually potassium iodide or iodate. The iodine compound could be mixed in a dry form or sprayed on salt using in solution. Potassium iodate is the compound of choice, being more stable than potassium iodide. The equipment required consists of relatively simple measuring devices, sprayers, feeders and mixers.

Salt production and distribution

Salt producers are often a heterogeneous group consisting of private companies, cooperatives and individuals which may be operating outside any legal or administrative framework.

Multiple small salt producers and erratic distribution patterns make management of the programme difficult.

Primitive methods of production lead to poor salt quality, for example, uneven distribution of iodide with large crystals and impurities, which affect iodine retention in salt. Visible impurities cause householders to wash salt before cooking, resulting in the loss of virtually all iodine.

Inadequate packaging, for example in jute rather than high-density polyethylene, aggravates iodine losses during transport, handling and storage.

There are several approaches to these issues.

A health code (temporary production code at the beginning of the programme) could be given to all producers provided that they change their production line to produce iodized salt.

Small firms could be brought under a system of registration by which they should periodically report to the appropriate local government authority.

Wherever possible, the small manufacturers could be organized into cooperatives for producing and marketing their salt. If the small-scale producers are dispersed, the iodization and marketing of the iodized salt alone could be done on a cooperative basis.

Technical and financial assistance should be made available to plan for and help upgrade the technology of production and processing of salt in a way that makes iodization easy.

Strategy for effective salt iodization

The preparation of iodized salt is only the first stage of the social process by which it eventually reaches the consumer. The likelihood of an effective salt iodization programme depends, in particular, on the salt production and distribution process. This needs to be analysed carefully prior to the initiation of a programme. It will enable the incorporation of the iodization process with the minimum disruption of the existing system of salt production and distribution. Every successful iodization programme depends on a number of support measures to enhance its effectiveness.

Monitoring of the iodine content at the production site, the final distribution point and at consumer level is necessary in order to ensure quality control. Delays in transit and exposure to heat (which will cause loss of iodine by evaporation) and moisture will cause variation in the concentration of the iodine available for consumption. The control of the iodine concentration in salt at production level should be performed using the titration method. In the case of imported salt, the iodine level in salt should also be measured using the titration method, though at times, because of certain restrictions, reliable test kits at the point of entry may be used. In the latter case, consignments with suspect iodine levels should be rechecked by titration.

National monitoring programmes should include monitoring to carry out the following activities: monitoring periodically salt iodine levels in retail shops and households using reliable test kits, and measuring regularly urinary iodine content. In order to determine the proportion of households using adequately iodized salt in a large geographic area, it is recommended to use cluster surveys at provincial or national levels. It is also recommended to

identify high-risk communities, or "hot spots", where there are an inadequate proportion of households using adequately iodized salt.

An effective programme requires legislative and enforcement measures in addition to quality control. However, public awareness and publicity is also necessary so that there is a demand for iodized salt. If the iodization of salt for human use becomes mandatory, this part is of little significance. But in the case of a dual market, it is necessary to make the public aware and raise such a demand.

Present status of iodized salt programmes

Iodized salt was first introduced in Switzerland and the USA in the 1920s, when it was shown to be a successful intervention. New Zealand followed in 1941 but only very low levels were used in the first 20 years. In the 1950s and 1960s a number of European countries followed with the expected benefits.

In general, iodization of salt was a simple procedure in these countries because the salt industries were large operations with automated refining plants. The addition of iodine was possible at very little extra cost and production could be readily achieved.

It was with confidence from this experience that salt iodization programmes were initiated in several central and south American countries. In Guatemala, Colombia, Argentina and Chile considerable progress was made with the control of IDD. However, in Bolivia, Ecuador and Peru the IDD problem persisted, revealing that the initiation and successful maintenance of a public health programme is strongly dependent on political stability.

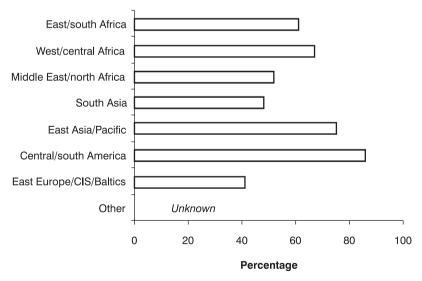
However, there have been great difficulties in transferring the successful results with a population of thousands to a population of millions. A failure to achieve an effective programme in any country can have an adverse effect on neighbouring countries, especially those depending on salt importation. Monitoring is also another issue in maintaining an effective IDD elimination programme.

It is estimated that approximately 60% of the households in the world use adequately iodized salt. The greatest progress towards USI has been observed in south America (86% of households), followed by east Asia and the Pacific (75%) region and west and central Africa (67%). Eastern Mediterranean countries (52%) and the former Eastern Bloc has made the least progress (41%), although the use of iodized salt is improving rapidly in these parts of

the world. Figure 3 shows the situation of iodized salt consumption worldwide. These data were reproduced for a United Nations special session on children in 2002.

The present global state of USI means that the brains of at least 75 million newborns entering the world in 2002 were protected against the risk of brain damage from iodine deficiency. The documentation shows that the greatest numbers of "protected newborns" were in the east Asia and Pacific region (20.8 million, or 16% of the global total of newborns) and south Asia (17.9 million, 14%), whereas the fewest were born protected in the former Eastern Bloc (2.6 million, 2%). Since many of the most developed countries do not formally report on household use of iodized salt, the brain-protection status estimates for their newborn populations are not included in some cases.

Of the 58 million newborns entering the world without demonstrated brain protection, by far the highest proportion is born in south Asia (20.0 million or 15% of the global total of newborns). The east Asia and Pacific region (9.0 million, 7%) and east and south Africa (5.0 million, 4%) rank second and third.



Source: United Nations Special Session on Children, 2002

Figure 3. Household iodized salt consumption in various parts of the world

Large countries (greater than 0.5 million newborns per year) with recent survey data (year 2000 or later) and a high percentage of household salt iodized (≥ 90%) include Kenya, Sudan and Uganda in Africa, and Mexico in Latin America. Though without recent data, Nigeria (Africa), Islamic Republic of Iran and China (Asia) and Argentina, Brazil, Colombia, Peru and Venezuela (South America) are likely in the same category.

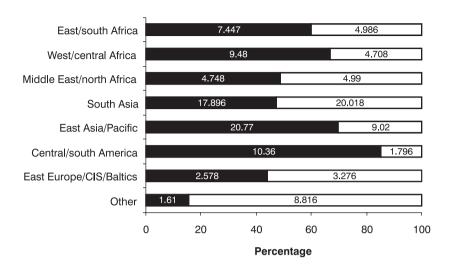
Countries with recent survey data (2000 or later) and greater than or equal to 0.5 million newborns "unprotected" each year include Ethiopia (28% household salt iodized, 1.9 million unprotected newborns), Egypt (28%, 1.4 million protected newborns), Bangladesh (70%, 1.2 million unprotected newborns), Vietnam (40%, 1.2 million unprotected newborns) and Myanmar (46%, 0.7 million unprotected newborns). Though recent survey data are not available for the following countries, best estimates indicate that they have greater than or equal to 0.5 million newborns unprotected: India (49%, 13.8 million), Pakistan (19%, 3.5 million), Indonesia (64%, 1.7 million), Philippines (22%, 1.7 million), China (91%, 1.5 million), Afghanistan (1.2 million), Russia (30%, 0.9 million), Saudi Arabia (0.8 million), Democratic Republic of Congo (72%, 0.7 million), Morocco (0.7 million), Malaysia (0.6 million), South Korea (0.6 million), Angola (10%, 0.5 million), Mali (9%, 0.5 million) and Turkey (64%, 0.5 million).

Also, a number of industrialized countries are believed to have greater than or equal to 0.5 million newborns unprotected: United States (4.3 million), Japan (1.1 million), United Kingdom (2%, 0.6 million), and Italy (3%, 0.5 million). Of these countries, only Italy is listed in the WHO literature as being "IDD affected"

Figure 4 shows the number of newborns protected from IDD by using iodized salt worldwide.

Some of the issues in the way of reaching the defined goals to eliminate IDD are as follows.

In many countries salt continues to be produced along traditional semi-agricultural lines mainly by solar evaporation of sea water, lake water or underground water in shallow ponds. Individual fields are small and worked by farmers who are not under any form of government regulation or registration.



■ Newborns protected □ Newborns unprotected

Source: United Nations Special Session on Children, 2002

Figure 4. Number of newborns protected from IDD by using iodized salt worldwide

At times the quality of salt produced is poor and sold in loose form without proper packaging. When the salt is iodized, transported and stored under humid conditions most of the iodine leaches out of the salt by the time it reaches the consumer.

