WHO/NHD/01.1
Distribution: General
English only

Assessment of Iodine Deficiency Disorders and Monitoring their Elimination

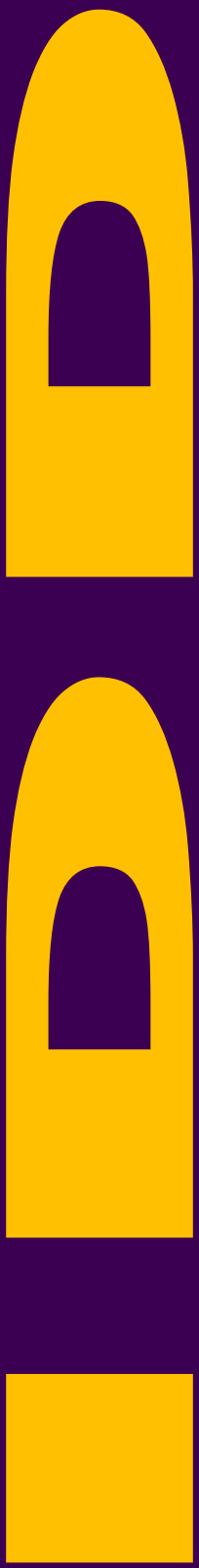
A guide for programme managers

Second edition

International Council for Control of Iodine Deficiency Disorders

United Nations Children's Fund

World Health Organization



This document is intended primarily for managers of national programmes for the prevention and control of micronutrient malnutrition.

It sets out principles governing the use of surveillance indicators in implementing the recommended intervention - salt iodization - to prevent, control, and monitor the epidemiology of iodine deficiency disorders (IDD). It also presents guidelines on the procedures for monitoring salt iodine content, whether at the factory, importation site, or household level.

Also included are recommendations on methods for monitoring iodine status and determining urinary iodine; and on the characteristics and criteria for selection of clinical and biochemical indicators, age and physiological groups, and survey sample size.

Finally, indicators are presented for monitoring progress towards achieving the goal of sustainable elimination of IDD as a significant public health problem.

Assessment of
Iodine Deficiency Disorders
and Monitoring their Elimination

A guide for programme managers

Second edition

Executive summary

Elimination of Iodine Deficiency Disorders (IDD) is a most important health and social goal. Iodine deficiency at critical stages during pregnancy and early childhood results in impaired development of the brain and consequently in impaired mental function.

While a variety of methods exists for the correction of iodine deficiency, in practice the most commonly applied is universal salt iodization – the addition of suitable amounts of potassium iodate to all salt for human and livestock consumption.

There are three major components of a sustainable programme to eliminate IDD: political support, administrative arrangements, and assessment and monitoring systems.

The provision of scientific data implies measuring progress to demonstrate that adequate amounts of iodine are reaching the target population. This requires the selection of appropriate indicators of both the salt iodization process and its impact. This manual describes these indicators and their application, and the indicators to assess whether iodine deficiency has been eliminated in a sustainable way.

The iodine content of salt is the indicator of the salt iodization process. This is accurately measured by titration. The most important place for monitoring salt iodine levels is at the production level. This is the responsibility of the producer, with verification by an external body such as the national food standards authority.

Rapid test kits give a qualitative estimate of whether iodate is present in salt, but cannot reliably determine iodine concentration. They are useful in the field for assessing whether salt is iodized, for example during household surveys. They can also be used by salt producers who do not have access to titration, as is the case for most small producers, provided that results are always backed up by titration.

The principal indicator of impact is median urinary iodine concentration. Thyroid size, as measured by palpation or ultrasound, has a more limited role because it reflects chronic rather than immediate iodine deficiency, but remains useful in the baseline assessment of IDD severity. Thyroid stimulating hormone (TSH) levels in neonates, while critical, have limited applicability in most developing countries due to cost, but are a useful impact indicator where a control programme exists.

Thirty-cluster surveys carried out in either households or schools, depending on local circumstances, are the most suitable survey method for iodine status assessment at the community level. Sentinel surveillance may also play an important role in monitoring changes in iodine status.

The sustainable elimination of IDD requires that:

- median urinary iodine levels in the target population are at least 100 μg/l and no more than 20% of values are below 50 μg/l;
- at least 90% of households are using salt with an iodine content of 15 parts per million (ppm) or more; and
- there is evidence of sustainability, as judged by the attainment of at least eight out of ten specified programmatic indicators.

Contents

Contents *(continued)*

Contents *(concluded)*

Tables

Tables *(continued)*

iv Figures

V Abbreviations

BSA	Body surface area
HDPE	High-density polyethylene
HIV	Human immunodeficiency virus
ICCIDD	International Council for Control of IDD
IDD	Iodine deficiency disorders
IIH	Iodine-induced hyperthyroidism
IQ	Intelligence quotient
ISO	International Organization for Standardization
LDPE	Low-density polyethylene
LQAS	Lot quality assurance sampling
MIHCS	Multiple indicator household cluster survey
N	Number
P	Percentile
PAMM	Programme Against Micronutrient Malnutrition
ppm	Parts per million
PPS	Proportionate to population size
SD	Standard deviation
T3	Triiodothyronine
T4	Thyroxine
Tg	Thyroglobulin
TGR	Total goitre rate
TSH	Thyroid stimulating hormone
UI	Urinary iodine
UN	United Nations
UNICEF	United Nations Children's Fund
US	United States of America
USI	Universal salt iodization
WHO	World Health Organization
µg	Micrograms (millionths of a gram)
<	Less than
>	More than

vi Acknowledgements

The World Health Organization gratefully acknowledges the participants in the consultation for their valuable contributions to this manual, in particular: Charles Todd, who has been closely associated with the development of the document; and François Delange and John Dunn, who gave a large part of their time to the revision of the manuscript. Special thanks are also due to Bruno de Benoist for coordinating the overall production of the document, and Ross Hempstead, who edited and designed the book.

vii

Preface

In 1994, WHO produced a document in collaboration with UNICEF and ICCIDD entitled "Indicators for assessing iodine deficiency disorders and their control through salt iodization" to provide guidance concerning the use of surveillance indicators for iodine deficiency disorders (IDD). Since then, a considerable amount of knowledge has been drawn from the use of those indicators in the field, and from research studies that have shed new light on their practicality and their public health significance.

For these reasons, revision of the document was considered necessary. As a first step, experts in the field of IDD were commissioned to review and update various sections of the document. The ensuing updated sections were then used as the background document for an expert technical consultation held in Geneva, Switzerland from 4-6 May 1999, with the objective of conducting a critical analysis of the revised sections and of subsequently developing a new document which would serve as a review version of the present text. That version was distributed widely to participants in the consultation and to other experts in IDD prevention and control, whose helpful comments and suggestions are reflected herein.

Salt iodization has been recommended as the preferred strategy to control and eliminate IDD. Over the last decade, intensive efforts have been made by the governments of IDD-affected countries to implement salt iodization programmes. To be fully effective in correcting iodine deficiency, however, salt not only must reach the entire affected population - in particular those groups that are the most susceptible, pregnant women and young children - but it also needs to be adequately iodized.

This process requires that mechanisms be established to ensure that iodine levels in salt are continously checked along the food chain, from the iodization site to the household. Such monitoring necessarily involves both governments and the salt industry, requiring close collaboration between the public and private sectors. Hence, this new version emphasizes process indicators, in particular those related to the monitoring of iodized salt quality control at the production and/or importation levels, and iodized salt consumption in the population.

Impact indicators are meant to monitor the effects of the intervention on the iodine status of a population, and to assess the magnitude of IDD as a public health problem. The manual recommends the use of urinary iodine to monitor a programme of IDD control, in particular of salt iodization.

However, the usefulness of urinary iodine to readjust a programme is more effective if salt is adequately iodized: ideally, it is the primary role of the process indicators - and not that of the impact indicators - to indicate that salt is adequately iodized. On the other hand, the measurement of thyroid size is meant to signal the presence of a public health problem. Blood TSH and thyroglobulin are also useful for assessing impact, but their use is still limited by the fact that most countries where IDD is endemic have low income economies that cannot afford to measure these indicators.

For each impact indicator, this manual provides information on biological features, methods of measurement and criteria for selecting those methods, and the interpretation of results. The statistical methodology employed to carry out a survey is also described.

IDD elimination is achieved only if salt iodization can be sustained. The final chapter addresses this issue, and provides criteria to determine whether a programme of IDD control is sustainable. Included in particular are adequate iodine status as defined from urinary iodine, and adequate availability and consumption of iodized salt.

The document is intended primarily for managers of national programmes dealing with the prevention and control of micronutrient malnutrition, as well as for policy makers. We hope that the information included in this manual will be useful, and that it will contribute to our common goal of the elimination of IDD.

World Health Organization

International Council for Control of Iodine Deficiency Disorders

United Nations Children's Fund

1 Introduction

1.1 About this manual

The importance of iodine deficiency disorders (IDD)

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

People living in areas affected by severe IDD may have an intelligence quotient (IQ) of up to about 13.5 points below that of those from comparable communities in areas where there is no iodine deficiency (*1*). This mental deficiency has an immediate effect on child learning capacity, women's health, the quality of life of communities, and economic productivity.

On the other hand, IDD are among the easiest and cheapest of all disorders to prevent. The addition of a small, constant amount of iodine to the salt that people consume every day is all that is needed. The elimination of IDD is a critical development issue, and should be given the highest priority by governments and international agencies.

Recognizing the importance of preventing IDD, the World Health Assembly adopted in 1991 the goal of eliminating iodine defiency as a public health problem by the year 2000. In 1990, the world's leaders had endorsed this goal when they met at the World Summit for Children at the United Nations. It was reaffirmed by the International Conference on Nutrition in 1992. In 1993, WHO and UNICEF recommended universal salt iodization (USI)[1] as the main strategy to achieve elimination of IDD.

[1] Universal salt iodization (USI) is defined as when all salt for human and animal consumption is iodized to the internationally agreed recommended levels.

Since 1990, there has been tremendous progress in increasing the amount of salt which is adequately iodized. As a result, many countries are now on the threshold of achieving IDD elimination. In those countries, the emphasis will shift to ensuring that the achievements are sustained for all time.

Objectives of this manual

Progress towards the elimination of IDD can only be demonstrated if it is measured. This requires the selection of appropriate indicators of both process and impact (*what* is measured and *why*).

Techniques are then needed to measure these indicators (*how* they are measured). These techniques have to be applied using suitable epidemiological methods (*who, where,* and *when*).

Finally, the results have to be presented in a digestible format, comparable with those from other regions or countries.

Specifically, the objectives of this manual are to describe:

- the indicators used in assessing the baseline severity of IDD, and in monitoring and evaluating salt iodization and its impact on the target population;
- how to use and apply these indicators in practice;
- how to assess whether iodine deficiency has been successfully eliminated; and
- how to judge whether achievements can be sustained and maintained for the decades to come.

Target audience

This book is aimed primarily at IDD programme managers and others in government who are involved in the implementation of IDD control programmes. It is also aimed at the salt industry and all others involved in IDD elimination.

Origins of this book

This is a revised version of the original document, which was entitled "Indicators for assessing Iodine Deficiency Disorders and their control through salt iodization" (*2*). That document was produced following a consultation held in Geneva in November 1992.

Since that consultation, a considerable body of new information on the identification, prevention and control of IDD has been generated, and the public health focus regarding this significant problem has shifted to emphasize the importance of the process indicators. To continue the battle against IDD into the new millennium, these new concepts have been incorporated into international guidelines for assessing and eliminating these disorders.

The Consultation on which this book is based was held in Geneva from 4 to 6 May 1999. It involved experts on IDD from all three partner organizations, WHO, UNICEF and ICCIDD, representing all regions of the world (see Annex 7).

1.2 Definitions

Iodine Deficiency Disorders refer to all of the ill-effects of iodine deficiency in a population, that can be prevented by ensuring that the population has an adequate intake of iodine. For further details, see section 2.

An ***indicator*** is used to help describe a situation that exists, and can be used to track changes in the situation over time. Indicators are usually quantitative (i.e. measurable in some way), but they may also be qualitative.

Monitoring is the process of collecting, and analysing on a regular basis, information about a programme for the purpose of identifying problems, such as non-compliance, and taking corrective action so as to fulfil stated objectives.

Evaluation is a process that attempts to determine as systematically and objectively as possible the relevance, effectiveness, and impact of activities in the light of their objectives (*3*).

1.3 Monitoring and evaluating IDD control programmes

Monitoring of any health intervention is essential, to check that it is functioning as planned and to provide the information needed to take corrective action if necessary. In addition, periodic evaluation of health programmes is necessary to ensure that overall goals and objectives are being met.

Salt iodization programmes, like any other health interventions, therefore require an effective system for monitoring and evaluation. The challenge is to apply the IDD indicators using valid and reliable methods while keeping costs to a minimum. To this end, it is essential to formulate clearly the questions to which answers are needed, since the methods used to gather data may be very different. Important questions that will need to be answered include:

- Is all the salt that is being produced or imported iodized to the country's requirements?
- Is the salt adequately iodized?
- Is adequately iodized salt reaching the target population?
- What impact is salt iodization having on the iodine status of the population?
- Have IDD been eliminated as a public health problem?

In some countries there is still inadequate information on IDD, and programmes have not yet been implemented. Here the questions may be:

- Is there a significant IDD problem?
- What is the prevalence of IDD in a given population?
- Where does the salt come from that people buy?

Answering these questions requires different approaches to gathering data. It is therefore very important to be quite clear about the purpose of a particular survey.

1.4 Indicators described in this manual

This manual describes the various indicators which are used in monitoring and evaluating IDD control programmes. The indicators are divided into three main groups:

- ***Indicators to monitor and evaluate the salt iodization process (process indicators)***

  These indicators involve salt iodine content at the production site, point of packaging, wholesale and retail levels, and in households.

- ***Indicators to assess baseline IDD status and to monitor and evaluate the impact of salt iodization on the target population (impact indicators)***

  Once a salt iodization programme has been initiated, the principal impact indicator recommended involves urinary iodine levels. Changes in *goitre prevalence* lag behind changes in iodine status and therefore cannot be relied upon to reflect accurately current iodine intake, although they may be useful in following trends.

  Goitre assessment, by palpation or by ultrasound, should remain a component of surveys to establish the baseline severity of IDD. Neonatal thyroid stimulating hormone (TSH) levels may also play a role here if a country already has in place a screening programme for hypothyroidism.

- ***Indicators to assess whether iodine deficiency has been successfully eliminated and to judge whether achievements can be sustained and maintained for the decades to come (sustainability indicators)***

  This involves a combination of median urinary iodine levels in the target population, availability of adequately iodized salt at the household level, and a set of programmatic indicators which are regarded as evidence of sustainability.

2 IDD and their control, and global progress in their elimination

2.1 The Iodine Deficiency Disorders

Recommended iodine intake

WHO, UNICEF, and ICCIDD (*4*) recommend that the daily intake of iodine should be as follows:

- 90 µg for preschool children (0 to 59 months);
- 120 µg for schoolchildren (6 to 12 years);
- 150 µg for adults (above 12 years); and
- 200 µg for pregnant and lactating women.

The Iodine Deficiency Disorders

Iodine deficiency occurs when iodine intake falls below recommended levels. It is a natural ecological phenomenon that occurs in many parts of the world. The erosion of soils in riverine areas due to loss of vegetation from clearing for agricultural production, overgrazing by livestock and tree-cutting for firewood, results in a continued and increasing loss of iodine from the soil. Groundwater and foods grown locally in these areas lack iodine.

When iodine intake falls below recommended levels, the thyroid may no longer be able to synthesize sufficient amounts of thyroid hormone. The resulting low level of thyroid hormones in the blood (hypothyroidism) is the principal factor responsible for the damage done to the developing brain and the other harmful effects known collectively as the Iodine Deficiency Disorders (*5*). The adoption of this term emphasized that the problem extended far beyond simply goitre and cretinism (see Table 1).

Table 1: The spectrum of the Iodine Deficiency Disorders (IDD)

FETUS	Abortions Stillbirths Congenital anomalies Increased perinatal mortality Increased infant mortality Neurological cretinism: *mental deficiency, deaf mutism, spastic Diplegia squint* Myxoedematous cretinism: *mental deficiency, dwarfism, hypothyroidism* Psychomotor defects
NEONATE	Neonatal hypothyroidism
CHILD & ADOLESCENT	Retarded mental and physical development
ADULT	Goitre and its complications Iodine-induced hyperthyroidism (IIH)
ALL AGES	Goitre Hypothyroidism Impaired mental function Increased susceptibility to nuclear radiation

The most critical period is from the second trimester of pregnancy to the third year after birth (*6*, *7*). Normal levels of thyroid hormones are required for optimal development of the brain. In areas of iodine deficiency, where thyroid hormone levels are low, brain development is impaired.

In its most extreme form, this results in cretinism, but of much greater public health importance are the more subtle degrees of brain damage and reduced cognitive capacity which affect the entire population. As a result, the mental ability of ostensibly normal children and adults living in areas of iodine deficiency is reduced compared to what it would otherwise be.

Thus, the potential of a whole community is reduced by iodine deficiency. There is little chance of achievement, and underdevelopment is perpetuated. Indeed, everybody may seem to be slow and rather sleepy. The quality of life is poor, and ambition blunted.

The community becomes trapped in a self-perpetuating cycle. Even the domestic animals, such as the village dogs, are affected. Livestock productivity is also dramatically reduced (*8*).

Identification of the occurrence of IDD

In the past, the likely occurrence of IDD in a given region was regarded as being signalled by certain geographical characteristics. These include mountain ranges and alluvial plains, particularly at high altitude and at considerable distance from the sea. This occurrence is confirmed by a high prevalence of goitre in the resident population.

However, the greater availability of urinary iodine estimation and other methods for assessing iodine deficiency has demonstrated that IDD can and do occur in many areas where none of these conditions are met. Indeed, significant iodine deficiency has been found:

- where the prevalence of goitre, as based on palpation, is normal;
- in coastal areas;
- in large cities;
- in highly developed countries; and
- where IDD have been considered to have been eliminated, either by prophylactic programmes or general dietary changes.

In recognition of the much wider occurrence of IDD than previously thought, certain countries have come to regard the whole country as being at risk of iodine deficiency and therefore the entire population as a target for IDD control by iodized salt. The need for continued vigilance is underlined, as is the importance of all countries carrying out periodic urinary iodine surveys.

2.2 Correction of iodine deficiency

An iodine deficient environment requires the continued addition of iodine, which is most conveniently and cheaply achieved by the addition of iodine to the salt supply. Most humans eat salt in roughly the same amount each day.

A decrease in salt intake can be readily met by increasing the iodine content. Where a significant amount of processed food is consumed, it is important that the salt used by the food industry in preparing such food - as well as the salt used in the home - is iodized.

Universal salt iodization, which ensures that all salt for human and animal consumption is adequately iodized, has been remarkably successful in many countries. At this stage, however, sustainability of this successful correction of iodine deficiency becomes the challenge, as iodine deficiency may recur at any time (*9*).