Erratic and unknown distribution patterns also make it difficult to monitor the movement of salt. Iodized salt is more expensive than non-iodized salt so that poorer people who are more vulnerable to IDD are more likely to prefer the latter.

At government level legislation may be ineffective if no enforcement is in place.

Characteristics of effective salt iodization programmes

While salt iodization is technically a straightforward process, its sustained large-scale implementation requires changes within political, administrative, technical and sociocultural spheres.

Although in some countries, this process has run smoothly, others have been struggling for many years to establish effective salt iodization programmes. Information available on the experiences of various countries indicates that certain key issues have a bearing on the success of national programmes.

Political commitment

Several health and nutrition programmes compete for priority action by policy-makers. Raising the level of awareness of the problem and the effectiveness of its control within a short period through salt iodization has been an important factor in generating political will to support serious control and monitoring efforts. Awareness must be created by assessing epidemiological information on IDD prevalence and bringing the meaning and significance of these data to the attention of high-level politicians and bureaucrats. To obtain the best result this event should be initiated by both scientists and managers in a collaboration effort; producing pictures, films and documentaries related to IDD, in particular with respect to retardation of mental functioning and learning capacities.

Involvement of multiple sectors in the planning and administration of salt iodization programmes

Though the responsibility for initiating, coordinating and monitoring an IDD elimination programme rests primarily with the health sector, its planning and implementation requires active involvement of other sectors such as industry, trade, planning, transport, legislators, communicators and educators in order to implement and integrate iodization into the salt production and distribution system.

Strong advocacy with the salt manufacturing and trading community

Since the salt sector is the key player in the project, its motivation and involvement is essential. In several countries, the salt industry needs communication support and orientation, as well as technical, marketing and financial support. The commitment of salt producers to produce iodized salt will lead to the effective iodization of salt.

Well conceived information, education and communication (IEC) campaigns incorporating a social marketing approach to educate consumers, generate demand for and encourage the use of iodized salt

Consumers have to be convinced of the importance of iodine to their health. People's knowledge about goitre and other less obvious manifestations of

IDD must be addressed by educational strategies. A social marketing approach enhances the IEC component by focusing messages on the perceptions and attitudes of consumers. All in all, the content of the educational messages are restricted to a few basic ideas. The actual communication of these messages occurs in a variety of ways—print media, radio, television, traditional drama forms and face-to-face counselling.

Economic and marketing incentives

In almost all countries potassium iodate is provided free of cost to producers at least for the first three to five years of the programme. Iodization equipment and technical assistance in production and quality control may also be provided.

Monitoring of iodine levels in salt

For a successful programme frequent testing of iodine levels at iodization plants and periodical controlling at intermediate points in the distribution network, retail outlets and the household level is a must. More details will be given in the chapter for monitoring the programme.

Legislation and enforcement

Legislation is an important factor in the success of IDD elimination programmes. Enforcement of the regulations is also critical to ensure the quality of iodized salt, especially in countries with a large number of small-scale producers. Non-iodized salt identified must be collected and the producer informed or penalized based on the penalties put forward in the legislation. Legal sanctions in the form of fines and newspaper publication of noncompliant brand names are used for the purpose of quality control.

Financial and technical assistance by external donors

Financial and technical assistance by external donors has been critical to the success of initial and often ongoing efforts for salt iodization in many countries. In almost all developing countries, international financing has been responsible for the establishment of IDD elimination programmes under which salt iodization is implemented. External technical consultation and training of national technical staff involved in different parts of the programme has contributed to the development of iodization activities. External financial support for the import of iodization equipment, quality control accessories and iodine for an initial period has also been a key input. International agencies

may at times play an important coordinating role between the different sectors involved.

Programme monitoring

Monitoring procedures should be active from the outset of the iodization programme up to the kitchen of salt consumers. These systems should be able to rapidly analyse the data and disseminate it to keep the managers informed of the decisions regarding changes and corrective measures taken at different levels. The results should be communicated with all those involved.

Programme leadership

The leadership usually rests with the ministry of health. Coordination between different sectors, whether governmental or private, and supervision of the entire programme during and after implementation will be the responsibility of the leadership of the programme.

Regional cooperation

There have been agreements to ensure that all salt produced for human and animal consumption in a regional grouping of countries is iodized at source. The iodization level being at a uniform concentration is the best benefit of such regional cooperation.

Ensure national ownership for a sustainable programme

An effective, functional national body (council or committee) should be responsible for the national programme for the elimination of IDD. This council is usually formed by the minister of health and should be a multidisciplinary body involving the relevant sectors for nutrition, medicine, salt industry, education and the media, with a chair appointed by the minister of health.

Salt industry participation in IDD elimination

The salt industry has a leading role in salt iodization programmes. To have an effective programme it is necessary that the governmental sector and the salt industry work closely, to map out salt production and importation and to understand and recognize each other's points of view, concerns and interests. The provision of technical and financial support, especially at the beginning of the programme, can enthuse the salt producers in the initial phase of iodized salt production. Raising the public demand for iodized salt is also another way to make salt producers interested in investing in iodized salt production.

Implementation

Each country will have a unique solution to the sustained elimination of IDD through salt iodization, based on its particular size, economic resources, and cultural and political context and market structure. The implementation of the salt iodization programme is derived from that of the polio eradication programme and consists of assessment, attack and consolidation phases. But it should be kept in mind that in order to have a sustainable IDD control programme all these phases would operate in parallel.

Assessment phase

- Complete a situation analysis.
- Establish an understanding of the nature of the problem: brain development instead of goitre; its geographic distribution (urban and everywhere instead of just rural); and its magnitude (loss of cognitive capacity in all developing brains, not just causing cretinism and severe mental retardation).
- Attain high-level multisectoral sponsorship for the programme.
- Prepare or update legislation and regulation.
- Collect key information for an advocacy and marketing campaign.
- Mobilize the salt importers, producers and traders, and strengthen public/ private cooperation.

Action phase

- Establish the mandate and regulatory environment to ensure implementation
- Establish the capacity of producers and distributors to begin iodization of all salt.
- Implement a marketing plan.
- Phase in monitoring activities to ensure that adequately iodized salt is being produced and reaches households.
- Use action teams to find problem areas and implement solutions to these problems.

Consolidation phase

• Amend regulations to phase in quality standards for iodized salt.

- Move to more routine monitoring with greater reliance on established government inspection to ensure high compliance with legal requirements.
- Undertake periodic assessment at the community level to ensure that IDD elimination has been reached and maintained.
- Ensure that the programme elements are incorporated as routine activities in both government and business.

It should be kept in mind that in successful countries, start-up, action or implementation, and consolidation are parallel processes, and once an IDD control programme is started, the implementation phase and consolidation phase start together in order to make the programme well established and sustainable by the time the urgent action is complete. In all successful programmes, all of these phases have been carried out simultaneously in order to achieve the goals set; because allocation of resources is a constant struggle and not a one-time decision. We must not forget that communication is the key element in implementation, an element that is constant and needing regular renewal.

Sustained elimination phase

This is the most important phase in an IDD elimination programme. Regular, periodic and meticulous monitoring and evaluation could guarantee the sustainability of any programme, as iodine deficiency may return at any time if the programme fails.

Once a political decision is made on a national IDD control programme with appropriate allocation of resources, implementation can proceed according to the plan that has been submitted. This will involve discussion and coordination with the various sections of the health department (nutrition, family health, mental health, food and drug, environmental health and centre for disease control in the matter of immunization programmes). Training programmes on a continuous basis are needed for policy-makers, government staff and salt industry personnel, due to staff turnover. Purchases of iodized salt will need to be made. Communication issues should also be considered. Individuals come and go; other priorities may arise reducing the importance of what has been achieved. The importance of maintaining the achievements must also be emphasized in order to increase public awareness of the importance of maintaining the achievements and the dangers of programme failures. Targets need to be set, so that progress can be assessed. The best long-term action

for IDD elimination has to be outlined along with all the legislative force and political commitment needed to sustain the programme. Monitoring and evaluation measures also play an important role in the implementation plan in the long run.

Monitoring

Monitoring is the continuous collection, analysis and interpretation of data and use of the information to identify problems for correction or to help sustain sustainable activities. It provides the necessary information from which to make decisions about programme activities, such as adjustments in the iodine levels and changes in storage procedures, communication requirements, new legislation or regulations, different educational methods, budget allocation and human resources. While clinical and biological indicators such as goitre grading, thyroid stimulating hormone (TSH) and urinary iodine can be used to measure the impact of programme activities, proper monitoring of the salt iodization process followed by appropriate decisions to remedy problems will guarantee a positive impact.

Monitoring is a prerequisite for successful action where and when the responsibility for acting up on the monitoring information is vested in the mandate of a national coalition, composed of those in leadership positions and commanding the authority to make those changes.

Monitoring is done at a number of levels and should be integrated with other activities. Regardless of the stage of the programme or the political and cultural factors affecting its implementation, monitoring of activities is a prerequisite for assuring quality, success and sustainability. In countries having well established monitoring systems for other public health programmes, salt monitoring can easily be incorporated. Others have baseline information on iodine deficiency but limited development of an ongoing programme to monitor salt. In developing a monitoring plan, it may be helpful to consider different stages of programme development and phase in monitoring activities over time.

The objectives of monitoring the IDD control programme are:

- ensure that people receive and consume iodized salt in the required amounts
- manage and sustain the programme to eliminate iodine deficiency effectively, including political will, legislation and enforcement, communication, education, personnel, budgets, etc.

IDD monitoring system

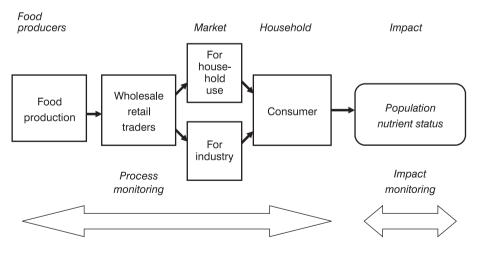
The system to monitor iodized salt consists of process monitoring and impact monitoring (Figure 5).

Process monitoring

Process monitoring is carried out in order to identify and correct problems at critical control points in the iodization programme, from production to distribution and to consumption [7]. In achieving this objective process monitoring should address the following:

The iodization programme should function as planned. This can be ascertained through:

- the amount of iodine in salt is equal to the standards of production, retail and household level (product/salt monitoring)
- everyone, in all areas, has sufficient access to iodized salt
- the target population is aware of the benefits of iodized salt (communication)
- sufficient financial and human resources are allocated to the programme
- appropriate legislation is in place and is enforced
- personnel are well trained to carry out inspections and laboratory tests



Source: Ibrahim Parvanta, Centers for Disease Control and Prevention, GAIN programme development workshop, Geneva, 2003.

Figure 5. Food fortification monitoring system

- quality assurance and quality control laboratories are well equipped in order to ensure correct reporting
- the percentage of the population consuming iodized salt has reached the level foreseen (over 90%).

Process indicators

Process indicators measure the condition of progress of an IDD control programme by monitoring and evaluating the salt iodization process. The iodine content of salt can be monitored at the site of production, port of entry, point of final packaging, retail level and community level. The first site is the most important of all, because if the results show that the salt contains the desired amount of iodine, it may be concluded that salt at other sites is also sufficiently iodized. Therefore, a salt map should be drawn, and major producers or importers should be identified and monitored to save time and effort. However, in a good monitoring system, evaluation at the final packaging and at retail level adds better control to the programme. Household iodized salt consumption is the most important process indicator. In a successful IDD programme more than 90% of households should consume adequately iodized salt.

Impact monitoring

This will ascertain whether the iodine status of the population has improved according to the trend of IDD prevalence and the population protected against IDD.

Outcome (impact) indicators

Outcome (impact) indicators provide a measure of IDD status and include both clinical and biochemical indicators, which help in monitoring and evaluation of the impact of salt iodization on the target population. The most important biochemical indicator is urinary iodine (UI) level. Sustained normal UI confirms normal iodine status of a population and elimination of IDD. Another biochemical indicator is serum TSH > 5 μ /L in less than 3% of newborns, which may be considered in countries with screening programmes in operation for congenital hypothyroidism.

Clinical indicators (goitre size by palpation or ultrasonography and cretinism rate) may add interesting results to a monitoring programme. But due to their low precision and the time it sometimes takes for the changes to become evident WHO/ICCIDD/UNICEF have omitted these indicators from the monitoring plan of any IDD control programme.

In both process monitoring and impact monitoring the following topics should be addressed in order to make good use of the information collected.

- What information/data should be collected?
- Who should the data/information be collected from?
- Where should these data be gathered?
- How will the party/person responsible gather these data?
- Who should collect the data/information?
- When and how often should these data be collected?

Product monitoring indicators

In order to make sure of the product with the appropriate amount of iodine is reaching the population, salt will be monitored at different stages of production, importation, production, wholesalers, retail and household level (see Annex 1, Form 2).

Monitoring at the point of importation

Monitoring imported salt depends upon national legislation and regulations, and guidelines for importers should be developed. Some countries will require imported salt to contain a certain level of iodine, whereas in others non-iodized salt may be imported and then iodized within country. In both situations it will be important to monitor points of entry. Although in some countries trade is informal and passes across borders that are not controlled, in most cases salt is imported by rail, ship or road. Importers must ensure that all salt meets the criteria stipulated in the purchase orders.

The responsible government ministry (ministry of health or ministry of industry) should authorize an agency to check all imported salt in order to determine if the incoming shipments meet government standards. Once verified by appropriate authorities, the shipment is granted a clean bill of findings and is cleared for distribution. If non-iodized salt intended for human and livestock consumption is allowed into the country, steps should be taken to ensure that it is shipped to an iodization plant and that the same quality control procedures are followed as are used for iodizing domestic salt.

Producers, importers and regulatory agencies should jointly develop requirements to cover such situations where imported salt fails to meet government specifications. When a shipment is found to be of inadequate quality, the government may take any one of the following actions:

- attempting to have the problem corrected at the expense of the shipper
- publishing information on products (salt brands) with unfavourable inspections
- restricting or revoking import licenses
- imposing civil fines as designated in national regulations.

In exceptional circumstances confiscating salt which is of poor quality (and arranging for re-iodization) and imposing criminal penalties may be implemented.

Monitoring at the point of production

Monitoring salt at the point of production is the most important step in a monitoring plan, and is undertaken through a combination of internal quality assurance measures and external inspection.

Internal quality assurance

The manufacturers should conduct their own monitoring using the titration method, and moderate to large-scale salt producers should be urged to hire a person trained specifically in internal quality assurance. This person should be trained and licensed by the reference laboratory responsible. If a batch of salt is not adequately iodized at production level, it should be re-iodized before distribution. All results should be written down in a logbook to be situated in the laboratory of salt producing units.

From internal monitoring it is essential to know:

- whether internal quality control measures ensure that industry standards are being met, and whether the process of iodization is proceeding effectively
- whether adjustments in the iodization process are required.

Key indicators at this level are:

- number of tonnes of salt produced
- amount of iodized salt produced
- percent of food grade salt effectively iodized (meeting industry standards in terms of iodine content, packaging and labelling)
- adequacy of internal monitoring process.

Data should be routinely reported and records must be made available for government inspection.

Internal quality assurance is the responsibility of the private sector. In most instances individual producers take the responsibility. Small-scale producers can form cooperatives and contract services for monitoring their salt.

External inspection

Government inspectors, from the ministry of health or the standards bureau for example, should do external monitoring of production-level quality assurance. External monitoring should be done through unannounced, random visits (see Annex 1, Form 3). For effective external monitoring the following steps should be met:

- review legislation and regulations
- develop a monitoring plan.

The plan differs depending on the number and size of iodized salt producers.

The overall plan should describe:

- frequency of monitoring
- method of determining which producers to monitor at a given time
- methods used and the individuals responsible for each step
- corrective actions to be taken
- list of producers for inspection
- conduct of external inspection of salt producers
- recording of data
- implementation of enforcement procedures.

External monitoring provides essential information—whether internal quality control is being performed correctly and equipment is properly maintained to assure adequate iodization.

During external inspection routine reports from producers should be regularly reviewed and samples analysed. These samples are taken during random visits to factories and sent to a provincial (subnational) laboratory to measure the iodine level in the salt sample using the titration method.

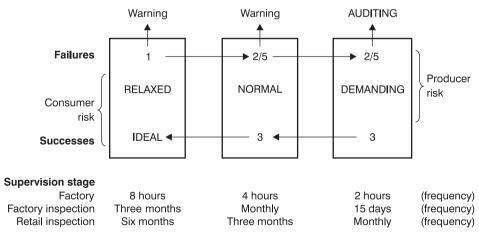
The group for external inspection will be responsible for enforcing the regulations when standards are not met.

A government, in collaboration with producers, should develop requirements that spell out the steps to be taken in the event that standards are not met. Guidelines should specify exactly what authority has been granted to the inspectors of the government agency responsible for external inspection. Reference should be made to regulations and enforcement procedures that might be called into play in order to ensure timely corrective action. This might include fines, loss of tax incentives or other penalties. The data obtained must be sent to the sector in charge of the programme, usually within the ministry of health using a simple and uniform format. The frequency and intensity of sampling for external inspection is shown in Figure 6. An iodized sample assessment form is shown in Form 3 (Annex 1) as an example.