In some regions, iodization of salt may not be a practical option for the sustainable elimination of IDD, at least in the short term. This is particularly likely to be the case in remote areas where communications are poor or where there are numerous very small-scale salt producers.

In such areas, other options for correction of IDD may have to be considered, such as:

- administration of iodized oil capsules every 6-18 months (*10*);
- direct administration of iodine solutions, such as Lugol's iodine, at regular intervals (once a month is sufficient); or
- iodization of water supplies by direct addition of iodine solution or via a special delivery mechanism.

There is much evidence that correction of iodine deficiency has been followed by a "coming to life" of a community suffering from the effects on the brain of hypothyroidism due to iodine deficiency. Such an increase in vitality is responsible for improved learning by schoolchildren, improved work performance of adults, and a better quality of life. The economic significance of the prevention of iodine deficiency disorders needs to be clearly understood (*11*).

Education about these basic facts has to be repeated, with the inevitable changes over time in Ministries of Health and among technocrats and salt producers. Otherwise, a successful programme will lapse, as has occurred in a number of countries.

2.3 Universal salt iodization

In nearly all countries where iodine deficiency occurs, it is now well recognized that the most effective way to achieve the virtual elimination of IDD is through universal salt iodization (USI).

USI involves the iodization of all human and livestock salt, including salt used in the food industry. Adequate iodization of all salt will deliver iodine in the required quantities to the population on a continuous and self-sustaining basis.

National salt iodization programmes are now applied worldwide, and have followed a common pattern of evolution, which includes the following phases.

- ***Decision phase:*** the purposes of this phase are to enable a decision on universal salt iodization supported by industry mobilization, standards and regulation, and to prepare a plan for implementation.

- ***Implementation phase:*** this phase ensures infrastructure for iodization and packaging of all human and livestock salt, and supports that infrastructure with quality assurance, communications, regulation, and enforcement.

- ***Consolidation phase*:** once the goal of universal iodization is achieved, it needs to be sustained through ongoing process and impact monitoring and periodic evaluation; the latter may include international multidisciplinary teams.

A successful salt iodization programme at the national level depends upon the implementation of a set of activities by various sectors:

- government ministries (legislation and justice, health, industry, agriculture, education, communication, and finance);
- salt producers, salt importers and distributors, food manufacturers;
- concerned civic groups; and
- nutrition, food and medical scientists, and other key opinion makers.

Opening the channels of communication and maintaining commitment and cooperation across these various groups is perhaps the greatest challenge to reaching the IDD elimination goal and sustaining it forever.

Salt producers and distributors are instrumental in ensuring that IDD is eliminated. Protecting consumers requires that a framework be established to ensure the distribution of adequately packaged, labelled, iodized salt. The setting of this framework is the main responsibility of the government.

Ensuring a demand for the product and understanding the reason for insisting upon only iodized salt is a *shared responsibility* of the private salt marketing system, the government, and civic society. The establishment and maintenance of such an alliance and all of the associated programme elements will determine the success and sustainability of the programme.

A guideline has been developed as a useful tool to aid the review of all aspects of a comprehensive salt iodization programme (*12*). This guideline, however, will need to be modified according to the particular country situation.

2.4 Sustainability

The remarkable progress of universal salt iodization in the current decade poses the issue of sustainability. Indeed, sustainability is absolutely critical.

IDD cannot be eradicated in one great global effort like smallpox and, hopefully, poliomyelitis. Smallpox and poliomyelitis are infectious diseases with only one host – man. Once eliminated, they cannot come back.

By contrast, IDD is a nutritional deficiency that is primarily the result of deficiency of iodine in soil and water. IDD can therefore return at any time after their elimination if control progammes fail. Indeed, there is evidence that iodine deficiency is returning to some countries where it had been eliminated in the past (*13*).

IDD can only be eliminated once and for all if control programmes are constantly maintained. In other words, iodine must be provided permanently to populations living in iodine deficient environments or where no iodized food is imported.

Whether countries are deemed IDD-free, close to the goal of universal salt iodization, or still have some distance to go, the vital message is clear. All efforts must be maintained, and programmes must be sustained. Where they are weak, they must be strengthened.

Three major components are required to consolidate the elimination of IDD and to sustain it permanently:

- ***Political support***
- ***Administrative arrangements***
- ***Assessment and monitoring system***

Political support

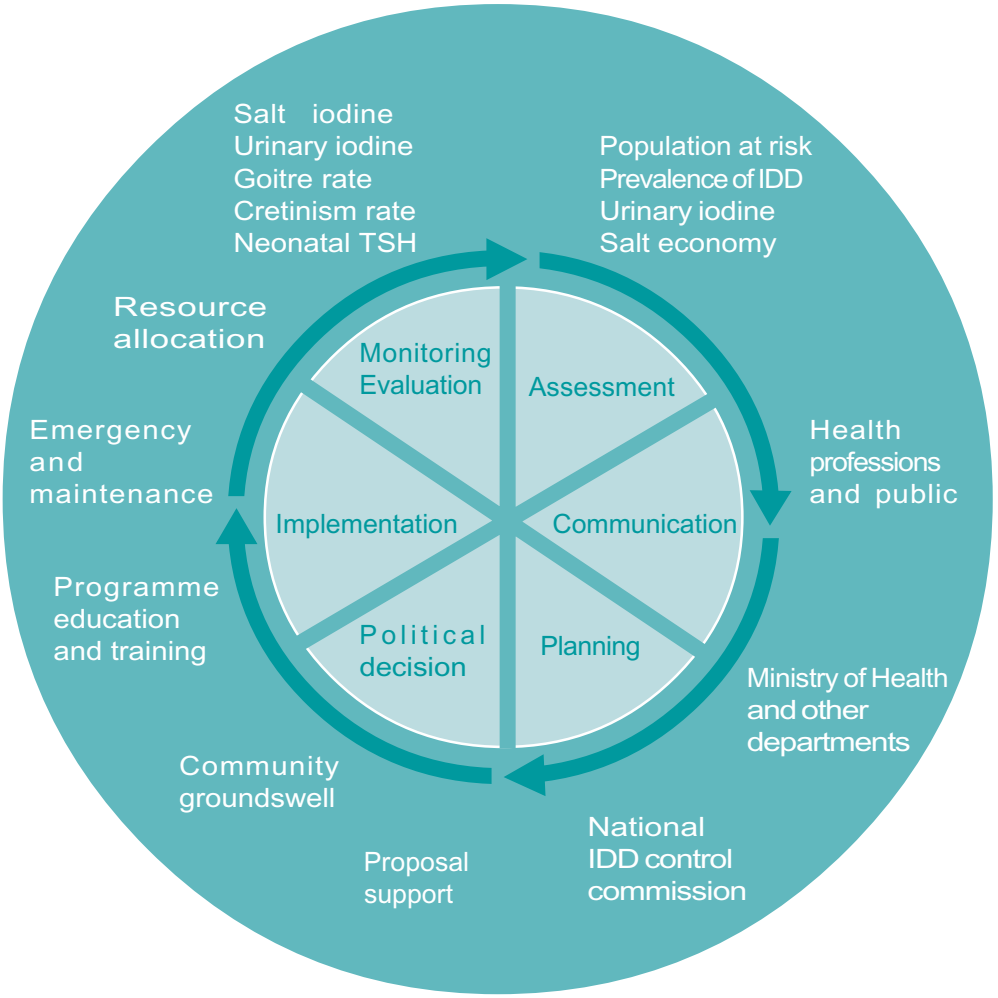
This refers primarily to support at governmental level, through the Minister of Health and the executive group of government (Cabinet or equivalent). Political support for the elimination of IDD depends on community awareness and understanding of the problem.

Without this community awareness, politicians are unlikely either to be aware or willing to act. Political support is essential for the passage of laws or regulations on salt iodization through the legislature.

Administrative arrangements

The National Body responsible for the management of the IDD control programme should operate with a process model. A useful example of such a process model is known as the “wheel” (Figure 1, following page).

Figure 1: Social process model for a national IDD control programme



Adapted from Hetzel BS, Pandav C. *SOS for a billion. The conquest of iodine deficiency disorders,* 2nd ed. New Delhi, Oxford University Press, 1996.

This model shows the social process involved in a national IDD control programme. The successful achievement of this process requires the establishment of a national IDD control commission, with full political and legislative authority to carry it out. This model, which is described in detail on the opposite page, is being followed in a number of countries.

The social process involves six components, clockwise in the hub of the wheel.

1. ***Assessment of the situation*** requires baseline IDD prevalence surveys, including measurement of urinary iodine levels and an analysis of the salt situation.

2. ***Dissemination of findings*** implies ***communication*** to health professionals and the public, so that there is full understanding of the IDD problem and the potential benefits of elimination.

3. ***Development of a plan of action*** includes the establishment of an intersectoral task force on IDD and the formulation of a strategy document on achieving the elimination of IDD.

4. ***Achieving political will*** requires intensive education and lobbying of politicians and other opinion leaders.

5. ***Implementation*** needs the full involvement of the salt industry. Special measures, such as negotiations for monitoring and quality control of imported iodized salt, will be required. It will also be necessary to ensure that iodized salt delivery systems reach all affected populations, including the neediest. In addition, the establishment of cooperatives for small producers, or restructuring to larger units of production, may be needed. Implementation will require training at all levels in management, salt technology, laboratory methods, and communication.

6. ***Monitoring and evaluation*** require the establishment of an efficient system for the collection of relevant scientific data on salt iodine content and urinary iodine levels.

The multidisciplinary orientation required for a successful programme poses special difficulties in implementation. Experience indicates that particular problems often arise between health professionals and the salt industry – with their different professional orientations. There is need for mutual education about the health and development problems of IDD, and about the problems encountered by the salt industry in the continued production of high quality iodized salt. Such teamwork is required for sustainability to be achieved.

The additional cost of iodine fortification in the process of salt production (less than 5 US cents per person per year in 1999) should eventually be borne by an educated community. This will greatly assist sustainability.

Assessment and monitoring system

It is necessary to provide adequate dietary iodine to prevent brain damage in the fetus and in the young infant when the brain is growing rapidly. Whether or not a national programme is providing an adequate amount of iodine to the target population is reliably assessed by reference to measurements of salt iodine (at the factory, retail, and household levels) and urinary iodine (measured in casual samples from schoolchildren or households). Additional contributive measurements are estimation of thyroid size and blood tests.

Measurements of salt and urinary iodine thereby provide the essential elements for monitoring whether IDD is being successfully eliminated. These measurements must be carried out regularly, according to the procedures described in this manual.

Accordingly, appropriate measures can be taken, if necessary, to ensure the normal range of intake of iodine. All these procedures require internal and external quality control in order to ensure reliability of the data collected.

In order to be effective, the surveillance system needs:

- ***laboratories***, for measurement of salt iodine and urinary iodine, which are available at the country and regional levels with some support from international laboratories for quality control: regional reference laboratories are important for sample exchange to ensure external quality control; and

- ***production quality assurance charts and databases*** at the country level, for recording the results of the regular monitoring procedures - particularly for salt iodine, urinary iodine, thyroid size and, when available, neonatal TSH.

These facilities must be backed up by the provision of adequate resources. Money, trained manpower, equipment, and materials are also required to support the implementation of salt iodization and the establishment of monitoring systems.

2.5 Global progress in the elimination of IDD

In 1999, WHO estimated that of its 191 Member States, 130 had a significant IDD problem. A total of approximately 740 million people were affected by goitre – 13% of the world's total population (*14*). Given that goitre represents the tip of the IDD iceberg (*5*), it is likely that a much greater proportion of the population suffers from IDD and, in particular, from some degree of mental retardation.

While the struggle to conquer IDD started in the early years of the twentieth century, the last decade has seen the greatest progress. That progress has been particularly rapid in Asia and Africa.

In spite of this progress, however, the estimated number of the total affected population at the global level has not changed substantially compared with the figure previously published in 1993 (*15*). The reason lies in the fact that in 1993 the magnitude of the problem had been underestimated because some of the information was not yet available.

Table 2: Current magnitude of IDD by goitre by WHO Region (1999)

WHO Region	Population *in millions**	Population affected by goitre *in millions*	*% of the Region*
Africa	612	124	20%
The Americas	788	39	5%
South-East Asia	1477	172	12%
Europe	869	130	15%
Eastern Mediterranean	473	152	32%
Western Pacific	1639	124	8%
Total	**5858**	**741**	**13%**

Source: WHO Global IDD Database (to be published).
**Based on UN Population Division estimates, 1997.*

In 1999, WHO in collaboration with UNICEF and ICCIDD reviewed the IDD global situation (*14*). Of the 130 countries with IDD, 98 (75%) now have legislation on salt iodization in place, and a further 12 have it in draft form.

Following the promulgation of legislation on salt, and the sensitization of the salt industry, there has been an enormous increase in the consumption of iodized salt. The latest data for each of WHO's Regions are summarized in Table 3.

Table 3: Current status of salt iodization coverage by WHO Region (1999)

WHO Region	Percentage of households with access to iodized salt*
Africa	63%
The Americas	90%
South-East Asia	70%
Europe	27%
Eastern Mediterranean	66%
Western Pacific	76%
Overall	**68%**

Source: adapted from WHO, UNICEF, ICCIDD. Progress towards elimination of iodine deficiency disorders (*14*).

* *Total population of each country multiplied by the percentage of households with access to iodized salt. Numbers then totalled for each Region and divided by the total population of that Region.*

This report (*14*) emphasizes the importance of monitoring for ensuring the sustainability of IDD control programmes. The latest data from the same report, concerning the status of monitoring programmes in the various WHO Regions, are summarized in Table 4.

Table 4: Current status of monitoring activities and laboratory facilities in IDD-affected countries (1999)

WHO Regions	Number of IDD-affected countries	Number of IDD-affected countries		
		monitoring salt quality	*monitoring iodine status*	*with laboratory facilities**
Africa	44	29	24	28
The Americas	19	19	19	19
South-East Asia	9	8	7	6
Europe	32	17	13	13
Eastern Mediterranean	17	14	10	11
Western Pacific	9	8	6	7
Total	**130**	**95**	**79**	**84**
Per cent	**100%**	**73%**	**61%**	**65%**

* *These figures reflect countries with the capacity for both urinary iodine and/or salt iodine level analyses. Standard of laboratories and expertise for each of these, however, is very different.*

2.6 Challenges for the future: consolidating the achievement

It is clear that, despite the great success in many countries, there remain challenges for the future.

- Continued and strong government commitment and motivation, with appropriate annual budgetary allocations to maintain the process, are essential to eliminate IDD.
- The salt industry should have the mandate and the access to resources to ensure effective iodization. Producer compliance, quality assurance, logistical problems, and bottlenecks need to be addressed through effective advocacy and social communications.

- Monitoring systems should be in place to ensure specified salt iodine content, and should be coordinated with effective regulation and enforcement.

- Small-scale producers need to be included in this process, to ensure that their products are also brought up to standard and that they deliver the right amount of iodine to the population. This is often best achieved by the formation of cooperatives or through working with a common distributor, thus reducing the need for many small iodization units.

- In some countries, salt for animal consumption has not been included in the iodization programme and is not covered by legislation. Animal productivity is also enhanced by elimination of IDD. Ensuring this salt is iodized also means eliminating leakage of uniodized salt into the market and resultant consumption by the general population.

- There are still numerous places in the world where iodized salt is not available. Identifying these areas and developing in them a market for iodized salt is critical to successful IDD elimination. This process includes creating consumer awareness and demand.

Ensuring the required daily intake of iodine to maintain normal brain function is as important as the provision of clean water. There is adequate knowledge and expertise to ensure the sustained elimination of IDD from the entire world.

Thus, an ancient scourge of mankind can be eliminated with the application of existing technology. The achievement of the sustained elimination of IDD will constitute one of the major public health triumphs of our time.

3 Indicators of the salt iodization process

3.1 Factors that determine salt iodine content

Iodization may take place inside the country at the main production or packing sites, or outside the country by importing salt which has already been iodized. Salt is iodized by the addition of fixed amounts of potassium iodate, as either a dry solid or an aqueous solution, at the point of production.

Iodate is recommended in preference to iodide because it is much more stable (*16, 17*).[2] The stability of iodine in salt and levels of iodization are questions of crucial importance to national health authorities and salt producers, as they have implications for programme effectiveness, safety, and cost.

The actual availability of iodine from iodized salt at the consumer level can vary over a wide range as a result of:

- variability in the amount of iodine added during the iodization process;
- uneven distribution of iodine in the iodized salt within batches and individual bags;
- the extent of loss of iodine due to salt impurities, packaging, and environmental conditions during storage and distribution; and
- loss of iodine due to food processing, and washing and cooking processes in the household.

[2]Potassium iodate and potassium iodide have a long-standing and widespread history of use for fortifying salt without apparent adverse health effects. Potassium iodate has been shown to be a more suitable substance for fortifying salt than potassium iodide because of its greater stability, particularly in warm, damp, or tropical climates. In addition, no data are available indicating toxicological hazard from the ingestion of these salts below the level of Provisional Maximum Tolerable Daily Intake or PMTDI, (see reference *16*).

In order to determine appropriate levels of iodization, an accurate estimate is required of the losses of iodine occurring between the time of iodization and the time of consumption. Control of moisture content in iodized salt throughout manufacturing and distribution, by improved processing, packaging, and storage, is critical to the stability of the added iodine.

A recent laboratory study (*18*) examined the effects of humidity and packaging materials on the stability of iodine in typical salt samples from countries with tropical and subtropical climates. The study showed that high humidity, coupled with porous packaging, resulted in 30-80% loss of iodine within a period of six months.

The study also determined that losses could be significantly reduced (in the range of 10-15%) by using packaging with a good moisture barrier, such as low-density polyethylene (LDPE) bags. However, longer storage - beyond six months - aggravated losses. Therefore, it is recommended that the time required for distribution, sale and consumption of iodized salt be minimized as far as possible, to ensure effective use of the added iodine.

Additional measures can be taken to retain the storage efficiency of low-density polyethylene films, in a system of high mechanical strength and resistance to puncture. Woven high-density polyethylene (HDPE) bags, with a continuous film insert or laminate of low density polyethylene, should be considered as an effective low-cost packaging method for iodized salt.

Recommendations

WHO/UNICEF/ICCIDD recommend (*19*) that, in typical circumstances, where:

- iodine lost from salt is 20% from production site to household,
- another 20% is lost during cooking before consumption, and
- average salt intake is 10 g per person per day,

iodine concentration in salt at the point of production should be within the range of 20-40 mg of iodine per kg of salt (i.e*.,* 20-40 ppm of iodine) in order to provide 150 µg of iodine per person per day. The iodine should be added as potassium (or sodium) iodate. Under these circumstances median urinary iodine levels will vary from 100-200 µg/l.

However, in some instances the quality of iodized salt is poor, or the salt is incorrectly packaged, or the salt deteriorates due to excessive long-term exposure to moisture, heat, and contaminants. Iodine losses from point of production to consumption can then be well in excess of 50%. In addition, salt consumption is sometimes much less than 10 g per person per day. As a result, actual iodine consumption may fall well below recommended levels.