Monitoring intermediate distribution points: wholesale and retail levels

In developing salt monitoring programmes, the wholesale and retail levels are two potential distribution points where surveys or monitoring is useful (see Annex 1, Form 4). Reasons for monitoring salt at these levels are:

 when monitoring shows adequate salt iodization during production or importation but the iodine content at household level is found to be inadequate, an investigation may identify problems at the wholesale and retail levels



Source: Dary O, Making use of American Science and Technology (MOST/USAID) Micronutrient Programme, GAIN programme development workshop, Geneva, 2003

Figure 6. Factory and retail inspection and monitoring schema (frequency and intensity of sampling)

- to assure that wholesalers and retailers store salt properly and sell salt on a first in/first out basis
- to assure that wholesalers and retailers purchase and distribute only iodized salt. Sources of non-iodized salt for human or animal consumption should be identified and actions taken to ensure that salt is adequately iodized.

Villages found to have an inadequate proportion of households using iodized salt may need to identify reasons for the inadequacy and identify solutions.

In some settings, monitoring salt in households may be difficult and therefore monitoring salt in the market may be a proxy.

In monitoring at these levels it is essential to:

- determine that the salt sold meets government standards
- determine adequacy of salt storage
- determine availability of iodized salt in market
- review iodine losses during transport and storage
- identify sources of non-iodized salt.

The salt must be tested using rapid test kits to assure of the presence of iodine in salt. Samples should be taken also to confirm the amount of iodine present using the titration method. The persons responsible in this phase should carry out the following activities according to laws and practising regulations.

If salt from a specific manufacturer is found to be inadequately iodized, through the titration method, a review of the manufacturer's internal and external monitoring records is indicated. Reviewing how the salt was transported from the manufacturer to the wholesale or retail level may also be useful in order to identify where iodine losses may have occurred.

Comprehensive monitoring can also:

- inform wholesalers and retailers of regulations and legislation regarding salt
- strengthen social marketing efforts and other educational campaigns in order to increase awareness of wholesalers and retailers about the importance of iodized salt

- encourage wholesalers and retailers to promote iodized salt
- if possible, confiscate non-iodized salt (proved through titration) from wholesalers and retailers

Measuring iodine levels with rapid test kits is used as a quantitative method just to show the presence of iodine in the sample tested. Samples taken at wholesale and retail levels will also be sent to a provincial laboratory in order to determine the iodine content of the salt sample using the titration method. This will be done routinely even if the results of the test kits reveal the presence of iodine in the sample, as these kits are not the gold standard for measuring iodine. Erroneous results may be seen when the kits are old or the wrong iodine compound is checked. In case the kit shows negative results, the result must be confirmed using the titration method. The iodized salt assessment form will also be filled at this level to determine the iodine content of the salt samples using the titration method.

Centres providing food to the public are also places to be checked to make sure that salt used in their food provided is iodized also. Such places are kindergartens, barracks, restaurants, etc. For reporting, a USI form has been designed (See Annex 1, Form 5).

Figure 7 shows a schematic representation of the monitoring process at production and distribution levels in the Islamic Republic of Iran. Modifications of the process may be needed in each country according to the specifics of programmes, laws and regulations.

Monitoring at the household level

When production monitoring reveals that adequately iodized salt is being produced in sufficient quantities, it will be essential to ascertain whether the product is reaching households with enough iodine. Essentially, there are two methods and purposes for monitoring household salt.

Coverage surveys are used to determine the proportion of households with adequately iodized salt; these surveys are most often performed at provincial or national level. This is carried out in order to determine the proportion of households with adequately iodized salt. Representative household surveys must be undertaken every two or three years, and can be undertaken as an addition to other national sample surveys (see Annex 1, Form 6).

Ongoing process monitoring is used to identify high-risk communities where too few households have adequately iodized salt; this monitoring is most

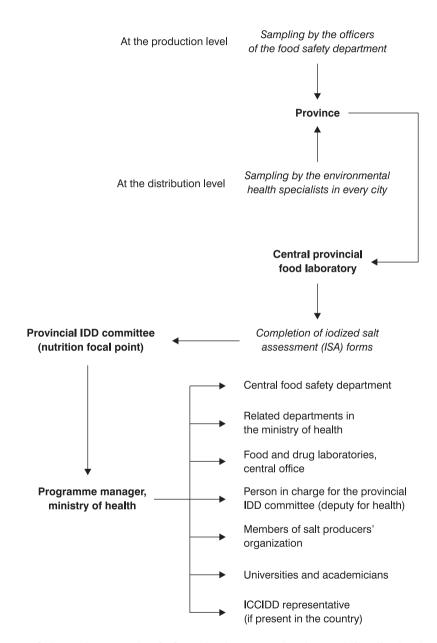


Figure 7. Schematic example of of monitoring at production and distribution levels

often done at the district level to obtain information on individual villages. Ongoing monitoring of household salt may be done more frequently to ensure that the salt iodization programme is proceeding well and reaching all areas of the country. Monitoring should particularly identify specific villages where iodized salt supply is inadequate and corrective action is required. It could also be used to determine why adequately iodized salt is not reaching households.

To ensure that a family is consuming enough iodized salt to meet the daily iodine needs of the body, personal iodine status must also be measured. To this end the urinary iodine levels of schoolchildren aged 8–10 years are measured at fixed intervals to make sure that the amount of iodine intake is sufficient. Any change in this amount should alert the national committee to take measures in order to balance the salt iodine content.

Quality control in laboratories

A quality control system should be established and maintained in laboratories, both internally and externally. This is to make sure of the validity of tests carried out by the laboratory on salt samples.

Internal quality control

Known positive iodized salt sample(s) should be obtained by the laboratory and stored in sufficient quantities for analysis every time salt titration of unknown samples is done, for example daily or weekly.

External quality control

This type of control is to supplement the internal quality control. Each year packages of salt with different levels of iodine, known only to the central food and drug laboratory, are sent to provincial laboratories to be checked for their iodine content. Results are then compared with those of the national food and drug laboratory In case of any differences seen, the provincial laboratory technician must be trained and updated.

Representative forms for quality control of iodine content of salt and urinary iodine are shown in Forms 7 and 8 in Annex 1).

Monitoring impact indicators

In order to determine if a family is consuming adequate amounts of iodized salt urinary iodine concentration is measured on a yearly basis. Although, the urinary iodine content may differ during the same day in one

person, the median urinary iodine level is a very good indicator of the iodine intake status of a population.

In a monitoring programme, the school-based PPS cluster sampling method is recommended, using 30 samples of urine from each of 30 clusters. If the survey is performed in different ecological zones, each zone should be treated separately and surveys carried out in each (see Annex 1, Form 9). Table 14 shows the relation between median urinary iodine level and severity of IDD in the country. It must be kept in mind that adequacy among schoolchildren does not give assurance that pregnant women and thus their newborns have adequate iodine status.

It must be kept in mind that although UI concentration is a good way to determine the sufficiency of iodine intake, it is an epidemiological indicator and reveals the situation in a given population. The median urinary iodine cannot be representative of the IDD status of each individual in a given community. Annex 2 provides a method for urinary iodine measurement.

Legislation and regulations

A comprehensive, well drafted salt iodization law, implementing regulations, includes monitoring activities, which support effective enforcement of legal requirements for iodized salt. Without effective enforcement, a government cannot ensure the universal availability of properly iodized salt [8].

Legal provisions on monitoring should cover two forms of monitoring.

• Internal/self-monitoring, by the salt production industry, referred to as quality assurance. With internal monitoring, the industry routinely

iodine intake	
Median urinary iodine concentration (µg/l)	lodine intake
<20	Severely insufficient
20- 49	Moderately insufficient
50- 99	Mildly insufficient
100–199	Sufficient
200–299	More than required
>300	Too much

Table 14. Relation between urinary iodine level and iodine intake

- examines its own processes and procedures in order to identify and correct any problems found.
- External monitoring by the responsible government ministry using its inspection and investigation powers. External monitoring provides a government with the information necessary to enforce the law whenever noncompliance with legal requirements is found.

Because of the integral role of legislation and regulations in a salt iodization programme, there should be coordination and integration of programme requirements and legislation. As a first step, existing food legislation and regulations should be assessed for their ability to compel the adequate iodization of salt.

It may be necessary to engage local legal experts with knowledge of food fortification and legislative and regulation drafting, because laws, legal systems and customs vary from country to country.