Regular surveys of median iodine urinary levels should therefore be carried out in a representative sample of the at-risk population, to ensure that those levels are within the recommended range (100-200 μg/l). If not, the level of iodization of salt, and factors affecting the utilization of iodized salt, should be reassessed focusing on:

- salt quality and the iodization process;
- factors affecting iodine losses from salt, such as packaging, transport, and storage; and
- food habits in relation to salt intake and cooking practices.

National authorities should establish initial levels for iodization in consultation with the salt industry, taking into account expected losses and local salt consumption. Once iodization has commenced, regular surveys of salt iodine content and urinary iodine levels should be carried out to determine if the programme is having the desired effect.

Discussions and regulations about iodine levels in salt must clearly specify whether they refer to total content of iodine alone or to content of iodine compound (KIO_3 or KI).

It is recommended that the level be expressed as content of iodine alone. This approach emphasizes the physiologically important component (iodine) and facilitates comparison of its different forms.

3.2 Determining salt iodine levels

The iodine content of salt can be determined quantitatively with the titration method, and qualitatively using rapid test kits.

Titration method

The iodine content of salt can be determined by liberating iodine from salt and titrating the iodine with sodium thiosulphate using starch as an external indicator. The method of liberating iodine from salt differs depending on whether salt is iodized with iodate or iodide. Details of the method are given in Annex 1. Facilities for titration are usually available in a public health or food standards laboratory. Large- and medium-scale salt producers should carry out titration on site.

Titration is preferred for accurate testing of salt batches produced in factories or upon their arrival in a country, and in cases of doubt, contestation, etc. This method is recommended for determination of the concentration of iodine in salt at various levels of the distribution system where such accurate testing is required. Once the method is established, it is necessary to adhere to proper internal and external quality control measures. However, the titration method is time-consuming, and is not recommended for routine monitoring purposes throughout the country.

Rapid test kits

These are small bottles of 10-50 ml, containing a stabilized starch-based solution. One drop of the solution placed on salt containing iodine (in the form of potassium iodate) produces a blue/purple coloration. These kits should therefore be regarded as qualitative rather than quantitative.

Coloration indicates that iodate is present, but the concentration cannot be reliably determined. In cases where there is suspicion of alkalinity in the salt sample, a drop of the 'recheck solution' may be used and the test may be dropped over the drop of recheck solution to indicate the presence of iodine (see Annex 1 for further details).

An advantage of rapid test kits is that they can be used in the field to give an immediate result. They are therefore useful to health inspectors and others who are involved in carrying out spot checks on food quality or household surveys.

They may also play a valuable educational role, in that they provide a visible indication that salt actually is iodized. Accordingly, they can be used for demonstration purposes in schools and other institutions. However, because rapid test kits do not give a reliable estimate of iodine content (*20, 21*), results must be backed up by titration.

There are a large number of test kits available on the market; moreover, many countries are currently producing their own. UNICEF also supplies countries with test kits.[3] However, a comprehensive review to assess these kits is still needed.

3.3 Monitoring systems

External monitoring systems by governments

This system is based upon the establishment of a law which mandates that all salt for human and - in most countries, animal - consumption is iodized. Details of implementation, inspection, and enforcement are set out in the regulations. Guidelines for developing regulations are available (*23*), and a good example of such a law is the ASIN law in the Philippines (Annex 6). It is crucial to state in the regulations the amount of potassium iodate to be added at the point of production.

Other legal requirements should include packaging in polyethylene bags, labelling to identify the iodine level and the name and address of the company packaging the salt. The regulation also needs to designate a government agency or department which will be responsible for a system of licensing producers, importers, and distributors, and inspecting their facilities.

That agency must also be responsible for periodically checking the quality assurance records that must be kept, and for spot checking the salt for iodate content. Although monitoring at the production and household levels is considered extremely important, retail outlets also need to be checked periodically to determine what is happening in the salt market and to ensure that all sources of salt have been identified. Several monitoring and inspection systems have emerged in different countries.

[3] Test kits can be obtained by directing requests to MBI, 85 GN Chetty Road, III Floor, T Nagar, Madras 600 017, India.

Often this monitoring becomes a function of the Food and Drugs Bureau of the Health Ministry. In other countries, the Ministry of Industry, or Mines, or Agriculture has this responsibility. In the case of importation of salt, the Customs Authority is often in charge of checking the specifications in the importation document, and in some circumstances taking samples to check the iodate level in the salt.

As indicated above, the salt testing kits that are used by these government agencies should not be used in enforcement, as they often give both false positive and false negative results and the colour does not always accord well with titration. Government inspection systems need to have access to and use of salt titration in a standardized laboratory on a regular basis.

When countries first began to introduce salt iodization, inspection systems were used largely to guide salt iodization programme managers in identifying problems with salt iodization, and were rarely used for enforcement purposes. As countries increase the coverage to 50%, these systems should be strengthened and used for enforcement against those producers who fail to comply with the law.

It is often the less expensive uniodized salt in the market that prevents the realization of elimination of IDD. Indeed, as the coverage of iodized salt increases, special efforts need to be made to identify the non-compliant importer, producer and distributor and systematically eliminate that problem.

Salt must be iodized indefinitely, or until it is demonstrated that an adequate iodine intake is available from other sources. The infrastructure, together with the annual budget to support the government inspection system, must be permanently established. In order to guarantee this, it is essential that inspection of iodized salt be integrated into the existing food inspection system in the country.

Internal monitoring systems by producers and distributors

For each type of salt production, and for each type of salt iodization system, there must be established a set of guidelines for best manufacturing processes. It is the responsibility of the producer to have such a set of guidelines for his own facility, as each has its own unique characteristics.

The Ministry of Industry, the Bureau of Standards, or Codex Alimentarius are useful reference sources for guiding producers in the process of iodizing salt. They can also establish the ultimate standards expected in the production of iodized salt.

Adherence to these manufacturing standards is perhaps the most important issue in the elimination of IDD. Therefore, the producer plays a pivotal role both in improving the accuracy of the iodization process and in reducing the considerable variations observed in iodine concentration in many countries.

Among the areas of greatest concern (*24*) is the very important mixing or spraying step. This area includes not only the actual iodization method chosen by a production or packaging facility, but also the assurance that the producer closely adheres to the amount of time for mixing.

Rapid test kits should be used frequently during shifts and, in addition, samples should be taken on a periodic basis for salt titration. The iodine concentration of each batch should be checked at least once.

For this reason, it is recommended that wherever possible at least two persons at a production plant should be trained and their skills standardized to determine accurately the iodine concentration using the titration method. Furthermore, key persons at each production site should be aware of the detrimental consequences of iodine deficiency and excess, as well as the health benefits of correctly iodized salt.

Results should be recorded and plotted in a quality assurance chart. When levels are not satisfactory, immediate corrective action should be taken and that action entered into the record book.

Because production methods and factory sizes vary so widely, it is beyond the scope of this manual to define this process in any greater detail. Whatever the method adopted, it should result in salt that has an iodate level that corresponds to that indicated on the label. That level should, of course, correspond to the level allowed for under the law.

When importers and distributors procure salt, they have the responsibility either to ensure that it meets specifications as stipulated in the requirements, or to ensure that these are met before salt goes out to the wholesale or retail market. This implies that they should have a quality assurance system that includes salt iodine titration measurements.

If the salt they receive is not up to standard, they will need to have their own iodization facility. All salt should be distributed in polyethylene bags, with appropriate labels as described above.

Monitoring at the household level

There are two basic methods for obtaining household-level data:

- Cross-sectional surveys; and
- Community-based monitoring.

Cross-sectional surveys

Cross-sectional surveys are conducted infrequently (see Chapter 5: Survey methods). A household questionnaire concerning the use of iodized salt and qualitative testing of that salt using a salt testing kit has been employed successfully to determine overall coverage of iodized salt and to identify geographic gaps in the programme.

This questionnaire was included in the UNICEF Multiple Indicator Household Cluster Survey (MIHCS) in 1996, and will be repeated in the next round. Some countries have successfully added the questionnaire to other national surveys, e.g., to either nutrition surveys or surveys that collect key economic and census data. These surveys provide estimates of the proportion of the population using adequately iodized salt, and identify areas where there is low use of iodized salt and/or where all the salt is uniodized.

The results allow for visual representations of variations of coverage and provide a basis for targeting resources and focusing interventions in areas where they are most needed. This type of monitoring should then be followed by specific action to identify further the reason for low iodized salt usage, and should result in a range of actions to correct the problem. Survey approaches that have been successfully used include Cluster Sampling, Lot Quality Assurance Sampling, and sentinel sample sites (*25*).

Community-based monitoring

Ongoing household-level monitoring is used more frequently than periodic surveys. This approach may be organized in the community or through the schools, particularly in areas with high rates of school enrolment. Providing salt testing kits to environmental health officers, community midwives, nutrition officers, schoolteachers, mayors, and other government workers responsible for community health, has been helpful in this process.

These approaches are very effective communication and awareness creation tools, particularly when this awareness is linked to action. This action could involve approaching the salt producers or distributors, and directly requesting them to supply iodized salt.

Finally, the occurrence of parallel markets in uniodized salt has frequently been a barrier to achieving universal salt iodization. National cross-sectional household surveys and community monitoring have often been useful in identifying such salt and in developing strategies to address the problem.

Figure 2 illustrates graphically the components of a USI monitoring system. General standards and specific practices can be checked by inspections, tests, and records to assure that responsible producers comply with the standards, and various actions can be taken according to the level of that compliance.

Figure 2: Components of a routine monitoring system for USI

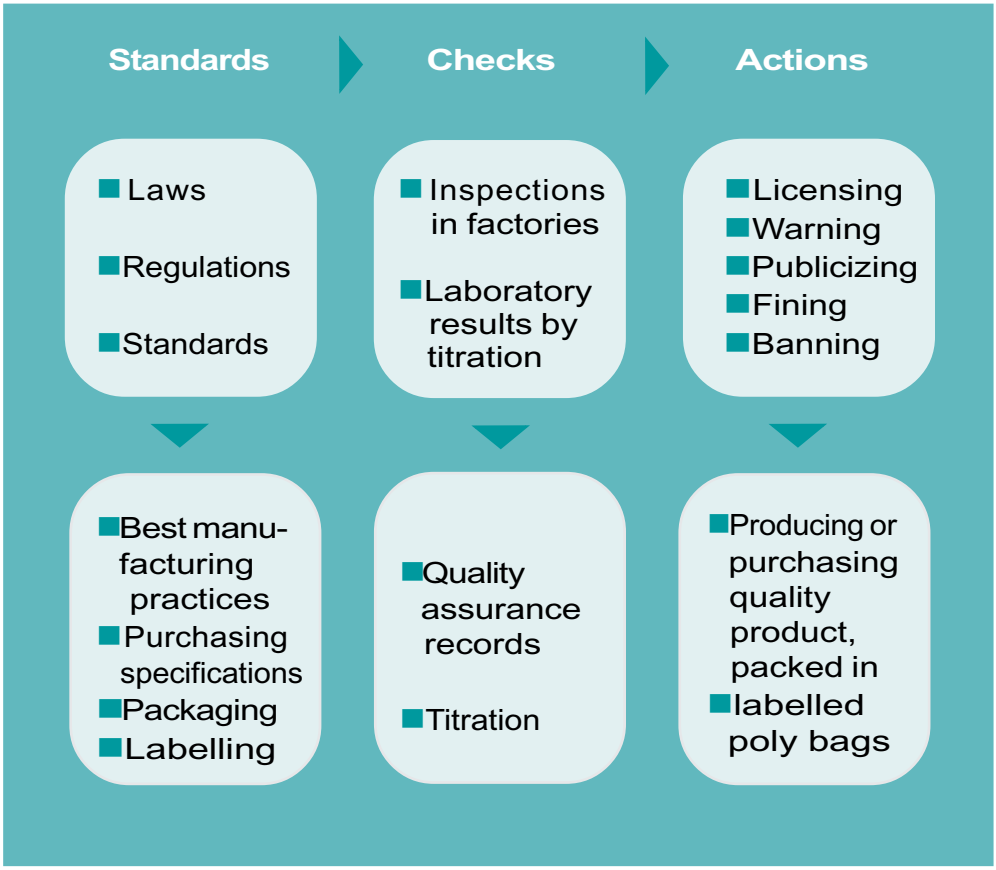
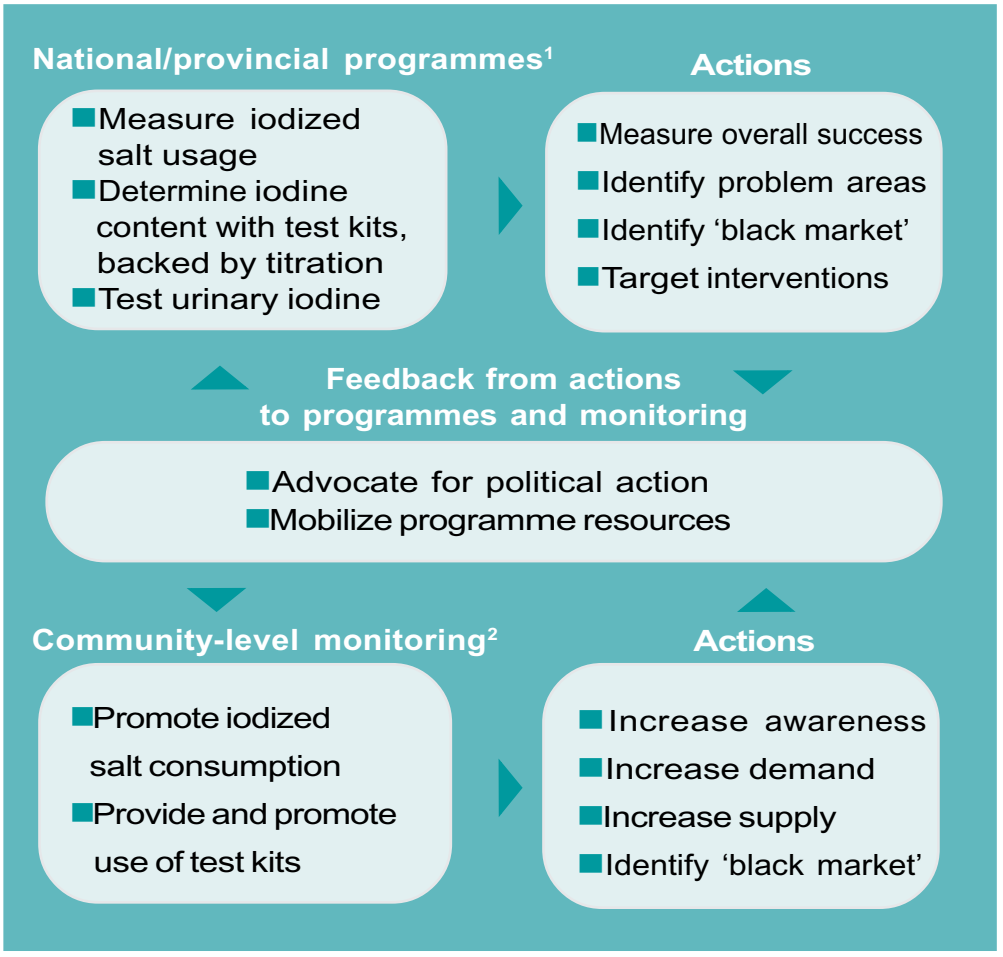


Figure 3 demonstrates a double loop which can be effectively established among national or provincial programmes and community-level monitoring, through their respective actions and the resultant feedback. Programmes take actions, which result in feedback, which aids and reinforces their activities. Similarly, monitoring enables actions, providing feedback to enhance monitoring.

Once begun, the process is continuous and self-reinforcing. By their activities, IDD programmes enable certain assessment and corrective actions. These actions can result in the desired effects, which will in turn assist programmes in better performing their respective tasks, and so on around the loops.

Figure 3: Programme monitoring and feedback loops



[1]Periodic cross-sectional survey at the national or subnational levels.
[2]Governor's Office, District Medical Officers, midwives, teachers, volunteers, etc.

4 Indicators of impact

4.1 Overview

Assessment of thyroid size by palpation is the time-honoured method of assessing IDD prevalence. However, because of the long response time after iodine supplementation is introduced this method is of limited usefulness in assessing the impact of programmes once salt iodization has commenced. In this case, urinary iodine is the most useful indicator because it is highly sensitive to recent changes in iodine intake.

Since most countries have now started to implement IDD control programmes, urinary iodine rather than thyroid size is emphasized in this manual as the principal indicator of impact. Thyroid size is more useful in the baseline assessment of the severity of IDD, and also has a role in the assessment of the long-term impact of control programmes.

The introduction of ultrasonography for the precise assessment of thyroid size has been a significant development. However, this approach requires costly equipment and a source of electricity in the field. Moreover, there are as yet no generally accepted standards for thyroid size in iodine-replete populations.

Two other indicators are included in this discussion: thyroid stimulating hormone (TSH) and thyroglobulin (Tg). While TSH levels in neonates are particularly sensitive to iodine deficiency, difficulties in interpretation remain. Furthermore, the cost of implementing a screening programme is too high for most developing countries. The value of thyroglobulin as an indicator of IDD status has yet to be fully explored and to gain wide acceptance.

4.2 Urinary Iodine

Biological features

Most iodine absorbed in the body eventually appears in the urine. Therefore, urinary iodine excretion is a good marker of very recent dietary iodine intake. In individuals, urinary iodine excretion can vary somewhat from day to day and even within a given day. However, this variation tends to even out among populations.

Studies have convincingly demonstrated that a profile of iodine concentrations in morning or other casual urine specimens (child or adult) provides an adequate assessment of a population's iodine nutrition, provided a sufficient number of specimens is collected. Twenty-four hour samples are difficult to obtain and are not necessary.

Relating urinary iodine to creatinine is cumbersome, expensive, and unnecessary. Indeed, urinary iodine/creatinine ratios are unreliable, particularly when protein intake - and consequently creatinine excretion - is low.

Feasibility

Acceptance of this indicator is very high, and spot urine specimens are easy to obtain. Urinary iodine assay methods are not difficult to learn or use (see below), but meticulous attention is required to avoid contamination with iodine at all stages. Special laboratory areas, glassware, and reagents should be set aside solely for this determination.

In general, only small amounts (0.5-1.0 ml) of urine are required, although the exact volume depends on the method. Some urine should also be kept in reserve. Samples are collected in tubes, which should be tightly sealed with screw tops. They do not require refrigeration, addition of preservative, or immediate determination in most methods. They can be kept in the laboratory for months or more, preferably in a refrigerator to avoid unpleasant odour.

Evaporation should be avoided, because this process artifactually increases the concentration. Samples may safely be frozen and refrozen, but must be completely defrosted before aliquots are taken for analysis.

Many analytical techniques exist, varying from very precise measurement with highly sophisticated instruments, to semi-quantitative 'low tech' methods that can be used in regional, country, or local laboratories. Most methods depend on iodide's role as a catalyst in the reduction of ceric ammonium sulfate (yellow colour) to the cerous form (colourless) in the presence of arsenious acid (the Sandell-Kolthoff reaction). A digestion or other purification step using ammonium persulfate or chloric acid is necessary before carrying out this reaction, to rid the urine of interfering contaminants.

A brief description of some of the methods introduced in this section is presented in the following pages.

Methods with ammonium persulfate (Method A)

Small samples of urine (250-500 ml) are digested with ammonium persulfate at 90-110 °C; arsenious acid and ceric ammonium sulfate are then added. The decrease in yellow colour over a fixed time period is then measured by a spectrophotometer and plotted against a standard curve constructed with known amounts of iodine (*26*). This method requires a heating block and a spectrophotometer, which are both inexpensive instruments. About 100-150 unknown samples can be run in a day by one experienced technician. Several versions of this method exist: details of one of these are given in Annex 3.

Methods with chloric acid (Method B)

Chloric acid can be substituted for ammonium persulfate in the digestion step, and the colorimetric determination carried out as for method A (*27*). A disadvantage is the safety concern, because the chemical mixture can be explosive if residues dry in ventilating systems. *Handling these chemicals in a fume cupboard and using a chloric acid trap when performing sample digestion is strongly recommended* (see Annex 3).

Other methods

A modification of Method B uses the redox indicator ferroin and a stopwatch instead of a spectrophotometer to measure colour change (*28*). Urine is digested with chloric acid and colour changes in batches of samples measured relative to standards of known iodine content. This places samples in categories (e.g., below 50 µg/litre, 50-100 µg/l, 100-200 µg/l, etc.) that can be adjusted to desired levels. This method is currently being adapted to ammonium persulfate digestion.

Another, semi-quantitative method is based on the iodide-catalyzed oxidation of 3,3',5,5'-tetramethylbenzidine by peracetic acid/H2O2 to yield coloured products that are recognized on a colour strip indicating three ranges: <100 µg/l, 100-300 µg/l, and > 300 µg/l (*22*). Interfering substances are removed by pre-packed columns with activated charcoal. Analyses must be run within two hours, and the procedure requires the manufacturer's pre-packed columns.

- ***Other methods*** *(continued)*

  In still another method, samples are digested with ammonium persulfate on microplates enclosed in specially designed sealed cassettes and heated to 110 °C (*29*). Samples are then transferred to another microplate and the ceric ammonium sulfate reduction reaction carried out and read on a microplate reader. Field tests are promising: up to 400 urine samples can be analysed in one day, depending on manufacturers' supplies.

Choice of method

Criteria for assessing urinary iodine methods are reliability, speed, technical demands, complexity of instrumentation, independence from sole-source suppliers, safety, and cost. The choice among the above and other methods depends on local needs and resources. Large central laboratories processing many samples may prefer 'high-tech' methods, while smaller operations closer to the field may find the simplest methods more practical.

Due to the potential hazards of chloric acid, Method A using ammonium persulfate is currently recommended. It can adequately replace the chloric acid method, since the main difference is the substitution of ammonium persulfate for chloric acid in the digestion step (see Annex 3). Results are comparable.

The other methods described above show promise but are not yet fully tested.

Quality control and reference laboratories

All laboratories should have clearly defined internal quality control procedures in place, and should be open to external audit. In addition, all laboratories should participate in an external quality control programme in conjunction with a recognized reference laboratory.

Active efforts are now in progress, both to define performance criteria for laboratories and to develop a global system of reference laboratories. These reference laboratories will provide reliable measurements of urinary iodine, and will conduct technical training and supervision. This initiative is a major priority for ensuring sustainability of iodine sufficiency.

Performance

Most of the above methods perform reliably, although some of the newer ones need further testing as of this date. All these methods routinely recognize urinary iodine concentrations in the range of 50-200 μg/l.

With appropriate dilutions, they can be extended upward to examine whatever range is desired. The coefficient of variation is generally under 10% for all methods. Proper training is necessary but not complicated.

Since casual specimens are used, it is desirable to measure a sufficient number from a given population to allow for varying degrees of subject hydration and other biological variations among individuals, as well as to obtain a reasonably narrow confidence interval (see Annex 4). In general, 30 urine determinations from a defined sampling group are sufficient.

Interpretation

Simple modern methods make it feasible to process large numbers of samples at low cost and to characterize the distribution according to different cut-off points and intervals. The cut-off points proposed for classifying iodine nutrition into different degrees of public health significance are shown in Table 5.

Frequency distribution curves are necessary for full interpretation. Urinary iodine values from populations are usually not normally distributed. Therefore, the median rather than the mean should be used as the measure of central tendency. Likewise, percentiles rather than standard deviations should be used as measures of spread.

Median urinary iodine concentrations of 100 μg/l and above define a population which has no iodine deficiency, i.e. at least 50% of the sample should be above 100 μg/l. In addition, not more than 20% of samples should be below 50 μg/l.

Alternatively, the first quintile (20th percentile) should be at least 50 μg/l. In adults, a urinary iodine concentration of 100 μg/l corresponds roughly to a daily iodine intake of about 150 μg under steady-state conditions.

Table 5: Epidemiological criteria for assessing iodine nutrition based on median urinary iodine concentrations in school-aged children

Median urinary iodine (μg/l)	Iodine intake	Iodine nutrition
< 20	Insufficient	Severe iodine deficiency
20-49	Insufficient	Moderate iodine deficiency
50-99	Insufficient	Mild iodine deficiency
100-199	Adequate	Optimal
200-299	More than adequate	Risk of iodine-induced hyperthyroidism within 5-10 years following introduction of iodized salt in susceptible groups (see last paragraph, section 4.2)
>300	Excessive	Risk of adverse health consequences (iodine-induced hyperthyroidism, autoimmune thyroid diseases)

Urinary iodine concentration is currently the most practical biochemical marker for iodine nutrition, when carried out with appropriate technology and sampling. This approach assesses iodine nutrition only at the time of measurement, whereas thyroid size reflects iodine nutrition over months or years. Therefore, even though populations may have attained iodine sufficiency by median urinary iodine concentration, goitre may persist, even in children.

With rapid global progress in correcting iodine deficiency, examples of iodine excess are being recognized, particularly when salt iodization is excessive and poorly monitored (*21*). Tolerance to high doses of iodine is quite variable, and many individuals ingest amounts of several milligrams or more per day without apparent problems.

The major epidemiological consequence of iodine excess is iodine-induced hyperthyroidism (IIH) (*30, 31*). This occurs more commonly in older subjects with pre-existing nodular goitres, and may occur even when iodine intake is within the normal range.

Iodine intakes above 300 μg/l per day should generally be discouraged, particularly in areas where iodine deficiency has previously existed. In these situations, more individuals may be vulnerable to adverse health consequences, including iodine-induced hyperthyroidism and autoimmune thyroid diseases.

In populations characterized by longstanding iodine deficiency and rapid increment in iodine intake, median value(s) for urinary iodine above 200 μg/l are not recommended because of the risk of iodine-induced hyperthyroidism. This adverse condition can occur during the 5 to 10 years following the introduction of iodized salt (*30, 31*). Beyond this period of time, median values up to 300 μg/l have not demonstrated side-effects, at least not in populations with adequately iodized salt.

4.3 Thyroid size

The traditional method for determining thyroid size is inspection and palpation. Ultrasonography provides a more precise and objective method. However, there is no agreement on reference values.

Both methods are described below. Issues common to palpation and ultrasound are not repeated in the section on ultrasound.

4.3.1 Thyroid size by palpation

The size of the thyroid gland changes inversely in response to alterations in iodine intake, with a lag interval that varies from a few months to several years, depending on many factors. These include the severity and duration of iodine deficiency, the type and effectiveness of iodine supplementation, age, sex, and possible additional goitrogenic factors.

The term “goitre” refers to a thyroid gland that is enlarged. The statement that “a thyroid gland each of whose lobes have a volume greater than the terminal phalanges of the thumb of the person examined will be considered goitrous” is empirical but has been used in most epidemiological studies of endemic goitre and is still recommended (see Table 6).

Feasibility

Palpation of the thyroid is particularly useful in assessing goitre prevalence, but much less so in determining impact. Costs are associated with mounting a survey, which is relatively easy to conduct, and training of personnel. These costs will vary depending upon the availability of health care personnel, accessibility of the population, and sample size. Feasibility and performance vary according to target groups, as follows:

Neonates: It is neither feasible nor practical to assess goitre among neonates, whether by palpation or ultrasound. Performance is poor.

School-aged children (6-12 years): This is the preferred group, as it is usually easily accessible. However, the highest prevalence of goitre occurs during puberty and childbearing age. Some studies have focused on 8-10 years.

There is a practical reason for not measuring very young age groups. The smaller the child, the smaller the thyroid, and the more difficult it is to perform palpation.

If the proportion of children attending school is less than 50%, schoolchildren may not be representative. In these cases, spot surveys should be conducted among those who attend school and those who do not, to ascertain if there is any significant difference between the two.

Alternatively, children can be surveyed in households. For further discussion, see chapter 5 on Survey Methods.

Adults: Pregnant and lactating women are of particular concern. Pregnant women are a prime target group for IDD control activities because they are especially sensitive to marginal iodine deficiency. Often they are relatively accessible given their participation in antenatal clinics. Women of childbearing age - 15-44 years - may be surveyed in households.

Technique

The subject to be examined stands in front of the examiner, who looks carefully at the neck for any sign of visible thyroid enlargement. The subject is then asked to look up and thereby to fully extend the neck. This pushes the thyroid forward and makes any enlargement more obvious.

Finally, the examiner palpates the thyroid by gently sliding his/her own thumb along the side of the trachea (wind-pipe) between the cricoid cartilage and the top of the sternum. Both sides of the trachea are checked. The size and consistency of the thyroid gland are carefully noted.

If necessary, the subject is asked to swallow (e.g. some water) when being examined - the thyroid moves up on swallowing. The size of each lobe of the thyroid is compared to the size of the tip (terminal phalanx) of the thumb of the subject being examined.[4] Goitre is graded according to the classification presented in Table 6.

Table 6: Simplified classification of goitre by palpation*

Grade 0	No palpable or visible goitre.
Grade 1	A goitre that is *palpable but not visible* when the neck is in the normal position, (i.e., the thyroid is not visibly enlarged). Thyroid nodules in a thyroid which is otherwise not enlarged fall into this category.
Grade 2	A swelling in the neck that is clearly *visible when the neck is in a normal position* and is consistent with an enlarged thyroid when the neck is palpated.

* *A thyroid gland will be considered goitrous when each lateral lobe has a volume greater than the terminal phalanx of the thumbs of the subject being examined.*

The specificity and sensitivity of palpation are low in grades 0 and 1 due to a high inter-observer variation. As demonstrated by studies of experienced examiners, misclassification can be high.

[4] Another method is to stand behind the subject with the neck in the neutral position and hold the fingers (not thumb) over the area of the gland. The person is asked to swallow and the gland is palpated by the fingers as it glides up. This is repeated on each side of the neck.

Interpretation

Table 7 gives the epidemiological criteria for establishing IDD severity, based on goitre prevalence in school-age children. The terms mild, moderate, and severe are relative and should be interpreted in context with information from other indicators.

It is recommended that a total goitre rate or TGR (number with goitres of grades 1 and 2 ÷ total examined) of 5% or more in schoolchildren 6-12 years of age be used to signal the presence of a public health problem. This recommendation is based on the observation that in normal, iodine-replete populations, the prevalence of goitre should be quite low. The cut-off point of 5% allows both for some margin of error of goitre assessment, and for goitre that may occur in iodine-replete populations due to other causes such as goitrogens and autoimmune thyroid diseases.

Table 7: Epidemiological criteria for assessing the severity of IDD based on the prevalence of goitre in school-aged children

	Degrees of IDD, expressed as percentage of the total of the number of children surveyed			
	None	*Mild*	*Moderate*	*Severe*
Total goitre rate (TGR)	0.0-4.9%	5.0-19.9%	20.0-29.9%	≥ 30%

Finally in this connection, it is emphasized that thyroid size in the community may not return to normal for months or years after correction of iodine deficiency.

4.3.2 Thyroid size by ultrasonography

Ultrasonography is a safe, non-invasive specialized technique, which provides a more precise measurement of thyroid volume compared with palpation. This becomes especially significant when the prevalence of visible goitres is small, and in monitoring iodine control programmes where thyroid volumes are expected to decrease over time. In the future, ultrasonography is poised to become widely used to assess IDD. The technical aspects of thyroid ultrasonography are reported in Annex 2.

Feasibility[5]

Portable (weight 12-15 kg) ultrasound equipment with a 7.5 MHz transducer currently costs about US $15,000. A source of electricity is needed, and the operator needs to be specially trained in the technique.

Interpretation

Results of ultrasonography from a study population should be compared with normative data. No universal normative values for thyroid volume measured by ultrasonography in schoolchildren of iodine sufficient populations are presently available.

Data from many countries have emphasized the importance of establishing normative values for the populations being examined. Normative values for thyroid volume in iodine replete schoolchildren aged 6-15 years should be presented as a function of age, sex, and body surface area (BSA) in order to take into account the differences in body development among children of the same age in different countries. This approach was considered potentially useful in countries with high prevalence of child growth retardation due to malnutrition with both stunting (low height-for-age) and underweight (low weight-for-age).

An advantage of the thyroid volume-for-BSA is that the age of the child is not required, which in some populations is not known with certainty. A limitation of the thyroid volume-for-BSA is that it requires the collection of weights and heights: in severely malnourished populations of schoolchildren, 10% or more may have a BSA below the lowest BSA cut-off of 0.8.

4.4 Blood constituents

Two blood constituents, TSH (thyroid stimulating hormone or thyrotropin) and thyroglobulin (Tg) can serve as surveillance indicators. In a population survey, blood spots on filter paper or serum samples can be used to measure TSH and/or Tg.

[5]The thyromobil is a worldwide project, designed to develop a model aimed at assessing the feasibility of measuring thyroid volume by ultrasound in various conditions, and to validate the normative values for thyroid volume measured by ultrasound in school-aged children. The model has already been tested and is still being tested in several countries around the world.

Determining serum concentrations of the thyroid hormones, thyroxine (T4) and triiodothyronine (T3), is usually not recommended for monitoring iodine nutrition, because these tests are more cumbersome, more expensive, and less sensitive indicators.

In iodine deficiency, the serum T4 is typically lower and the serum T3 higher than in normal populations. However, the overlap is large enough to make these tests not practical for ordinary epidemiological purposes.

4.4.1 Thyroid stimulating hormone (TSH)

Biological features

The pituitary secretes TSH in response to circulating levels of T4. The serum TSH rises when serum T4 concentrations are low, and falls when they are high. Iodine deficiency lowers circulating T4 and raises the serum TSH, so that iodine-deficient populations generally have higher serum TSH concentrations than do iodine-sufficient groups.

However, the difference is not great and much overlap occurs between individual TSH values. Therefore, the blood TSH concentration in school-age children and adults is not a practical marker for iodine deficiency, and its routine use in school-based surveys is not recommended.

In contrast, TSH in neonates is a valuable indicator for iodine deficiency. The neonatal thyroid has a low iodine content compared to that of the adult, and hence iodine turnover is much higher. This high turnover, which is exaggerated in iodine deficiency, requires increased stimulation by TSH. Hence, TSH levels are increased in iodine deficient populations for the first few weeks of life: this phenomenon is called transient hyperthyrotopinemia (*32*).

The prevalence of neonates with elevated TSH levels is therefore a valuable indicator of the severity of iodine deficiency in a given population. It has the additional advantage of highlighting the fact that iodine deficiency directly affects the developing brain.

In iodine sufficient populations, about 1 in 4000 neonates has congenital hypothyroidism, usually because of thyroid dysplasia. Prompt correction with thyroid hormone is essential to avoid permanent mental retardation.

Thyroid hormone affects proper development of the central nervous system, particularly its myelination, a process that is very active in the perinatal period. To detect congenital hypothyroidism and initiate rapid treatment, most developed countries conduct universal screening of neonates with blood spot TSH taken on filter papers, or occasionally with blood spot T4 followed by TSH.

While screening in developed countries is directed at detecting neonates with TSH elevations which are 20 mIU/l whole blood or higher, the availability of TSH assays sensitive to 5 mIU/l permits detection of mild elevations above normal. This permits detection of transient hyperthyrotopinemia. To be broadly applicable in a population, the screening must be universal, and not omit children born in remote or impoverished areas. For countries and regions that already have a system of universal neonatal screening with a sensitive TSH assay in place, the data can be examined and transient iodine deficiency recognized usually without further surveying.

Feasibility

Serum TSH is widely used in the field of thyroidology as a sensitive marker for both hypothyroidism and hyperthyroidism. Methods for determining TSH concentrations from either dried whole blood spots on filter paper or from serum, are well established and widely available. Typically, a few drops of whole blood are collected on filter paper from the cord or by prick of the heel or other site.

It is essential that sterile equipment be used, either lancets for blood spot collection or needles and syringes for collecting whole blood from which the serum is separated. Standard procedures for handling blood products or objects contaminated with blood should be followed. The risk of contracting HIV or hepatitis infection from dried blood spots is extremely low.

Blood can be taken either from the cord at delivery or by heel-prick after birth (usually after 72 hours). Some experimental data suggest normal values for cord blood are higher than those for heel prick blood. Blood spots, once dried, are stable. They can be stored in a plastic bag and transported even through normal postal systems and are usually stable for up to six weeks.

It must be emphasized that the primary purpose of screening programmes is to detect congenital hypothyroidism, and its use as an indicator of iodine nutrition will be a spin-off. Hence the only additional cost will be for data analysis.

It is not recommended that a neonatal screening programme be set up solely to assess community iodine deficiency. Less expensive means for obtaining this information exist.

TSH screening is inappropriate for developing countries where health budgets are low. In such countries, mortality among children under five is high due to nutritional deficiencies and infectious diseases, and screening programmes for congenital hypothyroidism are not cost effective.

Performance

A variety of kits for measuring TSH are available commercially in developed countries. Most have been carefully standardized, and perform adequately. Assays that utilize monoclonal antibodies, which can detect TSH as low as 5 mIU/l in whole blood spots, are more useful for recognizing iodine deficiency.

Interpretation

Permanent sporadic congenital hypothyroidism, with extremely elevated neonatal TSH, occurs in approximately 1 of 4000 births in iodine-sufficient countries. Other than infrequent cases of goitrogen exposure, iodine deficiency is the only significant factor to increase this incidence.

The increase in the number of neonates with moderately elevated TSH concentrations (above 5 mIU/l whole blood) is proportional to the degree of iodine deficiency. It may be higher than 40% in severe endemic areas.

Interpretation is complicated when antiseptics containing beta-iodine, such as povidone iodine (Betadine™), are used for cleaning the perineum prior to delivery or even the umbilical area of the baby. Beta-iodine increases TSH levels in the neonate in both cord blood and heel-prick specimens.

4.4.2 Thyroglobulin (Tg)

Thyroglobulin is the most abundant protein of the thyroid, providing the matrix for thyroid hormone synthesis. Normally, small amounts are secreted or leak from the thyroid into the circulation. When the thyroid is hyperplastic or injured, much larger amounts are released.