Once the review of the existing laws and regulations is completed, shortcomings discovered should be communicated to those with the political power to influence legislation and regulations. Any experts assisting with drafting amendments to the law should be informed.

If it is necessary to amend the existing law, sponsors must be found to introduce new legislation. Once introduced, the legislation might need lobbying for its enactment. Additionally, monitoring is necessary to watch for any amendments proposed by others that might weaken the law and thus make the programme difficult to administer.

If the law is adequate but the implementing regulations need amending, programme managers should alert the appropriate person within the ministry charged with enforcing and administering the existing law and should become involved in establishing the standards and requirements that will be contained in the regulations.

Once the law and regulations are in place, programme managers should assist in the development of clear guidelines that will help the industry understand and comply with the quality assurance requirements of the law and regulations. These guidelines should be developed in collaboration with industry, nongovernmental organizations, other ministries, and other potentially affected groups.

Provisions in the law and regulations directly related to monitoring should involve the areas of:

- quality assurance and record-keeping
- government inspections and investigations
- enforcement of legislation and regulation
- provisions indirectly related to monitoring should involve:
- standards for iodized salt, including level of iodization and other constituents
- requirements for packaging, labelling, transport and storage
- licensing or registration of manufacturers, importers and sellers, if applicable.

The law should be flexible so that as needs change, new legislation need not be enacted to amend the existing law. Introducing and passing legislation can be a very political and time-consuming process. To prevent undue constraints, the law should set out general requirements and place the details in the implementing regulations, which may be more easily enacted and amended by the overseeing ministry.

The law should require salt manufacturers, importers, transporters, distributors and sellers to undertake periodic quality assurance activities. In addition the law must give the ministry (or other appropriate body) broad authority to inspect and investigate the premises of any place where salt is manufactured, received, sold or found. The regulations can specify the procedures for inspections. The law should also specify the penalties and incentives available to a government for enforcement as well as certain enforcement procedures and protections. The regulations can provide the mechanisms and procedures for assessing penalties. Table 15 summarizes matters that can be appropriately included in laws or regulations.

Ultimately, iodized salt should meet stringent quality standards, such as low moisture content, small particle size and high purity, so that the level of iodine added to salt will be retained for as long as possible. Moreover, proper packaging is important to protect iodine content against environmental conditions that might cause diminution. However, in many countries, the salt industry is not financially or technically equipped for full-scale improvement of production and packaging activities. Thus, the salt industry might resist iodizing salt if initial standards are too stringent.

Table 15. Matters appropriately include	Regulations
Requirements for compulsory iodization of all salt intended for human or animal consumption with potassium iodate in compliance with all regulatory requirements	Potassium iodate levels at manufacture, import, wholesale and retail levels
Requirement that manufacturers, importers, retailers, and transporters must undertake periodic quality assurance activities	Quality assurance activities to be undertaken such as routine equipment and instrument calibration and sample testing of iodine content
Authority of the government to inspect or investigate any premises where salt is manufactured, imported, received, held, stored or found, or where it reasonably is believed this is the case	When the government may inspect or investigate, what the government may look at, or how the government may test salt samples
Penalties for noncompliance, including fines, license suspension or revocation, adverse publicity, or confiscation Incentives for compliance, including transport and display priority for iodized salt, exclusive use of logo, and favourable tax treatment	The circumstances under which each penalty or incentive may be applied, the amounts of fines and periods of suspension, and the procedural steps for imposing penalties

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If the salt industry is not yet fully prepared to meet new stringent standards, the government may initially require that all salt be iodized with high concentrations of iodine rather than simultaneously requiring wholesale improvements in salt production and packaging. This approach will get iodized salt out to the population relatively quickly so that IDD can begin to be addressed immediately. Once the new requirements to increase quality and purity of salt are phased in, the required iodine levels can be lowered.

Mechanics of quality assurance

Regulations should require that specific quality assurance activities examine:

- level of potassium iodate: to ensure the appropriate level of potassium iodate in the salt at manufacture, import, wholesale and retail, and the overall quality of the iodized salt
- packaging: to ensure the salt is properly packaged in bags made of nonporous material with a lining of high density polypropylene or retail packs of the proper size

- labelling: to ensure the label contains the legally mandated information, such as iodine level (expressed in ppm) and other principal ingredients, lot or batch number, manufacture and expiry date of the salt, net weight, price, identification and license number of the manufacturer, importer, wholesaler and retailers (so that noncompliant individuals can be traced), authorized use of logo and storage instructions
- storage, transport, and display of salt: to minimize losses of iodine by avoidance of direct or strong light, excessive heat, humidity or water, contamination, mixture with non-iodized salt, inadequate ventilation, excessive storage time, hooks or other sharp instruments, or stacking on any surface less than 10 centimetres above floor level.

The law should authorize the appropriate ministry to specify regulations for reporting quality assurance, such as a log of sample tests. In addition, it should authorize the ministry to regulate what should be done with improperly stored salt in order to keep it out of the human and animal consumption market.

Specific activities for quality assurance could be set out in guidelines developed by the government in collaboration with industry. Initially, the law might merely require the industry to monitor its production, packaging, labelling and storage activities, without specifying what these activities must be. Then, after the industry and government have had time to adjust technically and financially, more stringent quality assurance requirements could be set out in legally binding regulations. Input from industry will ensure that quality assurance requirements are feasible and effective.

External monitoring: government inspections and investigations

The government must have legal authority to conduct periodic inspections of salt manufacturers, wholesalers, retailers and others in the salt manufacture/distribution chain. It also must have authority to investigate complaints and suspicions of noncompliance with legal requirements.

Village health workers, consumer groups and other nongovernmental entities may be able to carry out salt monitoring activities, such as simple tests, with permission from households or stores. They also can determine the origin of defective salt and pass this information on to the government. The government then would verify noncompliance before taking any enforcement action.

Inspection and investigation authority should be vested in the most competent government ministry or agency and at different levels (local, district, provincial and national) least likely to be dominated by political influence or corruption. If political influence is likely to interfere with external monitoring, some extragovernmental oversight of the whole process might be called for.

Enforcement

Enforcement authority should also be vested in the government ministry or agency at the level of highest competence. Political interference with enforcement seems to be a universal problem that must be anticipated and dealt with in legislation and regulations.

Programme managers, government enforcers, legislative and regulatory drafters, nongovernmental organizations, and industry and consumer representatives can and should work together, both formally and informally, on the following activities:

- establishing effective and realistic quality assurance activities
- developing guidelines for industry
- sharing monitoring information
- acknowledging or rewarding good performance by businesses
- training.

A working group should be established to link the government, industry, nongovernmental organizations and agencies as a mechanism for continuous dialogue, drawing upon the expertise of each to ensure fair and feasible inputs into the system.

General framework for salt monitoring from production to the household

Once the legislation and necessary infrastructure are in place for salt iodization, a series of operational guidelines can be developed for ongoing monitoring of the availability and adequacy of iodized salt at any of the five distribution points: importation, production, wholesale, retail and household. The frequency and procedures required for collecting data at each of these points will differ.

Several factors can lead to iodine loss in the salt, including:

- purity of salt
- iodine compound used and amount added at the time of fortification
- packaging
- transportation and storage conditions
- length of distribution time
- climate.

Cultural practices such as washing salt prior to cooking, may reduce the iodine content.

Monitoring production or importation should focus on ensuring that salt meets government standards. This is primarily the responsibility of the private sector. Once salt has left the production facility (or point of importation), monitoring becomes more complex. It is important to understand whether losses are occurring during distribution, and this may require monitoring at the wholesale or retail level. Finally, coverage surveys can monitor whether salt reaching households is adequately iodized. The amount of monitoring at each level will depend on the national situation. The closer these monitoring efforts get to the consumer, the more useful the measurement, but the higher the cost. Regardless of the monitoring priorities, ultimately the impact of iodization efforts will have to be demonstrated using biologic indicators.

As the situation improves in certain areas, it should be possible to modify the monitoring plan and collect data less frequently. A general overview of the procedures for monitoring iodine levels in salt from point of import and production to household consumption is presented in Table 16 (p. 71).

Evaluation of IDD control programmes

Each control programme should be evaluated from time to time, every two to five years in order to find the rate of success or failure, problems and constraints. This will enable programme managers to take necessary measures according to the results.

Of the indicators used for IDD assessment, TGR (total goitre rate) is not suitable for evaluation of an IDD control programme, because it is not precise, varies within and between examinations; also, in an effective IDD control programme, TGR may not change for number of years following iodine supplementation. This is due to inadequate intake of iodine in

the first years of life in examined schoolchildren; and it has been shown that deficiency established in infancy and childhood may not regress with iodine supplementation, therefore, the most important process and impact indicators—iodized salt consumption and urinary iodine, respectively—be used for evaluation and monitoring of IDD control programmes.