The thyroid hyperplasia of iodine deficiency is regularly associated with increased serum Tg levels. In this setting, it reflects iodine nutrition over a period of months or years. This contrasts to urinary iodine concentration, which assesses more immediate iodine intake.

Several studies have shown a good correlation with other markers of iodine deficiency, particularly goitre. The laboratory technique is similar to that for TSH and other immunoassays. It has been successfully applied to blood spots (*33*), but this particular application has not yet been developed commercially or studied further.

5 Survey methods

5.1 Overview

This book has so far dealt with what should be measured, i.e. the indicators of process and impact. This chapter describes how to apply these indicators in the field.

First, it covers methodologies for *monitoring the process* of salt iodization alone. Then it deals with *monitoring and evaluating the impact* of salt iodization on target communities. In practice, during surveys at schools or in households, both salt and the impact indicators can be assessed at the same time (iodine status assessment).

Attention to survey methods is important. It will help both to ensure that subjects who are surveyed or samples which are collected are representative of the study population, and that the surveys are carried out as efficiently as possible.

5.2 Salt monitoring

An IDD control programme based on salt iodization clearly cannot succeed unless all salt for human consumption is being adequately iodized. Therefore the most important thing to monitor is the salt itself, and the most important place to monitor it is at the site of production.

Monitoring iodine content at site of production

Salt monitoring at the site of production is the responsibility of the salt producer. It should be done by titration, or with rapid test kits provided they are backed up by titration. A modified Lot Quality Assurance Sampling (LQAS) scheme is recommended for implementation by producers (*34*).

Government food inspectors or health inspectors should carry out periodic visits to salt production facilities to check on the in-house quality control mechanisms. They should also collect samples for titration.

Monitoring iodine content at port of entry

Large producers should certify that the salt which they produce is iodized within a specified range. Such producers should seek certification by the International Organization for Standardization (International Standard ISO 9000 series) as an added guarantee that their salt is satisfactorily iodized.

At the actual point of entry, customs officers can realistically be expected to check documentation on large consignments of salt, and visibly inspect all imports to check that the salt is suitably packed and labelled. Each consignment should be tested with a rapid test kit, accepting that this is not any kind of representative sampling. Suspect salt should be held at the border. However, it should be noted that salt may be imported for industrial purposes and is then not covered by iodization regulations.

Establishing titration laboratories at points of entry for salt would appear to be an attractive option, but is difficult to implement in practice. Unloading bags from a lorry or railway wagon to check a consignment thoroughly is difficult, and only a few easily accessible bags can be tested. Staff would have to be specially recruited and laboratories established at considerable expense.

Monitoring salt at the point of final packing

In countries where salt is repacked into small packets (500 g, 1 or 2 kg), samples from each consignment should be collected for titration to ensure that the salt is adequately iodized.

Monitoring salt at the wholesale and retail levels

In many countries, health inspectors carry out regular inspections of wholesale and retail premises to ensure compliance with food regulations. During these inspections, samples of food may be collected for laboratory testing. Such inspections therefore provide an ideal opportunity for checking the salt on sale, testing it with rapid test kits, and collecting samples for titration. All salt samples should be carefully labelled before dispatch to the laboratory.

The results of formal salt monitoring should be provided to producers. Where a specific producer consistently fails to comply, appropriate legal steps should be taken.

Monitoring salt at the community level

Salt monitoring, using test kits, should be conducted at the community level to ensure that only iodized salt is on sale to the public. This should be carried out by environmental health workers, village or community health workers, or others. Salt samples should be collected at the household level during periodic surveys to evaluate coverage (described below).

5.3 Iodine status assessment[6]

Iodine status assessment requires conducting a cross-sectional survey of a *representative* sample of the entire target population. The recommended survey method is multistage "proportionate to population size" (PPS) cluster sampling (*35*). This method has been in use for many years for the evaluation of immunization (EPI) coverage, and can be applied to many other health indicators. The target population for the survey should be either school-aged children or women of childbearing age. Surveys should be either school-based or household-based.

These notes are intended as a general guide to the principles underlying the conduct of such surveys. Surveys are expensive, and the issues of sample size and selection of sites must be given very careful consideration. It is recommended that expert epidemiological help be sought at an early stage in the design of an IDD prevalence survey.

The principal requirement for applying the PPS method is that a listing (sampling frame) is available of all the sampling units and their respective populations. For IDD surveys, the sampling unit should be either communities or schools. In the latter case, a list of the enrolments (total number of pupils) of each school is required.

This sampling scheme ensures that larger communities or schools are more likely to be selected than smaller ones. Each selected sampling unit is one cluster. In a defined geographical area, thirty clusters should be studied altogether to ensure a valid prevalence estimate; examining fewer clusters can lead to estimates that differ substantially from the true prevalence (*36*).

[6]See Annex 4 for a detailed explanation of survey methods.

If a complete listing of school enrolments is not available, schools should be selected on the basis of simple random sampling. The final result is then adjusted by weighing the results obtained using the number of students actually enrolled in the schools selected for the survey.

Within each cluster, a specified number of school-aged children or adult women are selected for study. Each selected subject provides a urine specimen and a sample of salt from their home.

While the number of samples of each that should be collected is somewhat flexible, *thirty samples of both urine and salt per cluster are generally recommended*. Selection of at least 30 samples allows for inference at the cluster level, i.e. it permits looking at differences among clusters and giving an indication of localities where iodine deficiency may still be a problem.

School-based or household-based surveys?

The school-based PPS cluster sampling method is recommended as the most efficient and practical approach for performing an iodine status or an IDD prevalence survey. However, school-based PPS cluster surveys may not be appropriate under all circumstances, as shown in Table 8.

Stratification

One 30-cluster survey is not sufficient for all countries, particularly those with large populations or those that are spread over a wide area. For example, consider a country that is divided into two ecological zones - lowlands and mountains - where IDD was previously only a recognized problem in the mountains.

In this case, the two ecological zones should be treated separately and surveys carried out in each. Frequently a country is divided into subnational units, such as regions or provinces, and each of these may form the basis for a survey.

Table 8: Circumstances when school-based PPS cluster surveys may not be appropriate

Reason	Effect	Recommended action
Low school enrolment or attendance (below 50% of target population).	Schoolchildren may come from better off families and are then unrepresentative of the general population.	*Either:* Compare goitre prevalence in children attending school with that in those who are not at school. If no significant difference proceed with school surveys. *Or:* Survey adult women or school-aged children in households.
School feeding schemes (particularly if specific micronutrient supplements are included).	Iodine status of schoolchildren is better than that of the community as a whole.	Survey adult women (less than 30 years old) in households.
Low enrolment of girls in schools (more than 25% below that of boys).	Survey is biased towards boys, while girls as future mothers are the most important target group.	Survey adult women (less than 30 years old) in households, or school-aged children in households and schools.
Another micronutrient deficiency survey at household level is planned.	Resources are unnecessarily wasted on two separate surveys.	Combine the two surveys (see 5.4).

Survey methodology

Thirty clusters are selected from the overall sampling frame by systematic sampling. The total population or total enrolment divided by 30 determines the sampling interval (k). The starting point of the survey is chosen by selecting a random number between 1 and k.

In a school survey, the thirty children selected for urine collection should be chosen by systematic random sampling. Only children between the ages of 6 and 12 years inclusive should be selected.

Salt samples should also be collected for titration at the same time as the IDD prevalence survey is performed. If possible, advance notice should be given so that the same children selected for urine collection may bring salt to school on the day in question. If advance notice is not given, ten salt samples should be collected in households in the nearest village to the school.

In a household survey, the team should identify the centre of the chosen community and there spin a bottle to choose in which direction households should be selected. Each house should be visited according to the direction the bottle is pointing, and either a woman or a child selected in each household (maximum one per household) until the target number is reached.

5.4 Combined micronutrient deficiency surveys

IDD prevalence surveys may be efficiently combined with those aimed at assessing the prevalence of other micronutrient deficiencies, such as vitamin A and iron, or indeed other cluster surveys. The recommended methodology for such surveys is also PPS cluster sampling.

The sampling units should be communities, not schools, since these surveys take place in households in order to identify women and young children - the most vulnerable groups.

The simplest way of including an IDD component is to collect urine for iodine estimation from the same women or children who are selected for collection of blood for assessment of vitamin A and/or iron status, and to ask for a household salt sample at the same time. Alternatively, the nearest school to the selected community should be visited and urine samples collected as outlined above.

5.5 IDD surveys in areas with no prevalence data

When attempting to answer the question “does IDD occur?”, the selection of schools or communities for surveying should be purposive, i.e. on the basis of IDD being suspected or predicted in that particular location. Factors which may lead to the suspicion that IDD occurs in a particular area are outlined in Chapter 1. The most useful type of survey for this purpose is usually primary-school based.

Goitre palpation of each subject takes very little time. The examination of a statistically representative number of children will provide a good picture of the overall IDD status in the area, and will allow a reliable assessment of goitre rates. This is particularly important if no estimate of overall goitre prevalence is available.

It is recommended that at least 200 children be examined in a given school, or the entire enrolment if this is a lower number. For instance, assessment of total goitre prevalence in a school of 600 pupils - with 95% confidence and the same relative precision - requires examining 83 children if the estimated overall prevalence is 50%, but 234 children if the latter percentage is 20%. In addition, at least 30 children should be selected for urine collection in any school.

5.6 Sentinel surveillance

Large-scale, representative cross-sectional surveys are generally too costly to be used as an instrument for the regular monitoring of IDD control. To assess the change in iodine status of a defined population over time, the method of monitoring which has proved most practical is that done through the selection of *sentinel districts*. Such districts are chosen on the basis of their being remote and being affected by moderate or severe IDD prior to the implementation of the IDD control programme.

In each sentinel district, at least three rural schools should be chosen at random for surveying. An urban area should also be included to act as a control, and again at least three schools should be selected.

In each selected school in the sentinel districts, urine and household salt samples should be collected as outlined above. If resources are limited, the number of urine samples collected per school may be reduced to a total of at least 60 samples in the district as a whole, with 20 from each school.

Sentinel surveillance surveys should be performed at least every two years in the early stages of an IDD control programme. Once the situation appears stable, surveys can be reduced in frequency to one every two or three years.

It is, however, important to be flexible when establishing a system for monitoring IDD control. For example, if there are reports of persistent goitre in a particular district, or concerns that a certain border area is receiving significant amounts of illegally imported, uniodized salt, then surveys should also be carried out in those areas.

5.7 Measuring progress towards achieving long-term micronutrient goals

Periodic prevalence surveys, as described earlier in this section, are necessary to measure change in prevalence over time. Measuring progress towards achieving long-term micronutrient goals requires that surveys be representative of the population concerned (see also Chapter 6).

5.8 Target groups for surveillance

There are three target groups for surveillance of IDD control programmes.

School-aged children: School-aged children are a useful target group for IDD surveillance because of their combined high vulnerability, easy access, and applicability to a variety 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 helminth infections, anaemia, and behavioural factors affecting health, can be assessed. Appropriate educational interventions can then be 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 (see Table 8). If school enrolments or attendance are low, school-aged children can be surveyed during household surveys.

Women of childbearing age: Screening women aged 15-44 years provides an opportunity to establish the iodine status of a group that is particularly crucial because of the susceptibility of the developing fetus to iodine deficiency. However, after age 30 goitre rates are no longer reliable indicators of current iodine intake.

In household surveys, accessibility may be limited because of the expense and logistical constraints associated with performing such surveys. In rural areas, women may go to the fields during the day. In some countries, many women may migrate to town at certain times of the year to join their husbands. In areas where antenatal clinic attendance is high, screening pregnant women in clinics may be a practical alternative, but the methodology for such a survey has not been developed.

Neonates*:* Neonatal screening to identify congenital defects is well established in many developed countries and is being introduced in some relatively prosperous developing countries. Regular collection of blood-spot specimens, where this is practised, is an important source of information for IDD surveillance given their use in assessing TSH status.

Elevated TSH levels, especially during infancy, suggest a deficiency of iodine. However, this approach is recommended for monitoring IDD control only when a screening programme is already established.

5.9 Interpreting and presenting results[7]

Taken alone, raw results from a survey do not mean very much. They must be processed and analysed. If there is a small number of results, for example 100 or so, then processing by hand is fairly easy. With large numbers of data, such as those from a cluster survey of urinary iodine where there may be over 900 results, use of a personal computer makes processing those data much easier.

Data should be entered using a suitable programme. Possibilities include a spreadsheet (*37*) which contains a special module for analysis of cluster sampling. Theoretically, data should be importable from one to the other, but in practice this is not always easy.

[7]See also Annex 5.

Requirements involve deriving a measure of central tendency and a measure of variability, or spread of the distribution. Unfortunately, many IDD parameters are not normally distributed. Rather, the results may be highly skewed in one direction.

For example, the distribution of both 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 non-parametric methods should be used to summarize and compare distributions.

The *median* (which is simply the middle value of the distribution) is used as the measure of central tendency. The median is the same thing as the 50th percentile. Half the results in the distribution are above the median and half are below. It is equidistant from either extreme.

A useful way of describing a spread of values which is not normally distributed involves the use of selected percentiles. The value of the 20th and 80th percentiles (first and fourth quintiles) would be suitable, and would give a sense of shape to the distribution of values. However, it has been customary practice 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. 500μg/l).

It is important not to overinterpret the results obtained. For example, it is a common fallacy to say that all children with a spot urine iodine value below 100 μg/l are iodine deficient. If the median is 100 μg/l, then by definition half of the values will be below this level. Individual spot urine iodine values are likely to be highy variable over time.

It should be noted 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 is decreased - but not eliminated - by increasing the sample size, but this also increases cost.

The use of confidence intervals gives an idea of the range in which the true population value is likely to lie. Ninety-five percent confidence intervals can be calculated for a median, and should be quoted alongside the value itself.

In compiling overall results of IDD surveys, e.g. 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. Rather, 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, as compared to presence or absence of goitre, which is a categorical variable.)

- Results from sentinel surveillance data are not nationally representative 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”.

6 Indicators of the sustainable elimination of IDD

In considering whether the sustainable elimination of iodine deficiency as a public health problem has been achieved, the following criteria should be met (see also Table 9).

With regard to salt iodization, availability and consumption of adequately iodized salt (>15 ppm iodine) must be guaranteed. This is demonstrated by its use by more than 90% of households. Preconditions for the use of this vehicle for eliminating IDD are:

- local production and/or importation of iodized salt in a quantity that is sufficient to satisfy the potential human demand (about 4-5 kg/person/year);
- 95% of salt for human consumption must be iodized according to government standards for iodine content, at the production or importation levels;
- the percentage of food-grade salt with iodine content of at least 15 ppm, in a representative sample of households, must be equal to or greater than 90%; and
- iodine estimation at the point of production or importation, and at the wholesale and retail levels, must be determined by titration; at the household level, it may be determined by either titration or certified kits.

With regard to the population's iodine status:

- the median urinary concentration should be at least 100 µg/l, with less than 20% of values below 50 µg/l; and
- the most recent monitoring data (national or regional) should have been collected in the last two years.

At least eight out of the following ten programmatic indicators should occur:

- 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 fields of nutrition, medicine, education, the salt industry, the media, and consumers, 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 human and agricultural salt, if the latter is not covered this does not necessarily preclude a country from being certified as IDD-free);
- commitment to assessment and reassessment of progress in the elimination of IDD, with access to laboratories able to provide accurate data on salt and urinary 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 the factory, retail and household levels;
- regular laboratory data on urinary iodine in school-aged children, with appropriate sampling for higher risk areas;
- cooperation from the salt industry in maintenance of quality control; and
- a database for recording of results or regular monitoring procedures, particularly for salt iodine, urinary iodine and, if available, neonatal TSH, with mandatory public reporting.

Table 9: Summary of criteria for monitoring progress towards sustainable elimination of IDD as a public health problem

Indicators	Goals
Salt iodization	
Proportion of households using adequately iodized salt	>90%*
Urinary iodine	
Proportion below 100 µg/l	<50%*
Proportion below 50 µg/l	<20%*
Programmatic indicators	
Attainment of the indicators specified on the opposite page	At least 8 of the 10

* *These goals are expressed as percentage of population.*

Acceptable iodine status

In addition to eliminating IDD, acceptable iodine nutrition will be achieved if median urinary iodine is not greater than 300 µg/l (see also Chapter 2.1).

Partnership evaluation

There is a need for periodic review of the entire programme, with the help of WHO, UNICEF, ICCIDD, and other appropriate organizations. Such external evaluation provides independent assessment, which is extremely helpful to a country programme. Partnership evaluation can also provide programmes with reassurance of their performance and effectiveness.

References

1. Bleichrodt N, Born MA. Meta-analysis of research on iodine and its relationship to cognitive development. In: Stanbury JB, ed. *The damaged brain of iodine deficiency.* New York, Cognizant Communication Corporation, 1994:195-200.

2. WHO, UNICEF, ICCIDD. *Indicators for assessing iodine deficiency disorders and their control through salt iodization.* Geneva, World Health Organization, 1994 (unpublished document WHO/NUT/94.6; available on request from Department of Nutrition for Health and Development, World Health Organization, 1211 Geneva 27, Switzerland).

3. Last JM, ed. *Dictionary of epidemiology,* 3rd ed. New York, International Epidemiology Association, Oxford University, 1995.

4. WHO, UNICEF, ICCIDD. *Recommended iodine levels in salt and guidelines for monitoring their adequacy and effectiveness.* Geneva, World Health Organization, 1996 (unpublished document WHO/NUT/96.13; available on request from Department of Nutrition for Health and Development, World Health Organization, 1211 Geneva 27, Switzerland).

5. Hetzel BS. Iodine deficiency disorders (IDD) and their eradication. *Lancet*, 1983, 2:1126-1129.

6. Delong GR. Observations on the neurology of endemic cretinism. In: Delong GR, Robbins J, Condliffe PG, eds. *Iodine and the brain*. New York, Plenum Press, 1989:231ff.

7. Delange F. Endemic cretinism. In: Braverman LE, Utiger RD, eds. *The thyroid. A fundamental and clinical text.* 8th ed. Philadelphia, Lippincott, 2000:743-754.

8. Hetzel BS, Pandav C. *SOS for a billion. The conquest of iodine deficiency disorders,* 2nd ed. New Delhi, Oxford University Press, 1996.

9. Dunn JT. What's happening to our iodine? *Journal of Clinical Endocrinology and Metabolism,* 1998, 83:3398-3400.

10. Delange F. The disorders induced by iodine deficiency. *Thyroid*, 1994, 4 (1):107-128.

11. Pandav CS, Rao AR. *Iodine deficiency disorders in livestock. Ecology and economics.* New Delhi, Oxford University Press, 1997.

12. MI, WHO, ICCIDD, USAID, PAMM, UNICEF. Houston R et al., eds. *Assessing country progress in universal salt iodization programs. Iodized salt program assessment tools (ISPAT).* Ottawa, Micronutrient Initiative Publications, 1999.