Indicators for sustainable elimination of IDD

WHO/UNICEF/ICCIDD have agreed in principle about the most important criteria (sustainability criteria) for monitoring progress towards sustainable elimination of IDD. These criteria are shown in Table 17.

- A sustainable and well functioning iodization programme yields the following programmatic indicators (See Annex 1, Form 10).
- An effective, functional national body (council or committee) responsible to the government for the national programme for the elimination of IDD. This council should be multidisciplinary involving the relevant sectors for nutrition, health, salt industry, education and the media, with a chairman appointed by the minister of health.
- Evidence of political commitment to universal salt iodization and the elimination of IDD.
- Appointment of a responsible executive officer for the IDD elimination programme.
- Legislation or regulations on universal salt iodization (while ideally regulations should cover both salt for human consumption and agricultural salt, if the latter is not covered this does not necessarily preclude a country from being certified as IDD-free).

Table 17. Criteria for monitoring progress towards sustainable elimination of IDD as a public health problem

Indicator	Goal
1. Salt iodization	
Proportion of households consuming effectively iodized salt	≥ 90%
2. Urinary iodine	
Proportion below 100 μg/l	< 50%
Proportion below 50 μg/l	< 20%
3. Programmatic indicators (see below)	
Attainment of the indicators listed	At least 8 out of 10

- Commitment to assessment and re-assessment of progress in the elimination of IDD, with access to laboratories able to provide data on salt and urine iodine.
- A programme of public education and social mobilization on the importance of IDD and the consumption of iodized salt.
- Regular data on salt iodine at factory, retail and household level.
- Regular laboratory data on urinary iodine in school-aged children with appropriate sampling for higher risk areas.
- Cooperation with the salt industry in maintenance of quality control.
- Database with recording of results or regular monitoring procedures, particularly for salt iodine and, if available, neonatal TSH.

Global scheme for evaluation and monitoring of IDD control programmes

The proper assessment procedure and the steps for the recognition of a country must be ascertained through establishment of a set of indicators to identify the achievement of a sustained programme for the control of IDD.

As early as April 2000, a large number of countries of the Eastern Mediterranean Region together with several major salt producers recommended that WHO and UNICEF establish a procedure for regional level assessment and recognition of member countries claiming to have brought IDD under control

The global network for sustained elimination of IDD was formed in 2000 in order to make more rapid global progress towards ending iodine deficiency forever. The network will help to harmonize support activities carried out by its participants in order to assist countries effectively reach the goal of eliminating iodine deficiency disorders in a sustainable way through universal salt iodization.

The network enjoys the support of the United Nations Children's Fund (UNICEF), the World Health Organization (WHO), Kiwanis International, the Salt Institute, the European Salt Producers' Association (ESPA), the Chinese National Salt Industry Association, the Micronutrient Initiative, the International Council for the Control of Iodine Deficiency Disorders (ICCIDD) and the Programme Against Micronutrient Malnutrition (PAMM).

The mission of the network is to support national efforts for the sustained elimination of iodine deficiency disorders as a public health problem, and to ensure that all populations affected by or exposed to the risk of iodine deficiency consume iodized salt. To fulfil its mission, the network will help to harmonize support activities carried out by its participants in order to assist countries to effectively reach the goal of eliminating iodine deficiency disorders in a sustainable way through universal salt iodization.

The objectives of the network are to:

- mobilize the international community towards eliminating iodine deficiency disorders
- identify national requirements for eliminating iodine deficiency disorders
- identify resources for meeting national needs.
- assist countries in developing national plans for controlling iodine deficiency disorders and for implementing programmes to eliminate iodine deficiency
- identify consultants to assist countries in implementing programmes to control iodine deficiency disorders
- promote national coalitions for monitoring progress
- assist countries to review progress made towards universal salt iodization and in the controlling of iodine deficiency disorders.

The government of a country may initiate the assessment by requesting a review and providing needed supports (Figure 8).

So far, few countries have hosted a team of external experts to review current status of iodine nutrition and the IDD elimination programme. Reports are available and may be obtained from the network.

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Table 16. General
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lable 10. Gellelal IIal		nework for a sail informed by stering			
Decision Ievel	Information needed	Managing information	Monitoring activities done	Responses needed	Responsibility
Private sector responsi	r responsibilities				
Factory	Adequacy of salt iodine content during production and packaging Meeting factory standards Appropriate labelling reflecting iodine content	Factory owners Plant manager Plant foreman Plant operator	Internal quality assurance Facilitate external inspections by regulatory agency Visual inspection of equipment, salt processing and final product	Make adjustments to iodization process Modify packaging, labelling, storage or procurement procedures	Plant manager
Wholesaler / trader	Salt procured is iodized lodine content checked	Traders Salt wholesalers	Inspection of bags Rapid testing of iodine levels in salt Review storage and transport practices	Ensure that traders transport only iodized salt and do not accept non-iodized salt from factories Improve storage practices at wholesale site; ensure first in and first out rule	Food inspector
Retailer	Supplying iodized salt Claim iodine content at the level Affordability of iodized salt All sections of the community purchase iodized salt lodized salt is stored properly	Shopkeepers	Rapid testing of iodine levels in salt Visual check on salt quality (moisture, contamination)	Demand that only iodized salt be supplied from wholesalers Ensure fair pricing so that there will be minimal difference between iodized and non-iodized salt Improve storage practices at retail level	Food inspector

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Decision level	Information needed	Managing information	Monitoring activities done	Responses needed	Responsibility
Government	Government responsibilities				
National	lodized salt is available to all areas of the country lodine level of salt is adequate at importation and production	National IDD committee Minister of health Salt commissioner Programme manager	External quality control of imported and domestic salt Inspection of internal quality assurance records Monitor proportion of households using adequately iodized salt Price of iodized salt	Develop legislation and enforcement procedures Demand that all imported and domestic salt meets government standards Provide technical support for production and monitoring of iodized salt Support communication efforts to increase awareness of salt producers, traders, retailers and consumers, including exclusive use of iodized salt and how to minimize losses Appropriate packaging: indication of weight, ppm, expiration date, etc.	Programme manager
Provincial	lodized salt is available to all consumers The iodine level in salt is adequate at production, wholesale, retail and household level	Provincial health superintendent Food inspector	Test salt at wholesale and retail level Assist with rapid testing of salt at household level	Promote use of iodized salt Enforce legislation	Deputy of health

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Decision Ievel	Information needed	Managing information	Monitoring activities done	Responses needed	Responsibility
District	lodized salt is produced and distributed lodized salt is preferred by the consumer lodized salt is available to households Particular villages/areas have low access to adequately iodized salt	District health workers Food inspectors Peripheral health workers Community health workers	Monitor salt iodine levels Develop and impose with rapid test kits local quality control. Take samples from procedures production and distribution level to be salt checked for the exact iodine content of the salt local only iodized salt shound in the salt only iodized salt shound incompanies in crease excessive increase information, education (IEC) on how to minimize losses of iodine, programs in the salt shound in the salt in the sal	Develop and impose local quality control procedures Promote use of iodized salt Inform retailers that only iodized salt sold for human and animal consumption Information, education, communication (IEC) on how to minimize losses of iodine, proper storage, et	Ministry of health or designated focal point
Community/household	household responsibilities	•			
Community/ household /	Community/ Salt with adequate household / iodine level purchased	Community groups Household members	Inspect packet label	Demand retailer to stock Ministry of health or only iodized salt designated focal poi	Ministry of health or designated focal point

Community/h	Community/household responsibilities	•			
Community/ household / school	Salt with adequate iodine level purchased and consumed lodized salt is more expensive than noniodized salt or not lodized salt labelling is adequate	Community groups Household members School teachers	Inspect packet label	Demand retailer to stock Ministry of heal only iodized salt designated focult wolve community leaders / community groups in efforts to ensure availability and quality of iodized salt IEC on how to minimize losses of iodine	Ministry of heal designated foce

Source: reference [4]

Framework for assessing progress towards optimum iodine nutrition

The following framework for assessing progress towards optimum iodine nutrition is designed to assist countries in determining the elimination of IDD as a public health problem.

Rationale

The reasons to assess the iodine status of a country can be one or several of the following:

- when a country has reached or is close to reaching optimum iodine nutrition through USI
- to assess progress made towards optimum iodine status;
- to reappraise the problem
- to suggest new approaches.

Assessment

The following steps are to be taken to initiate and continue the assessment process.