13. WHO, UNICEF, ICCIDD. Delange F et al., eds. *Elimination of iodine deficiency disorders in Central and Eastern Europe, the Commonwealth of Independent States, and the Baltic States. Proceeding of a Conference held in Munich, Germany, 3-6 September 1997*. Geneva, World Health Organization, 1998 (unpublished document WHO/EURO/NUT/96.1; available on request from Department of Nutrition for Health and Development, World Health Organization, 1211 Geneva 27, Switzerland).

14. WHO, UNICEF, ICCIDD. *Progress towards elimination of iodine deficiency disorders.* Geneva, World Health Organization, 1999 (unpublished document WHO/NHD/99.4; available on request from Department of Nutrition for Health and Development, World Health Organization, 1211 Geneva 27, Switzerland).

15. WHO, UNICEF, ICCIDD. *Global prevalence of iodine deficiency disorders.* Geneva, World Health Organization, 1993 (MDIS Working Paper # 1).

16. *Evaluation of certain food additives and contaminants. Thirty-seventh Report of the Joint FAO/WHO Expert Committee on Food Additives.* Geneva, World Health Organization, 1991 (WHO Technical Report Series, No. 806).

17. MI, ICCIDD, UNICEF, WHO. Mannar V, Dunn J, eds. *Salt iodization for the elimination of iodine deficiency.* The Netherlands, ICCIDD, 1995.

18. Diosady LL et al. Stability of iodine in iodized salt used for correction of iodine-deficiency disorders, II. *Food and Nutrition Bulletin* , 1998, 19:240-250 (The United Nations University).

19. WHO, UNICEF, ICCIDD. *Recommended iodine levels in salt and guidelines for monitoring their adequacy and effectiveness.* Geneva, World Health Organization, 1996 (unpublished document WHO/NUT/96.13; available on request from Department of Nutrition for Health and Development, World Health Organization, 1211 Geneva 27, Switzerland).

20. Pandav C et al. Field validation of salt iodine spot testing kit using multiple observers to assess the availability of iodized salt: experience from India. In: Geertman RM, ed. *Salt 2000*. *Volume 2. 8th World Salt Symposium. The Hague, 8-11 May 2000.* Amsterdam, Elsevier, 2000: 1039-1043.

21. Delange F, de Benoist B, Alnwick D et al. Risks of iodine-induced hyperthyroidism after correction of iodine deficiency disorders by iodized salt. *Thyroid,* 1999, (6):545-556.

22. Rendl J et al. Rapid urinary iodide test. *Journal of Clinical Endocrinology and Metabolism,* 1998, 83:1007-1012.

23. Nathan R. *Food fortification legislation and regulations,* 2nd ed. Atlanta, PAMM, 1995.

24. *Quality assurance, monitoring and enforcement of salt iodization programs. Report of a Training Workshop. Blantyre, Malawi 9-13 March 1998.* Atlanta, PAMM, 1998.

25. UNICEF, ICCIDD, PAMM, WHO, MI. Sullivan KM et al., eds. *Monitoring universal salt iodization programmes*. Atlanta, PAMM, MI, ICCIDD, 1995.

26. Pino S, Fang SL, Braverman LE. Ammonium persulfate: a new and safe method for measuring urinary iodine by ammonium persulfate oxidation. *Experimental and Clinical Endocrinology: Diabetes*, 1998, 106 (Suppl. 3): S22-S27.

27. Dunn JT et al. *Methods for measuring iodine in urine*. The Netherlands, ICCIDD, 1993.

28. Dunn JT, Myers HE, Dunn AD. Simple methods for assessing urinary iodine, including preliminary description of a new rapid technique (“Fast B”). *Experimental and Clinical Endocrinology: Diabetes*, 1997, 106(Suppl. 3): S10-S12.

29. Ohashi T et al. A newly developed method for determination of urinary iodine. *Clinical Chemistry*, 2000, 46: 529-536.

30. Stanbury JB et al. Iodine-induced hyperthyroidism, occurrence and epidemiology. *Thyroid,* 8 (1): 83-100.

31. Todd CH et al. Increase in thyrotoxicosis associated with iodine supplements in Zimbabwe. *Lancet*, 1995, 346:1523-1564.

32. Delange F, Bourdoux P, Ermans AM. Transient disorders of thyroid function and regulation in preterm infants. In: Delange F, Fisher D, Malvaux P, eds. *Pediatric thyroidology*. Basel, S. Karger, 1985:369-393.

33. Missler U, Gutekunst R, Wood WG. Thyroglobulin is a more sensitive indicator of iodine deficiency than thyrotropin: development and evaluation of dry blood spot assays for thyrotropin and thyroglobulin in iodine-deficient geographical areas. *European Journal of Clinical Chemistry and Clinical Biochemistry,* 1994, 32:137-143.

34. UNICEF, PAMM, MI, ICCIDD, WHO. Sullivan KM et al., eds. *Monitoring universal salt iodization programmes*, 1995.

35. Sullivan KM, May S Maberly G. *Urinary iodine assessment: a manual on survey and laboratory methods,* 2nd ed. UNICEF, PAMM, 2000.

36. Binkin NJ et al. Rapid nutrition surveys: how many clusters are enough? *Disasters,* 1992, 16:97-103.

37. Dean AG et al. *Epi Info, Version 6: a word processing, database, and statistics program for epidemiology on microcomputers.* Atlanta, Centers for Disease Control and Prevention, 1994.

annexes

annex 1

Titrimetric method for determining salt iodate content

The iodine content of iodated salt samples is measured using iodometric titration (see References on the following page for further details).

Description of the reaction

The reaction mechanism includes two steps:

- ***Liberation of free iodine from salt:*** addition of H_2SO_4 liberates free iodine from the iodate in the salt sample. Excess KI is added to help solubilize the free iodine, which is quite insoluble in pure water under normal conditions.

- ***Titration of free iodine with thiosulfate:*** free iodine is consumed by sodium thiosulfate in the titration step. The amount of thiosulfate used is proportional to the amount of free iodine liberated from the salt. Starch is added as an external (indirect) indicator of this reaction and reacts with free iodine to produce a blue colour. When added towards the end of titration (that is, when only a trace amount of free iodine is left) the loss of blue colour, or end-point, which occurs with further titration, indicates that all remaining free iodine has been consumed by thiosulfate.

Reaction steps for iodometric titration of iodate

1. IO_3^- (from salt) + $5I^-$ (from KI) + $6H^+$ (from H_2SO_4) $\rightarrow$ $3I + 3H_2O$

2. $2Na_2S_2O_3$ Sodium thiosulfate + I_2 Iodine $\rightarrow$ $2NaI$ Sodium iodide + $Na_2S_4O_6$ Sodium tetrathionate

Reagent preparation

The preferred water for this method should be boiled distilled water, which requires provision of a distillation unit. As a simpler alternative, regular tap water treated with a mixed bed deionizing resin can be used, thus avoiding the need for an expensive distillation unit.

0.005 M Sodium thiosulfate ($Na_2S_20_3$): Dissolve 1.24 g $Na_2S_20_35H_20$ in 1000 ml water. Store in a cool, dark place. This volume is sufficient for 100-200 samples, depending on their iodine content. The solution is stable for at least one month, if stored properly.

2 N Sulfuric acid (H_2S0_4): Slowly add 6 ml concentrated H_2S0_4 to 90 ml water. Make to 100 ml with water. This volume is sufficient for 100 samples. The solution is stable indefinitely. Always add acid to water, *not* water to acid, to avoid excess heat formation and spitting of acid. Stir solution while adding acid.

10% Potassium iodide (KI): Dissolve 100 g KI in 1000 ml water. Store in a cool, dark place. This volume is sufficient for 200 samples. Properly stored the solution is stable for six months, provided no change occurs in the colour of the solution.

Starch indicator solution: Dissolve reagent-grade sodium chloride (NaCl) in 100 ml double-distilled water. While stirring, add NaCl until no more dissolves. Heat the contents of the beaker until excess salt dissolves. While cooling, the NaCl crystals will form on the sides of the beaker. When it is completely cooled, decant the supernatant into a clean bottle. This solution is stable for six to twelve months. Dissolve 1 g chemical starch in 10 ml double-distilled water. Continue to boil until it completely dissolves. Add the saturated NaCl solution to make 100 ml starch solution. This volume is sufficient for testing 20 to 45 samples. Prepare fresh starch solution every day, since starch solution cannot be stored.

References

UNICEF, PAMM, MI, ICCIDD, WHO. Sullivan KM et al., eds. *Monitoring universal salt iodization programmes.* Atlanta, PAMM, MI, ICCIDD, 1995.

De Maeyer EM, Lowenstein FW, Thilly CH. *The control of endemic goiter.* Geneva, World Health Organization, 1979.

annex 2

Method for determining thyroid size by ultrasonography

Longitudinal and transverse scans are performed allowing the measurements of the depth (d), the width (w) and the length (l) of each lobe. The volume of the lobe is calculated by the formula :

$$V\ (ml) = 0.479 \times d \times w \times 1\ (cm).$$

The thyroid volume is the sum of the volumes of both lobes. The volume of the isthmus is not included.

Thyroid volume can be easily calculated using a calculator or personal computer during data entry. Portable ultrasound equipment is relatively rugged, but requires electricity. However, it can be operated from a car battery with the aid of a transformer. Trained operators can perform up to 100 or more examinations per day.

The body surface area is calculated using the formula of Dubois and Dubois (Archives of Internal Medicine, 1916, 17:863):

$$BSA\ (m^2) = W^{0.425} \times H^{0.725} \times 71.84 \times 10^{-4}$$

It should be emphasized that by using the ultrasonographic criteria, a thyroid gland will be called goitrous when its values will be above the 97th percentile of the volume found in an iodine replete population used as control.

Normal values for the median and 97th percentile for thyroid volume, as a function of both age and body surface area (BSA), are being developed. In areas with a high prevalence of protein-energy malnutrition, the BSA reference is recommended.

annex 3 Method for measuring urinary iodine using ammonium persulfate (Method A)

Principle

Urine is digested with ammonium persulfate. Iodide is the catalyst in the reduction of ceric ammonium sulfate (yellow) to cerous form (colourless), and is detected by rate of colour disappearance (Sandell-Kolthoff reaction).

Equipment

Heating block (vented fume hood not necessary), colorimeter, thermometer, test tubes (13 x 100 mm), reagent flasks and bottles, pipettes, balance scales.

Reagents

1. Ammonium persulfate (analytical grade)
2. As_2O_3
3. NaCl
4. H_2SO_4
5. $Ce(NH_4)_4(SO_4)_4 \cdot 2H_2O$
6. Deionized H_2O
7. KIO_3

Solutions

1.0 M Ammonium persulfate: Dissolve 114.1 g $H_2N_2O_8S_2$ in H_2O; make up to 500 ml with H_2O. Store away from light. Stable for at least one month.

5 N H_2SO_4: Slowly add 139 ml concentrated (36 $\underline{N}$) H_2SO_4 to about 700 ml deionized water *(careful - this generates heat!)*. When cool, adjust with deionized water to a final volume of 1 litre.

Arsenious acid solution: In a 2000 ml Erlenmeyer flask, place 20 g As_2O_3 and 50 g NaCl, then slowly add 400 ml 5 $\underline{N}$ H_2SO_4. Add water to about 1 litre, heat gently to dissolve, cool to room temperature, dilute with water to 2 litres, filter, store in a dark bottle away from light at room temperature. The solution is stable for months.

Ceric ammonium sulfate solution: Dissolve 48 g ceric ammonium sulfate in 1 litre 3.5 N H_2SO_4. (The 3.5 N H_2SO_4 is made by slowly adding 97 ml concentrated (36 N) H_2SO_4 to about 800 ml deionized water *(careful - this generates heat!)*, and when cool, adjusting with deionized water to a final volume of 1 litre). Store in a dark bottle away from light at room temperature. The solution is stable for months.

Standard iodine solution, 1 µg iodine/ml (7.9 µmol/l): Dissolve 0.168 mg KIO_3 in deionized water to a final volume of 100 ml (1.68 mg KIO_3 contains 1.0 mg iodine; KIO_3 is preferred over KI because it is more stable, but KI has been used by some laboratories without apparent problems). It may be more convenient to make a more concentrated solution, e.g., 10 or 100 mg iodine/ml, then dilute to 1 µg/ml. Store in a dark bottle. The solution is stable for months. Useful standards are 20, 50, 100, 150, 200, and 300 µg/l.

Procedure

1. Mix urine to suspend sediment.

2. Pipette 250 µl of each urine sample into a 13 x 100 mm test tube. Pipette each iodine standard into a test tube, and then add H_2O as needed to make a final volume of 250 µl. Duplicate iodine standards and a set of internal urine standards should be included in each assay.

3. Add 1 ml 1.0 M ammonium persulfate to each tube.

4. Heat all tubes for 60 minutes at 100°C.

5. Cool tubes to room temperature.

6. Add 2.5 ml arsenious acid solution. Mix by inversion or vortex. Let stand for 15 minutes.

7. Add 300 µl of ceric ammonium sulfate solution to each tube (quickly mixing) at 15-30 second intervals between successive tubes. A stopwatch should be used for this. With practice, a 15 second interval is convenient.

8. Allow to sit at room temperature. Exactly 30 minutes after addition of ceric ammonium sulfate to the first tube, read its absorbance at 420 nm. Read successive tubes at the same interval as when adding the ceric ammonium sulfate.

Calculation of results

Construct a standard curve on graph paper by plotting iodine concentration of each standard on the abscissa against its optical density at 405 μg/l (OD_{405}) on the ordinate.

Notes

1. This is modified from the former method (see reference below), substituting ammonium persulfate for chloric acid (more toxic) as digestant.

2. Since the digestion procedure has no specific end-point, it is essential to run blanks and standards with each assay to allow for variations in heating time, etc.

3. The exact temperature, heating time, and cooling time may vary. However, within each assay, the interval between the time of addition of ceric ammonium sulfate and the time of the reading must be the same for all samples, standards, and blanks.

4. With the longer ceric ammonium sulfate incubation and with 15 second interval additions of CAS, up to 120 tubes can be read in a single assay.

5. The volumes and proportions of samples and reagents can be varied to achieve different concentrations or a different curve shape, if conditions warrant. If different tube sizes are used, corresponding sized holes in the heating block are also needed.

6. If necessary, this method could probably be applied without a heating block, using a water, oil, or sand bath, but this is not recommended. It is essential that all tubes be uniformly heated and that the temperature be constant within the range described above.

7. Test tubes can be reused if they are carefully washed to eliminate any iodine contamination.

8. Various steps of this procedure are suitable for automation. For example, the colorimetric readings can be done in microtiter plates with a scanner, and the standard curves plotted and read on a simple desk computer.

Reference

ICCIDD, UNICEF, WHO. Dunn JT et al. *Methods for measuring iodine in urine.* The Netherlands, ICCIDD, 1993.

annex 4

Methodology for selection of survey sites by PPS sampling

In the selection of survey sites, the basic goal is to select sites that will be representative of the area to be surveyed. Methods used for performing household-based and school-based surveys are described in this annex.

Household-based surveys

The first step is to obtain the 'best available' census data for all of the communities in the area of interest. This information is usually available from the central statistical office within the Ministry that performs the census for the country.

From the census data, select the data for the area chosen for the survey. Make a list with four columns (see Table 10). The first column lists the name of each community. The second column contains the total population of each community. The third column contains the cumulative population - this is obtained by adding the population of each community to the combined population of all of the communities preceding it on the list. The list can be in any order: alphabetical, from smallest to largest population, or geographic.

The sampling interval (*k*) for the survey is obtained by dividing the total population size by the number of clusters to be surveyed. A random number (*x*) between 1 and the sampling interval (*k*) is chosen as the starting point using random number tables, and the sampling interval is added cumulatively. The communities to be surveyed are those with the $(x+n)^{th}$ person, the $(x+2n)^{th}$, $(x+3n)^{th}$, person and so on up to the $(x+30n)^{th}$ person.

The 30 clusters should be plotted on a map. Next, a logical sequence for the fieldwork should be developed for each of the survey teams.

An example of selecting communities in a cluster survey

In the fictitious area of El Saba, there are fifty communities (Table 10). In practice there would usually be many more than fifty communities, but this number is used for illustrative purposes to describe the method.

In Table 10 on the opposite page, the first column contains the names of the communities, the second column the population of each community, and the third column the cumulative population. A fourth column is used for identifying which communities will have one or more clusters selected.

Follow four steps to select communities to be included in the survey:

- Calculate the sampling interval by dividing the total population by the number of clusters. In this example, 24,940 / 30 = 831.
- Choose a random starting point (*x)* between 1 and the sampling interval (*k*, in this example, 831) by using the random number table. For this example, the number 710 is randomly selected.
- The first cluster will be where the 710th individual is found, based on the cumulative population column, in this example, Mina.
- Continue to assign clusters by adding 831 cumulatively. For example, the second cluster will be in the village where the value 1,541 is located (710 + 831 = 1,541), which is Bolama. The third cluster is where the value 2,372 is located (1,541 + 831 = 2,372), and so on. In communities with large populations, more than one cluster will probably be selected.

If two clusters are selected in one community, when the survey is performed the survey team would divide the city into two sections of approximately equal population size and perform a survey in each section. Similarly, if three or more clusters are in a community, the community would be divided into three or more sections of approximately equal population size.

Table 10: Selection of communities in El Saba using the PPS method

Name	Population	Cumulative population	Cluster
Utural	600	600	
Mina	700	1,300	1
Bolama	350	1,650	2
Taluma	680	2,380	3
War-Yali	430	2,810	
Galey	220	3,030	
Tarum	40	3,070	
Hamtato	150	3,220	4
Nayjaff	90	3,310	
Nuviya	300	3,610	
Cattical	430	4,040	5
Paralai	150	4,190	
Egala-Kuru	380	4,570	
Uwarnapol	310	4,880	6
Hilandia	2,000	6,880	7
			8
Assosa	750	7,630	9
Dimma	250	7,880	
Aisha	420	8,300	10
Nam Yao	180	8,480	
Mai Jarim	300	8,780	
Pua	100	8,880	
Gambela	710	9,590	11
Fugnido	190	9,880	12
Degeh Bur	150	10,030	
Mezan	450	10,480	
Ban Vinai	400	10,880	13
Puratna	220	11,100	
Kegalni	140	11,240	
Hamali-Ura	80	11,320	
Kameni	410	11,730	14
Kiroya	280	12,010	
Yanwela	330	12,340	
Bagvi	440	12,780	15
Atota	320	13,100	
Kogouva	120	13,220	16
Ahekpa	60	13,280	
Yondot	320	13,600	
Nozop	1,780	15,380	17
			18
Mapazko	390	15,770	19
Lotohah	1,500	17,270	20
Voattigan	960	18,230	21
			22
Plitok	420	18,650	
Dopoltan	270	18,900	
Cococopa	3,500	22,400	23
			24
			25
			26
			27
Famegzi	400	22,820	
Jigpelay	210	22,840	
Mewoah	50	22,890	
Odigla	350	23,240	28
Sanbati	1,440	24,680	29
Andidwa	260	24,940	30

School-based surveys

If a school-based survey is to be performed, the Ministry of Education should be contacted to obtain a listing of all schools with children of the appropriate age for the survey. Because the age range for the survey is 6-12 years, the grades in which these children are likely to be enrolled should be determined. Ideally, the Ministry of Education will have such a listing.