Step 1

The Regional Directors of the Eastern Mediterranean Region of WHO and UNICEF inform ministries of health about the review of the IDD situation in the countries of the Region and enquire about the interest of the countries of the Region in independent assessment and recognition.

Step 2

Establishing the Eastern Mediterranean Network for Sustained Elimination of IDD (EM/Network) inclusive of the following:

- UN agencies (FAO, UNICEF, WFP, WHO)
- bilateral agencies
- nongovernmental organizations (ICCIDD, Micronutrient Initiative)
- donor foundations (AGFUND/Kiwanis, Micronutrient Initiative)
- salt producer associations.

Step 3

A review schema of the IDD situation based on a stepwise framework is shown in Figures 8 and 9. The request will be transferred to the network by UNICEF an/or WHO office of the country, and if agreed process of review will be initiated by identification of external team (Figure 9).

Information needed to submit a request comprises:

- iodized salt consumption and urinary iodine excretion data from population-based surveys (preferably nationally representative) in the past two years
- laws and regulations, and inspection and enforcement processes for USI and some indication of practices and results
- salt importation and production, iodization process and distribution, lists of major companies, prices of products and market situation
- monitoring system
- laboratory facilities (type and number of laboratories and annual number of samples processed)
- programme infrastructure, oversight committee, staff, budget (sources of funding, part allocated by government, cost of iodate)
- IDD committee: members, plan of action incorporated in national development plan, ministry responsible)
- political commitment for sustaining optimum iodine nutrition and current communication programme
- activities by civil society in support of USI and iodine nutrition; education sector, agriculture sector, publications.

Once the request is ready it has to be assessed and approved. The request is submitted to the WHO and/or UNICEF country office. If it is approved, the request is forwarded to the EM/Network for IDD and shared with the board of the global network for review. If it is not approved, the request can go back to the government to be reviewed; the process of approval then repeats.

For appropriate forms see Annex 1.

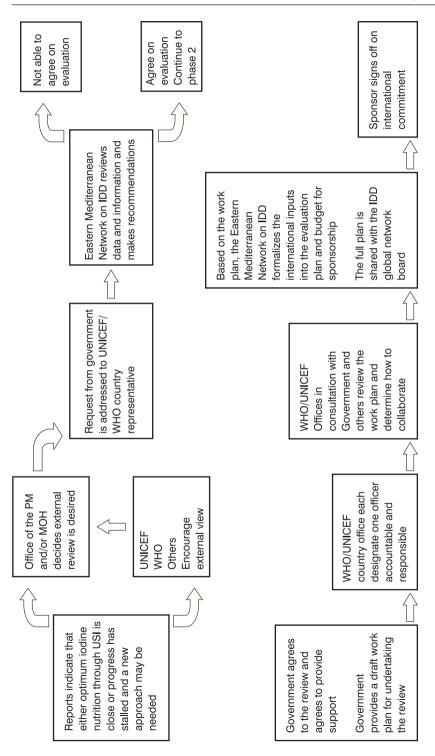


Figure 8. Development of regional assessment guidelines for assessment teams

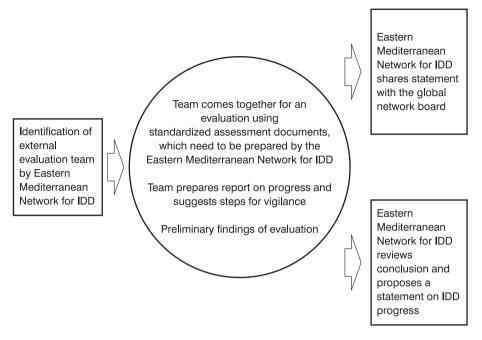


Figure 9. Review of the IDD situation

Procedures to identify the evaluation team

Principles

The evaluation team comprises two sub-teams:

- external evaluation team (EET)
- national evaluation team (NET).

EET is seconded by NET and they should both work in close collaboration during the assessment exercise

Members of EET are identified by EM/Network for sustained IDD elimination and submitted to the government (ministry of health and/or national IDD committee) for approval. The Government designates members of NET.

Composition

EET members are WHO and UNICEF staff who are international experts in the fields of:

- management of IDD control programmes
- IDD laboratories
- monitoring (salt quality)
- salt iodization
- communications
- NET members are:
- the national IDD programme manager
- the head of the IDD laboratory
- the head of the national food standards laboratory (where iodized salt quality is monitored)
- salt producers
- IEC experts responsible for IDD in the ministry of health
- WHO and UNICEF country representatives.
 - The review will include the assessment of:
- status of iodine nutrition (particularly population-based surveys measuring urinary iodine and household consumption of iodized salt)
- importation, production, and marketing of iodized salt
- status of the national programme including political commitment, legislation, inspection, enforcement, education, communications, monitoring and laboratory infrastructure and process, oversight committees, personnel and budgets.

All these will be viewed from public, private, and civic perspectives and for prospects for sustainability

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Annex 1. Forms

Form 1 Data master sheet

Province: District:		Date:	
Name of so	chool:	Urban □	
Age:		Rural □	
Number	Name	Sex (M/F)	Goitre (0, 1, 2)

Form 2 Quality control of iodized salt

Part A. Source	of iodiz	ed salt				
Internal						
Imported □						
Both						
Locally produce	ed iodiz	ed salt:				
Factory name		Location	Data a	t the sit	e of proc	luction
			Internal	control	Externa	I contro
			Yes	No	Yes	No
Imported iodize	d salt	Country	Dat	a at the	site of e	ntry
			Ye	es	N	lo
			_			
	lines (ir	nstructions) in each p			to monit	tor
iodized salt reg	ularly b	y titration method at	retail leve	l?		
Yes □	No □					
Are the results presentation?	of regu	lar monitoring availal	ble if/wher	n neede	d for	
Yes □	No □					

Form 3 lodized salt assessment at the production site

No.	Producer factory	Name of product		Sampling site		Sampling date	lodine content by	Insoluble materials
			Production	Distribution	Name of district		titration	(%)

The following measures were taken in provinces in cases where iodine levels were unacceptable:

Please check (√)	
Written warning	
Visit and temporary closure of the produ	uction line
Temporary closure of the factory	
Factory situated in another province; ca to food inspection bureau in that province	· II
Food drug inspection bureau officer	Food & inspection laboratory officer
Name & surname	Name & surname
Signature	Signature

Form 4
Assessment of iodine level and other characteristics of edible salt

Producer factory	Name of product		Sampling site		Sampling date	lodine content by	Insoluble materials	Other characteristics
		Production	Distribution	Name of district		titration	(%)	according to validated standards

Assessment: does it meet the standards	s for edible and iodized salt?
Yes □ No □	
The following measures should be tak level:	en in case of non-acceptable iodine
Written warning	
Visit and temporary closure of the produ	action line
Temporary closure of the factory	
Director-general of food and drug control association	Director-general of food and drug control laboratory
Name & surname	Name & surname
Signature	Signature

Form 5 Assessment of edible salt at retail level and public places

	Total number of samples examined	Number of iodized samples	Number of non- iodized samples
Hospitals			
Restaurants			
Food shops			
Barracks			
Factories			
Kindergartens			
Elementary schools			
Junior high schools			
High schools			

Kindergartens		,		
Elementary schools				
Junior high schools				
High schools				
Environmental heal	th officer of provinc	e/city		
Name & surname				
Signature				
Person responsible for data compilation				
Name & surname				
Signature				

Form 6 Household consumption of iodized salt

Household consumption of iodized salt (%)		
Year:		
Location(s):		
Number of samples:		
Population studied		
Investigated through		
DHS survey		
National survey		
Food consumption survey		
Testing iodized salt brought by schoolchildren at schools		
Other surveys		
Did the colour of salt change after adding the solution (rapid test kit)?		
Yes □ No □		

Form 7 Assessment of iodine content in the salt

Date	Operator	Salt weight
Salt expiration date	Producer	Salt no.