If one nationwide survey is performed, a listing of schools for the entire nation is needed. If subnational estimates are required, then a listing of the schools for each subnational area is needed. If enrolment information for each school is available, the PPS method should be used for selection. If enrolment information is not available, then systematic sampling can be performed.

Selecting schools

When performing school-based surveys in a geographical area, the first questions are:

- Is there a list of all schools in the geographic area with the appropriate age range?
- If there is a list of schools, is the number of pupils in each school known?

In most areas, a list of schools and their respective enrolments is available. Ensure that there are the same number of grades/levels in the schools. If a list of schools and enrolments is available, the selection of schools should be performed using the PPS method described for selecting communities. If there is a list of schools but the enrolments are not known, schools can be selected using systematic selection.

Using systematic selection, rather than PPS, complicates analysis somewhat. However, if enrolment information cannot be obtained easily there may be no alternative. If there is an extremely large number of schools in an area, or if a listing of all schools does not exist, another method can be used. This alternative method is described later in these guidelines.

Method 1 - schools when their enrolments are known

In this situation the PPS method for selecting communities, as described earlier in this chapter, should be used. First, generate a list of schools similar to that shown in Table 11. Second, determine the cumulative enrolment. Finally, select schools using the same PPS method as described for selecting communities (see Table 10).

Table 11: Selection of schools using the PPS method

School	Enrolment	Cumulative enrolment
Utural	600	600
Mina	700	1,300
Bolama	350	1,650
Etc.		

Method 2 - a list of schools is available, but enrolments are not known

When a list of schools is available but the enrolment of each school is not known, the systematic selection method should be employed as follows.

- Obtain a list of the schools and number them from 1 to *N* (the total number of schools).
- Determine the number of schools to sample (*n*), usually thirty.
- Calculate the "sampling interval" (*k*) by *N/n* (always round down to the nearest whole integer).
- Using a random number table, select a number between 1 and *k*. Whichever number is randomly selected, refer to the school list and include that school in the survey.
- Select every k^{th} school after the first selected school.

Example of systematic selection of schools

For illustrative purposes, Table 12 lists fifty schools. The following method would be used to select eight schools:

Step one:	There are fifty schools, therefore $N = 50$.
Step two:	The number of schools to sample is eight; therefore $n = 8$.
Step three:	The sampling interval is 50 / 8 = 6.25; round down to the nearest whole integer, which is 6; therefore, $k = 6$.
Step four:	Using a random number table, select a number from 1 to (and including) 6. In this example, suppose the number selected had been 3. Accordingly, the first school to be selected would be the third school on the list, which in this example is Bolama.
Step five:	Select every sixth school thereafter; in this example, the selected schools would be the 3rd, 9th, 15th, 21st, 27th, 33rd, 39th, and 45th schools on the list.

In some circumstances, this method might result in the selection of more than the number needed. In the above example, for instance, had the random number chosen in Step four been 1 or 2, then nine schools would have been selected rather than eight. This is because the value for *k* was rounded down from 6.25 to 6.

In this situation, to remove one school so that only eight are selected, again go to the random number table to pick a number. The school that corresponds to that random number is removed from the survey.

To analyse properly the data collected using systematic sampling, additional information needed would include the number of eligible pupils in each school. Note that usually thirty clusters are selected; the eight indicated in Table 12 have been selected in this example for illustrative purposes only.

Table 12: Selection of schools using the systematic selection method

School		Selected	School		Selected
1	Utural		26	Ban Vinai	
2	Mina		27	Puratna	Y
3	Bolama	Y	28	Kegalni	
4	Taluma		29	Hamali-Ura	
5	War-Yali		30	Kameni	
6	Galey		31	Kiroya	
7	Tarum		32	Yanwela	
8	Hamtato		33	Bagvi	Y
9	Nayjaff	Y	34	Atota	
10	Nuviya		35	Kogouva	
11	Cattical		36	Ahekpa	
12	Paralai		37	Yondot	
13	Egala-Kuru		38	Nozop	
14	Uwarnapol		39	Mapazko	Y
15	Hilandia	Y	40	Lotohah	
16	Assosa		41	Voattigan	
17	Dimma		42	Plitok	
18	Aisha		43	Dopoltan	
19	Nam Yao		44	Cococopa	
20	Mai Jarim		45	Famegzi	Y
21	Pua	Y	46	Jigpelay	
22	Gambela		47	Mewoah	
23	Fugnido		48	Odigla	
24	Degeh Bur		49	Sanbati	
25	Mezan		50	Andidwa	

Method 3 - an extremely large number of schools

In very large populations, it may not be possible or efficient to select schools using either the PPS or the systematic selection method. For example, Szechwan Province in China has a population of approximately 100 million. Even if a list of schools were available at the provincial level, it would take much time and effort to select schools using either of these methods.

Accordingly, another approach may be more appropriate. First, select districts using the PPS method. Develop a listing of the districts, their populations, and cumulative populations similar to the PPS selection described earlier. Next, determine the number of schools to survey, based on the cumulative population using PPS.

For districts with one or more clusters to be selected, select schools in each district using a random number table. For example, if a district has 200 schools, number them from 1 to 200. Then, randomly select a number from 1 to 200 using the table. If two schools are to be selected, then randomly select two numbers. Finally, and while not technically correct, it would be acceptable to analyse the school-based data as though the schools were selected using PPS methodology.

Other possibilities

In situations where male and female children attend the same school, the selection of schools and pupils would be the same as discussed above. In situations where males and females attend separate schools, when a school of one sex is selected the nearest school of the opposite sex should also be surveyed.

For example, a survey is to be performed in an area where males and females attend separate schools. Thirty schools are to be selected, and twenty pupils sampled in each. When an all-male school is visited, information should be collected on ten male pupils. Then, the nearest female school is visited, and information collected on ten female pupils.

Reference

Adapted from: Sullivan KM, May S, Maberly G. *Urinary iodine assessment: a manual on survey and laboratory methods,* 2nd ed. UNICEF, PAMM, 2000.

annex 5

Summarizing urinary iodine data: a worked example

Some actual urinary iodine data from schoolchildren in Cameroon, following the implementation of universal salt iodization, are presented in the first (left) column of Table 14. The data have been entered into a spreadsheet on a personal computer for ease of calculation. However, with small numbers such as these, the calculations are relatively easily performed by hand.

Steps in processing the data

1. Before proceeding, carefully check the data entered against the original. Ensure that the same number of data points (*n)* are present, and look for any anomalous results.

2. Next, sort the data from highest to lowest, or vice-versa. The spreadsheet will do this automatically. (In Microsoft *Excel*, use the Data Analysis function on the Tools menu, and select "Rank and Percentile".) The sorted data are shown under "Value" in Table 14, starting with the highest value. The next columns show the rank and percentile for each data point.

3. The median is the middle value of the ranked data. In other words, it is the value of the $(n + 1) / 2^{th}$ value. In this case, there are 98 data points, so the median is the value of (98+1) divided by 2 = 49.5^{th} data point. Accordingly, use the middle point between the 49^{th} and 50^{th} values: 122 and 121 µg/l, respectively. The mid-point is 121.5 µg/l, so the median is 121.5 µg/l.

4. Next, calculate the number of values below 100, 50, and 20 µg/l, respectively. The ranking will allow this to be done very easily. In this case, there are 33 values below 100 µg/l, 6 below 50 µg/l, and one below 20 µg/l. These should be calculated as percentages: 33 of 98 is 33.7%, 5 of 98 is 5.1% and 1 of 98 is 1.0%.

5. Check if any values are above 500 µg/l. There is one (1.0%).

6. The 20th and 80th percentiles may are readily observed, or automatically displayed using the PERCENTILE function [=PERCENTILE (range of cells,0.2)]. The 20th percentile (P20) is 82.4 µg/l and P80 is 191.8 µg/l.

7. The "Descriptive Statistics" function of Data Analysis in *Excel* provides all statistics shown: select "Summary Statistics" in the dialogue box. Note that the mean is much higher than the median, indicating that the distribution is heavily skewed to the right. This is also shown by the much greater distance between P80 and the median, compared to that between P20 and the median.

8. In addition, the data can be shown as a histogram using the "Histogram" function of Data Analysis in *Excel*. Convenient ranges need to be chosen for making the frequency distribution, which will be reflected in the height of each bar of the histogram. 50 µg/l is suggested (i.e., the first bar is 0-49 µg/l, the second 50-99 µg/l, the third 100-149 µg/l, and so on). Appropriate modifications can be made using "Chart Options" and related functions. The histogram is shown in Figure 4. A fully detailed description for constructing that histogram is not given here.

Table 13: Summary of results

Number	98
Median	121.5 µg/l
20th percentile	82.4 µg/l
80th percentile	191.8 µg/l
Distribution:	
<100 µg/l	33.7%
<50 µg/l	5.1%
<20 µg/l	1.0%
>500 µg/l	1.0%

These results indicate that there is no iodine deficiency, and that salt iodization is therefore having the required impact. There is no evidence of significant overiodization. No changes are needed on the basis of these results, but further follow-up is always essential.

Table 14: Urinary iodine data in Cameroon schoolchildren following salt iodization

UI(µg/l)	Value	Rank	Percent	Descriptive Statistics	
141	535	1	100.00%		
138	480	2	98.90%	Mean	142.7449
138	395	3	97.90%	Standard error	8.877338
154	340	4	96.90%	Median	121.5
162	320	5	95.80%	Mode	138
26	295	6	94.80%	Standard deviation	87.88117
63	273	7	92.70%	Sample variance	7723.099
111	273	7	92.70%	Kurtosis	5.463542
120	264	9	91.70%	Skewness	1.970291
65	261	10	90.70%	Range	525
190	240	11	89.60%	Minimum	10
142	232	12	87.60%	Maximum	535
138	232	12	87.60%	Sum	13989
95	224	14	86.50%	Count	98
273	208	15	85.50%	Confidence	
132	200	16	83.50%	level (95.0%)	17.61905
164	200	16	83.50%		
66	198	18	82.40%		
158	193	19	80.40%		
114	193	19	80.40%		
118	190	21	79.30%		
232	188	22	78.30%		
145	180	23	77.30%		
94	174	24	76.20%		
90	164	25	75.20%		
122	162	26	74.20%		
114	160	27	73.10%		
340	158	28	72.10%		
193	154	29	71.10%		
135	150	30	70.10%		
261	146	31	68.00%		
75	146	31	68.00%		
63	145	33	67.00%		

Table 14: Urinary iodine data in Cameroon schoolchildren following salt iodization *(continued)*

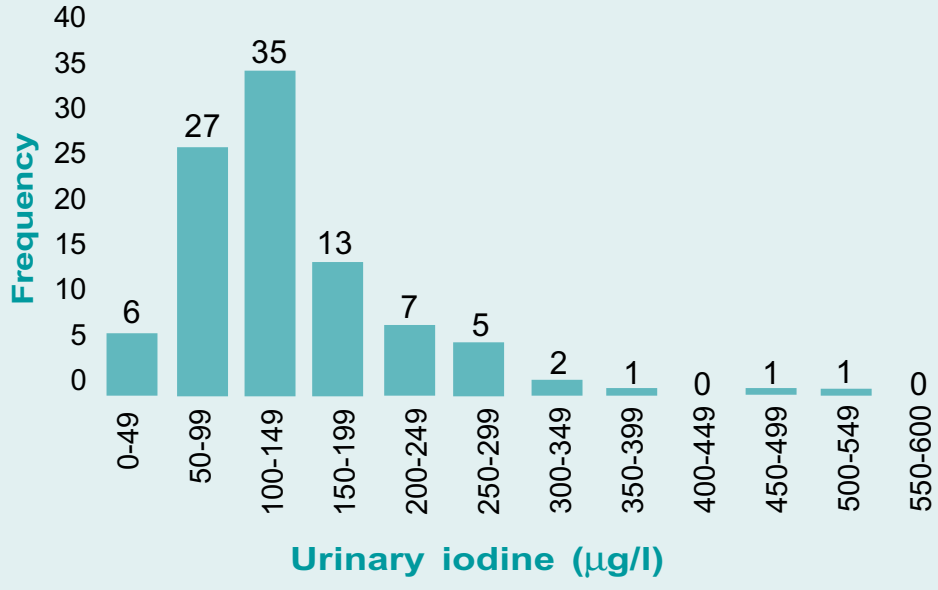
UI (µg/l)	Value	Rank	Percent	Descriptive Statistics
264	144	34	65.90%	
142	142	35	63.90%	
174	142	35	63.90%	
121	141	37	62.80%	
395	140	38	60.80%	
320	140	38	60.80%	
240	138	40	57.70%	
140	138	40	57.70%	
66	138	40	57.70%	
146	135	43	56.70%	
115	133	44	55.60%	
82	132	45	54.60%	
82	128	46	53.60%	
535	124	47	52.50%	
74	122	48	50.50%	
35	122	48	50.50%	The median lies half-way
83	121	50	49.40%	between these two values
104	120	51	46.30%	
64	120	51	46.30%	
208	120	51	46.30%	
49	118	54	45.30%	
89	117	55	44.30%	
109	115	56	42.20%	
106	115	56	42.20%	
32	114	58	40.20%	
128	114	58	40.20%	
232	111	60	39.10%	
88	110	61	38.10%	
115	109	62	37.10%	
144	108	63	36.00%	
86	106	64	35.00%	
150	104	65	34.00%	
224	96	66	32.90%	<100 µg/l
92	95	67	30.90%	
180	95	67	30.90%	
193	94	69	29.80%	

Table 14: Urinary iodine data in Cameroon schoolchildren following salt iodization *(concluded)*

UI (µg/l)	Value	Rank	Percent	Descriptive Statistics
133	92	70	28.80%	
80	90	71	26.80%	
87	90	71	26.80%	
96	89	73	25.70%	
120	88	74	24.70%	
146	87	75	22.60%	
160	87	75	22.60%	
124	86	77	21.60%	
90	83	78	20.60%	
10	82	79	18.50%	
55	82	79	18.50%	
108	80	81	16.40%	
480	80	81	16.40%	
80	75	83	15.40%	
122	74	84	14.40%	
198	66	85	12.30%	
200	66	85	12.30%	
87	65	87	11.30%	
200	64	88	10.30%	
188	63	89	8.20%	
54	63	89	8.20%	
273	55	91	7.20%	
120	54	92	6.10%	
140	49	93	5.10%	<50 µg/l
110	42	94	4.10%	
42	35	95	3.00%	
95	32	96	2.00%	
117	26	97	1.00%	
295	10	98	.00%	<20 µg/l

Figure 4: Frequency table and histogram to show distribution of urinary iodine values after iodization in Cameroon

Urinary iodine (µg/l)	Frequency
0-49	6
50-99	27
100-149	35
150-199	13
200-249	7
250-299	5
300-349	2
350-399	1
400-449	0
450-499	1
500-549	1
550-599	0



annex 6

Legislation on iodized salt: ASIN Law, The Philippines

Republic Act No.8172
An Act Promoting Salt Iodization Nationwide and for Related Purposes (ASIN LAW) and its Implementing Rules and Regulations

Republic of the Philippines
Congress of the Philippines
Metro Manila

First Regular Session

Begun and Held in Metro Manila, on Monday the twenty-fourth day of July, nineteen hundred and ninety-five

[Republic Act No. 8172]

AN ACT PROMOTING SALT IODIZATION NATIONWIDE AND FOR RELATED PURPOSES

Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled:

SECTION 1. ***Title.*** – This Act shall be known as "An Act for Salt Iodization Nationwide (ASIN)".

SEC. 2. ***Declaration of Policy.*** – It is hereby declared the policy of the State to protect and produce the health of the people, to maintain an effective food regulatory system, and to provide the entire population especially women and children with proper nutrition. For this purpose, the State shall promote the nutritional fortification of food to combat micronutrient malnutrition as a priority health program for the nation.

SEC. 3. ***Purposes.*** – The purposes of this Act are to:

a) Contribute to the elimination of micronutrient malnutrition in the country, particularly iodine deficiency disorders, through the cost effective preventive measure of salt iodization;

b) require all producers/manufacturers of food-grade salt to iodize the salt that they produce, manufacture, import, trade or distribute;

c) require the Department of Health (DOH) to undertake the salt iodization program and for its Bureau of Food and Drugs (BFAD), to set and enforce standards for food-grade iodized salt and to monitor compliance thereof by the food-grade salt manufacturers;

d) require the local government units (LGUs), through their health officers and nutritionist-dieticians, or in their absence through their sanitary inspectors, to check and monitor the quality of food-grade salt being sold in their market in order to ascertain that such salt is properly iodized;

e) require the Department of Trade and Industry (DTI) to regulate and monitor trading of iodized salt;

f) direct the Department of Science and Technology (DOST), in collaboration with the Technology and Livelihood Resource Center (TLRC), to initiate, promote, and cause the transfer of technology for salt iodization;

g) authorize the National Nutrition Council (NNC), the policy-making and coordinating body on nutrition, to serve as the advisory board on salt iodization;

h) provide mechanisms and incentives for the local salt industry in the production, marketing, and distribution of iodized salt; and

i) ensure the sustainability of the salt iodization program.

SEC. 4. ***Definition of Terms*** – For purposes of this Act, the following terms shall mean:

a) **Micronutrient malnutrition** – a disorder resulting from deficiencies in vitamin A, iron, iodine and other micronutrients which the body needs in minute quantities everyday.

b) **Iodine deficiency disorders** – a broad spectrum of deficiencies resulting from lack of iodine in the diet which leads to the reduction of intellectual and physical capacity affecting everyone who is iodine-deficient and may manifest as goiter, mental retardation, physical and mental defects, and cretinism.

c) **Food fortification** – the addition of nutrients to processed foods at levels above the natural state.

d) **Salt iodization** – the addition of iodine to salt intended for human or animal consumption in accordance with specifications as to form, fortificant, method, manner and composition as may be prescribed by the BFAD.

e) **Food-grade salt** – salt for human and animal consumption as distinguished from industrial salt.

f) **Regulatory requirements** – the provisions of all applicable laws regulations, executive orders, and other enactment's related to food quality and safety, purity, nutritional composition, and other aspects of food regulation or control.

g) **Industrial salt** – salt used in the treatment, processing, and/or manufacture of non-food commercial products.

h) **Manufacturer** –one who produces, imports, trades in and distributes salt.

i) **Subsistence producer/manufacturer** – one who produces, trades in or distributes salt not exceeding two metric tones (2m.t.) per year.

j) **Small producer/manufacturer** – one who produces, imports, trades in or distributes salt ranging from more than two metric tones (2m.t.) to three hundred metric tons (300 m.t.)per year.

k) **Medium producer/manufacturer** –one who produces, imports, trades in or distributes salt ranging from more than three hundred metric tons (300 m.t.) to two thousand metric tons (2,000 m.t.) per year.

l) **Large producer/manufacturer** – one who produces, imports, trades in or distributes salt exceeding two thousand metric tones (2,000 m.t.) per year.