Sample ID	Thiosulfate volume	Concentration (ppm)

Form 8 **Laboratory requirements**

In the measurement of urinary iodine the existence of the following data should be considered

Date

Operator's name

Number of rounds

Sample size in each round

Concentration	Optical density (OD)
2	
5	
10	
15	
20	
30	
40	

Sample ID (at least 60 samples)	Optical density (OD)

Controls	Optical density (OD)	Concentration
1		
2		
3		

Form 9 **Urinary iodine**

Province	MUI* (µg/I)	% MUI < 20 μg/l	% MUI < 50 μg/l
National			

^{*} MUI: median urinary iodine

Form 10 **Ten programme indicators**

Tick the programme indicators that have been attained in your country

	Yes	No
National body		
Political commitment		
Responsible executive officer		
Legislation or regulation for salt iodization		
Commitment to assessment of progress with access to standardized laboratories		
Public education and social mobilization		
Regular data on salt iodine at factory, retail and household levels		
Regular data on urinary iodine in schoolchildren		
Cooperation of salt industry		
A database for recording of results		

Annex 2

Method of urinary iodine measurement

Reagents

- 1) KClO₃, potassium chlorate
- 2) HClO₄, perchloric acid 70%
- 3) As₂O₃, Arsenic trioxide
- 4) NaCl, sodium chloride
- 5) H₂SO₄, sulfuric acid, concentrated, 36N
- 6) Ce(NH₄)₄(SO₄)₄.2H₂O, ceric ammonium sulfate
- 7) H₂O, deionized
- 8) KIO₃, potassium iodate

Solutions

- 1. Chloric acid solution: In a 2000 ml Erlenmeyer flask dissolve 500 g KClO₃ in 910 ml H₂O; heat until chlorate dissolves (this may take several hours and in our hands does not always go completely into solution). Then add 375 ml HClO₄ (perchloric acid, 70%) slowly (about 15 ml/minute) with constant stirring. Store in freezer overnight. Next day filter with filter paper (Whatman #1 or similar product), preferably on a Büchner funnel. Volume of filtrate is approximately 850 ml. Store in refrigerator.
- 2. 5N H₂SO₄: Slowly add 139 ml concentrated (36N) H₂SO₄ to about 700 ml deionized water (careful—generates heat!) When cool, adjust to final volume of 1 l with deionized water.
- 3. Arsenious acid solution: in a 2000 ml Erlenmeyer flask, place 20 g As₂O₃ and 50 g NaCl, then slowly add 400 ml 5N H₂SO₄. Add water to about 1 l, heat gently to dissolve, cool to room temperature, dilute with water to 2 l; filter; store in dark bottle, away from light, at room temperature. It will be stable for months.
- 4. Ceric ammonium sulfate solution: dissolve 48 g cerium ammonium sulfate in 1 1 3.5N H₂SO₄ (3.5N H₂SO₄ is made by slowly adding 97 ml concentrated (36N) H₂SO₄ to about 800 ml deionized water [careful—

- generates heat!] and when cool, adjusting to final volume of 1 l with deionized water). It should be stored in a dark bottle away from light at room temperature. It will remain stable for months.
- 5. Standard iodine solution—1 μg iodine per ml: dissolve 0.168 mg KIO₃ in deionized water to a final volume of 100 ml. It is frequently convenient to make a more concentrated solution, e.g., 10 or 100 mg/ml, and then dilute to 1 μg/ml. 1.68 mg KIO₃ contains 1.0 mg iodine. It should be stored in dark bottle and will be stable for months. (KIO₃ is usually preferred over KI for a standard because it is more stable, but KI has been used by some laboratories without apparent problems.) Standard curves for each assay can either be prepared fresh each time by appropriate dilutions of the 1 μg/ml solution of KIO₃ or one can make individual stock solutions of the desired iodine concentrations. The following are standard dilutions: 2, 5, 10, 20 and 40 μg/dl.

Procedure

- 1. Mix urine sample to evenly suspend any sediment.
- 2. Pipette 250 μ l of each urine sample into a 13 × 100 mm test tube.
- 3. (a) Pipette 250 μ l of H₂O into 13 × 100 mm test tube, for a blank.
 - (b) Pipette into 13×100 mm tubes, $250 \,\mu l$ of each iodine standard (2, 5, 10, 15 $\,\mu g/dl$) if stocks prepared; otherwise prepare standards by pipetting from the 1 $\,\mu g/ml$ KIO $_3$ solution into 13×100 mm test tubes either 5, 12.5, 25 or 37.5 $\,\mu l$, then adding H_2O to a final volume of 250 $\,\mu l$ for each tube (this gives iodine standards of 0–15 $\,\mu g/dl$, as above). Additional standards can be prepared if desired.
- 4. Add 750 μ l of chloric acid solution to each tube (samples, blank and standards); mix gently.
- 5. Heat all tubes, for 50–60 minutes in a heating block at 110–115 °C in a hood with a perchloric acid trap. The exact time and temperature are not critical as long as all tubes are heated the same. There will be very little volume change during heating. Some samples may be faintly yellow. Cool tubes to room temperature.
- 6. Add 3.5 ml arsenious acid solution to each tube; mix (by inversion or vortex) and let stand for about 15 minutes.

- 7. Add 350 µl of ceric ammonium sulfate solution to each tube and quickly mix by vortex or other means. Use a stopwatch or other precise timer to keep a constant interval between additions to successive tubes; usually 15–30 seconds is convenient. We usually use a 20 second interval.
- 8. Exactly 20 minutes after addition of ceric ammonium sulfate to the first tube, read its absorbency at 405 nm in a colorimeter, and read successive tubes at the same interval as that used for addition of the ceric ammonium sulfate, so that the time between addition of ceric ammonium sulfate and reading is exactly 20 minutes for each tube.

Calculation of results

- 1. Construct a standard curve on graph paper by plotting iodine concentration of each standard (abscissa) against its spectrophotometer reading (ordinate).
- 2. For each sample, find its spectrophotometric absorption on the standard curve and then locate the corresponding iodine concentration on the abscissa. This is the urinary iodine concentration in $\mu l/dl$.

Temperature control requirements

The Sandell–Kolthoff reaction is highly temperature-dependent; that is, the reaction rate changes with any change in temperature. Because of this, it is important that the reaction tubes are kept at a constant temperature during the above procedure. If the room temperature cannot be kept constant for this 30-minute period, the use of a water bath kept at a constant temperature a few degrees higher than normal room temperature is recommended.

Safety requirements

It is important that proper safety measures are taken when preparing reagents and performing the assay.

Safety glasses, laboratory coats and closed in shoes should be worn at all times.

Disposable gloves should be worn when handling and pipetting urine specimens before the digestion step (step 3).

Arsenic trioxide should be handled with extreme care, and disposed of properly as required by local authorities.

Broken or chipped glassware should be discarded immediately, including test tubes, which can be easily chipped during washing procedures. Broken glassware should be collected into glassware bins, separate from other laboratory waste, and disposed of properly, as required by local authorities.

Glassware washing requirements

Before use in the urinary iodine assay, all glassware (new or used) should be soaked overnight in concentrated nitric acid, then rinsed with deionized water and soaked overnight in a laboratory detergent (note—be careful with the choice of detergent, because some detergents contain iodine, so these must be avoided). Glassware should then be rinsed four times with tap water and four times with deionized water and dried in an air oven or at room temperature. After use in the assay, glassware should be rinsed with tap water, soaked overnight in detergent, then rinsed four times with tap water and four times with deionized water, and dried as above.

Laboratory contamination problems

Contamination of urinary iodine assay laboratories can occur when laboratory space and/or equipment (especially glassware) are shared with other techniques, or the analyst does not take particular care with the method, cleanliness and reagents. The major problems occur when reagents, glassware and/or equipment become contaminated with iodine.

A common contamination problem is automatic pipettes. Improper use of the pipettes can lead to solutions being sucked into the pipette mechanism. It is good laboratory practice to thoroughly clean pipettes weekly and whenever contamination is suspected.

Of special concern is the tendency to have salt iodine analysis performed in the same laboratory as urinary iodine assay. The levels of iodine in salt are far greater than in urine—salt iodine is measured in parts per million, whereas UI is measured in parts per billion. Therefore, the analysis of iodized salt samples in the UI laboratory is not recommended. Also, the potassium iodate used to prepare the iodine standards for the assay, should not be stored in the UI laboratory.

Cross-contamination of reagents can easily occur when chemicals are shared with other laboratories, or particular care is not taken when chemicals are being weighed. Use of unclean spatulas, weighing containers or balance should be avoided.

A 0.5% (w/v) aqueous solution of sodium thiosulfate should be used to wipe down floors and benches should contamination be suspected.

References

1. WHO/UNICEF/ICCIDD. Assessment of iodine deficiency disorders and monitoring their elimination. A guide for programme managers. Second edition. Geneva, World Health Organization, 2001 (Document no. WHO/NHD/01.1).

This manual presents an overview of iodine deficiency disorders (IDD) and provides detailed instructions in the monitoring and evaluation of IDD control and prevention programmes. Health and nutrition programme staff working at the provincial, district and field levels in the public health sector will find this guide particularly useful. It may also be used by interested iodized salt producers and those involved in the formulation of health and nutrition policy and programmes. The manual provides information on the selection of appropriate process and impact indicators and techniques on conducting IDD programme assessments.