SEC. 5. ***Applicability*** **-**

a) This Act shall apply to the entire salt industry, including salt producers/manufacturers, importers, traders and distributors, as well as government and non-government agencies involved in salt iodization activities.

b) Iodized salt that conforms to the standards set by the BFAD to meet national and nutritional needs shall be made available to consumers: *Provided*, That the implementation of this Act shall be enforced over a staggered period of one (1) year for large and medium producers/manufacturers; two (2) years for small producers/manufacturers; and five (5) years for subsistence producers/manufacturers.

c) All food outlets, restaurants, and stores are hereby required to make available to customers only iodized salt in their establishment upon effectivity of this Act. These establishments shall be monitored with the help of the LGUs through its health officers and nutritionist-dietitians, or in their absence, the sanitary inspectors to check and monitor the quality of food-grade salt being sold or served in such establishments.

d) In areas endemic to iodine deficiency disorders, iodized salt shall be made available. Local government officials at the provincial and municipal levels shall provide mechanisms to ensure enforcement of this provision through ordinances and public information campaigns.

e) All food manufacturers/processors using food-grade salt are also required to use iodized salt in the processing of their products and must comply with the provisions of this Act not later than one (1) year from its effectivity: *Provided*, That the use of iodized salt shall not prejudice the quality and safety of their food products: *Provided, however*, That the burden of proof and testing for any prejudicial effects due to iodized salt fortification lies n the said food manufacturers/processor.

f) Salt producers/manufacturers shall register with the BFAD, which shall maintain an updated registry of salt producers/manufacturers and shall monitor compliance with the salt iodization program.

g) All food-grade salt shall be labeled in a manner that is true and accurate, not likely to mislead purchasers and in accordance with the requirements prescribed by the BFAD.

h) For a period of three (3) years from the effectivity of this Act, the DOH shall provide free iodized salt to indigents residing in sixth class municipalities as may be allowed by their annual appropriations.

SEC. 6. ***Support to the Salt Industry*** – The following agencies and institutions shall support the salt iodization program through their respective internal programs:

a) the DTI is hereby required to assist and support local salt producers/manufacturers in upgrading their production technologies to include iodization by helping them obtain soft loans and financial assistance for the procurement of salt iodization machines, packaging equipment and technology and fortificant; and by ensuring the systematic distribution of the iodized salt in the market;

b) the Cooperative Development Authority (CDA) shall assist the formation of cooperatives of local salt producers/manufacturers in order that they can economically engage in salt iodization and distribution of iodized salt;

c) the DOST, in collaboration with the TLRC, shall develop and implement comprehensive programs for the acquisition of, design and manufacture of salt iodization machines and transfer of salt iodization technology to small and subsistence local salt producers/manufacturers; and

d) the Department of Environment and Natural Resources (DENR) and other appropriate government agencies shall identify areas that are suitable for use as salt farms with the purpose of protecting such areas from environmental risks to ensure sustainability of iodized salt production.

SEC. 7. ***Public Information*** **-** The benefits and rationale of the use of iodized salt shall be adequately disseminated and promoted through organized, systematic and nationwide information campaign which shall involve major sectors of society to be spearheaded by the DOH, in cooperation and coordination with the LGUs and other agencies concerned, particularly the Department of Education, Culture and Sports (DECS), the Philippine Information Agency (PIA), provincial science centers, private sector, and students.

The implementing agency, in coordination with the PIA, shall seek the cooperation of the media sector to assist in public information dissemination. Salt iodization and its benefits shall also be included and given emphasis in all levels of health subjects in both public and private schools.

SEC. 8. ***The Salt Iodization Advisory Board*** **-** The National Nutrition Council (NNC), as presently composed, including representatives of the DENR, the medical profession and the salt manufacturers, shall serve as the salt iodization advisory board and shall function as the policy and coordinating body on salt iodization programs and activities. It shall coordinate the efforts of all agencies concerned and monitor the implementation of the provisions of this Act. It shall also submit an annual report to the Congress of the Philippines on the progress of the salt iodization program and offer recommendations for its improvement.

SEC. 9. ***Sanctions*** **-** The procedures for imposing sanctions under this Act and for inspecting and investigating the premises where any salt is received, held, manufactured, labeled, stored, displayed, delivered, distributed, sold or located, or where it is reasonably believed these activities are being carried out or where salt is located, shall be in accordance with the provisions of the Republic Act No. 3720, otherwise known as the Food, Drugs and Cosmetics Act, As Amended: *Provided*, That any person, whether natural or juridical, who violates any of the provisions of this Act or any of the rules and regulations promulgated for its effective implementation shall be punished by a fine of not less than One thousand pesos (P1,000) nor more than One hundred thousand pesos (P100,000): *Provided, however*, That if the violation is committed by any officer, director or member of a business and a juridical entity acting beyond the scope of his authority, such officer, director or member responsible therefore shall be personally liable for the fine: *Provided, further*, That such violator shall suffer a revocation of its business permit and/or a ban of its product from the market: *Provided, finally*, That the BFAD, in coordination with the LGUs concerned, shall be authorized to impose and collect the fines from the violators, and such collections shall accrue to the BFAD for its use in the implementation of this Act.

SEC. 10. ***Appropriations*** **-** The amount necessary for the implementation of this Act shall initially be charged to the appropriations of the agencies concerned as may be appropriated, under the current General Appropriations Act. Thereafter, such amount as may be necessary for its implementation shall be included in the annual General Appropriations Act.

SEC. 11. ***Implementing Rules and Regulations*** **-** The DOH, in cooperation with the agencies concerned, shall formulate the necessary rules and regulations for the effective implementation of this Act within sixty (60) days from its approval.

SEC. 12. ***Separability Clause*** **-** If any portion of this Act is declared invalid, the remainder of this Act shall not be affected by such declaration and shall remain valid an enforceable.

SEC. 13. ***Effectivity Clause*** **-** This Act shall take effect fifteen (15) days after its publication in the Official Gazette or in two (2) national newspapers of general circulation, whichever is earlier.

This Act, which is a consolidation of Senate Bill No.112 and house Bill No.45 was finally passed by the Senate and the House of Representatives on November 16, 1995 and November 5, 1995, respectively.

IMPLEMENTING RULES AND REGULATIONS OF REPUBLIC ACT No. 8172
AN ACT PROMOTING SALT IODIZATION NATIONWIDE AND FOR RELATED PURPOSES

BACKGROUND

Pursuant to Section 2 of Republic Act No. 8172, entitled “An Act Promoting Salt Nationwide” (ASIN), approved by the President on 20 December 1995 and which took effect on 20 January 1996, mandating the Department of Health (DOH) as the lead agency in the implementation of said Act and, in accordance with Section 11 of said Act mandating the DOH to formulate the Implementing Rules and Regulations (IRR) in cooperation with the other government agencies involved in the implementation of the law, the following Rules and Regulations are hereby adopted to implement effectively the provisions of R.A. No. 8172.

RULE I
COVERAGE

SECTION 1. These Rules and Regulations shall apply to:

a) All producers/manufacturers/importers/traders of salt for human or animal consumption,
b) All restaurants and other food establishments where food is being served hot or sold,

c) All food manufacturers/processors using salt in their manufacturing processes,
d) All local government units (LGUs),
e) All other government agencies,
f) All non governmental agencies and related professional organizations; and
g) All government and private hospitals and other institutions.

RULE II
INTERPRETATIONS

SECTION 1. These Rules and Regulations shall be construed in a manner that can achieve the objectives of R.A. 8172 namely: a) to contribute to the elimination of micronutrient malnutrition, particularly iodine deficiency disorders; b) to require salt producers/manufacturers to iodize the salt they manufacture, produce, distribute, trade and/or import; c) for the government agencies to undertake their roles and responsibilities in carrying out the provisions of this Act; d) for the food processing and the food service industries to use only iodized salt; c) to provide mechanisms and incentives for the salt industry; and f) to ensure the sustainability of the salt iodization program.

Any question or doubt as to the intent and meaning of the provisions shall be construed or resolved in accordance with the Policy and Purposes as provided in R.A. 8172.

RULE III
DEFINITION OF TERMS

In the implementation of the Act, terms that have specific meaning shall be construed in accordance with the general definitions provided in Section 4 of the Act, to wit:

a) **Distribution** – means the exchange, transmittal, conveyance, consignment, supply, delivery, trade, sale, or disposal of food-grade salt, whether for remuneration or other considerations.

b) **Distributor** – refers to an establishment which distributes, sells or imports salt for distribution to retailers.

c) **Fortificant** – in relation to the process of salt iodization, the term shall refer to potassium iodate or other suitable fortificant as recommended by DOH, taking into consideration the circumstances of quality, effectiveness, stability, availability and new discoveries that can bring salt iodization in the most effective and economic manner.

d) **Food fortification** – the addition of nutrients to processed foods at levels above the natural state.

e) **Food-grade salt** – refers to salt for human and animal consumption as distinguished from industrial salt.

f) **Food manufacturers/processors** – refer to the business/enterprise of manufacturing or processing food using salt in their products.

g) **Food service establishments** – refer to hotels, restaurants, carinderias, catering firms, hospitals and other related outlets which serve or sell food to consumers.

h) **Industrial salt** – refers to salt used in the treatment, processing, and/or manufacture of non-food commercial products.

i) **Iodine deficiency disorders** – a broad spectrum of manifestations resulting from lack of iodine in the diet which leads to the reduction of intellectual and physical capacity affecting everyone who is iodine deficient and may manifest as goitre, mental retardation, physical and mental defects, and cretinism.

j) **Manufacturer** – one who produces, imports, trades in and distributes salt and is categorized as follows:

   1) Large producer/manufacturer – one who produces, imports, trades and /or distributes salt exceeding two thousand metric tons (2,000 MT) per year.

   2) Medium producer/manufacturer – one who produces, imports, trades in, distributes salt ranging from more than three hundred metric tons (300 MT) to two thousand metric tons (2,000 MT) per year.

3) Small salt producer/manufacturer – one who produces, imports, trades in, or distributes salt ranging from more than two metric tons (2MT) to three hundred metric tons (300 MT) per year.

4) Subsistence producer/manufacturer – one who produces, trades in or distributes salt not exceeding two metric tons (2MT) of salt per year.

k) **Method** – refers to the scientifically accepted technique that is perceived to bring about the best and most effective way of salt iodization.

l) **Micronutrient malnutrition** – refers to a disorder resulting from deficiencies in vitamin A, iron, iodine and other micronutrients which the body needs in minute quantities every day.

m) **Registration** – the process or acquiring a business/enterprise license/permit to manufacture, produce, trade or import iodized salt with the Bureau of Food and Drugs (BFAD) or appropriate LGU.

n) **Regulatory requirements** – the provisions of all applicable laws, regulations, executive orders, and other enactment's related to food quality and safety, purity, nutritional composition, and other aspects of food regulations and control. In applying or interpreting the regulatory requirements, reference may also be made to scientifically accepted standards or regulations.

o) **Salt industry** – refers to the business sector engaged in the production, distribution, trading, retailing and importation of salt.

p) **Salt iodization** – the addition of iodine to salt intended for human or animal consumption in accordance with specifications as to form, fortificant, method, manner and composition as may be prescribed by the BFAD of the DOH.

q) **Salt Iodization Advisory Board (SIAB)** – composed of the National Nutrition Council (NNC) Governing Board, including a representative each from the Department of Environment and Natural Resources (DENR), the medical profession, and the salt manufacturers.

r) **Stores** – refer to department stores, shops, groceries, mini-marts, and other outlets which wholesale or retail iodized salt for the consumers and users.

s) **Trading** – refers to the bullying and selling of food-grade salt by wholesale or retail.

RULE IV
STANDARDS and REQUIREMENTS

SECTION 1. Iodized salt to be sold/distributed in the Philippines, whether locally produced or imported, shall conform with the standards formulated by the BFAD or DOH which is in Annex 1 of these implementing rules and regulations. Such standards shall be periodically reviewed and updated by the BFAD in consultation with the SIAB and other concerned parties.

SECTION 2. Failure to comply with the quality specifications and labeling requirements prescribed in the standards shall mean a violation of the provisions on adulteration and misbranding under Sections 14 and 15 of R.A. 3720, otherwise known as the Food, Drugs and Cosmetics Act, as amended and the relevant provisions of R.A. 7394 otherwise known as the Consumer Act.

SECTION 3. To ensure the quality of iodized salt prior to distribution, all manufacturers of iodized salt shall conduct routine quality assurance activities. Such activities shall include, but shall not be limited to the following:

a) Iodine levels testing: at regular intervals on a daily basis, samples of iodized salt shall be collected from the production line and tested for iodine content.

b) Equipment inspection: at least twice daily to ensure its proper operation.

c) Mixing process: shall be monitored regularly to ensure consistent mixing and homogeneity of iodine content in the batch being processed.

d) Monitoring of salt ready for distribution: each lot shall be sampled to ensure conformity to prescribed iodine level.

e) Packaging and labeling inspection shall be routinely conducted to ensure the integrity of the package and conformity to prescribe labeling requirements.

f) Record keeping: daily control charts and weekly summaries of activities and corrective actions taken shall be maintained for a period of at least 12 months from date of manufacture. Manufacturers of iodized salt shall provide traders with a Certificate of Iodization of the specified batch or lot sold to the traders.

SECTION 4. Iodized salt shall be distributed and sold according to the principle of first in, first out. Iodized salt may be sold at retail or final distribution points within a period of not more than 12 months from the date of manufacture, after which it shall be considered expired. Expired salt shall be replaced by or returned to the last seller or distributor in the manufacturing-distribution chain.

SECTION 5. The DOH shall put in place a system to monitor the quality of iodized salt in collaboration with the LGUs and the Department of the Interior and Local Government (DILG). It shall also seek the assistance of the Department of Finance (DOF) and LGUs to determine the volume of production and sale of the locally manufactured and imported iodized salt.

SECTION 6. Until such time when all food-grade salt shall be iodized in accordance with R.A. 8172, salt manufacturers/producers, traders and retailers shall maintain the proper identification and segregation of iodized salt from non-iodized salt in storage and during display at retail. They shall make sure that salt buyers or consumers get the appropriate kind of salt they purchase.

SECTION 7. Within one (1) year from the effectivity of the Act, all food manufacturers and processors shall utilize iodized salt in their products expect when the use of iodized salt will have an adverse effect on a specified product. In such cases, the food manufacturers/processors shall present appropriate evidence to the BFAD which shall serve as basis for exemption from compliance with Section 5(e) of this Act. The BFAD shall submit to the SIAB a lit of food manufacturers utilizing iodized salt and those with definite exemption, and shall update this list annually.

RULE V
REGISTRTION OF IODIZED SALT MANUFACTURERS AND SALT IMPORTERS/DISTRIBUTORS

SECTION 1. All iodized salt manufacturers and salt importers/distributors shall register with the BFAD according to the following schedule: The large and medium manufacturers shall register within one (1) year from the effectivity of this Act; small manufacturers within two (2) years, and subsistence manufacturers within five (5) years. After the effectivity of these IRR, new salt producers/manufacturers shall register before operation.

SECTION 2. The BFAD shall issue a License to Operate (LTO) to iodized salt manufacturers and salt importers/distributors upon their compliance with prescribed documentary and technical requirements in Annex 2 and 3. Those engaged in manual salt iodized shall secure a Certificate of Training from the DOH before they can be provided with a LTO. If an importer is already holding a valid LTO as importer, he/she need not apply for another license; however, the importer must comply with the technical requirements and their products shall be subject to monitoring.

SECTION 3. The BFAD may delegate to the LGUs its authority to issue LTOs in cities and municipalities other than those in the National Capital Region (NCR) and in areas where the seat or office of the DOH-Regional Field Offices (RFOs) is located, through a memorandum of agreement between the BFAD and the LGU, or the BFAD and the RFO, with the suggested terms and conditions contained in Annex 4 hereof. Such agreements shall be considered part of these IRR.

SECTION 4. All distributors/traders of locally produced iodized salt, whether or not engaged in repacking iodized salt from bulk to retail containers, shall register with the LGUs.

RULE VI
ROLE OF AGENCIES CONCERNED IN THE SALT IODIZATION PROGRAM

SECTION 1. The DOH shall lead in the implementation of this Act. Specifically, it shall:

a) Spearhead a public information drive in cooperation and coordination with the LGUs and other agencies particularly the Department of Education, Culture and Sports (DECS), Philippine Information Agency (PIA), Provincial Science Centres-Department of Science and Technology (DOST), private sector and students. All sectors in the salt industry shall also assist in such information campaign through tri-media and all other social marketing activities for a systematic and sustained public information campaign;

b) Provide training on salt iodization technology and quality assurance and control through its Nutritional Service (NS) in coordination with the DOST and the Technology and Livelihood Resource Centre (TLRC); and

c) Set and enforce standards for food-grade iodized salt and monitor compliance thereof by the food-grade salt manufacturers through its BFAD.

SECTION 2. The LGUs shall support the development and sustainability of the salt industry through:

a) The formulation of ordinances and information campaigns promoting the availability and use of iodized salt;

b) Provision of budget for health and nutrition programs;

c) Assistance to other governmental agencies in the implementation of the salt iodization program;

d) Monitoring the quality of salt as provided by law through its respective health officers and nutritional-dietitians or, in their absence, through the sanitary inspectors; and

e) Establishment and maintenance of a list of salt producers in their respective territorial jurisdiction. A list of registered salt producers in every province shall be submitted to the BFAD within 6 months from the effectivity of these IRR and shall be updated annually. The list shall reflect the following information per salt producer/manufacturer:

1) Name and address of company and/or owner
2) Location of salt production site (sitio/barangay)
3) Annual production capacity (in metric tons)
4) Types of salt produced:
   i) food-grade (coarse or fine)
      - iodized salt
      - non-iodized salt
   ii) industrial salt

f) Distribution channels, such as:
- direct sale to consumers within the province
- traders within the province
- traders from other provinces/regions
- food manufacturers within the province
- food manufacturers outside the province/region

SECTION 3. The Department of Trade and Industry (DTI) shall assist and support local salt producers/ manufacturers in upgrading their production technologies to include iodization by helping them obtain soft loans and financial assistance for the procurement of salt iodization machines, packaging equipment and technology, and fortificants; and by ensuring the systematic distribution of the iodized salt in the market. Specifically, it shall:

a) Regulate an monitor the trading of iodized salt in accordance with R.A. 7581 otherwise known as the Price Act;

b) Provide incentives to the salt industry by including salt iodization as a priority investment program of the government through its Board of Investment;

c) Assist salt producers/manufacturers obtain soft loan for machines, equipment and other materials such as fortificant and other chemicals needed to upgrade the salt industry, through its Bureau of Small and Medium Business Development (BSMBD) and Small Business Guarantee and Finance Corporation (SBGFC); and

d) Provide assistance to salt producers/manufacturers on matters of package design and packaging technology through its Product Development and Design Centre of the Philippines (PDDCP).

SECTION 4. The Department of Science and Technology (DOST) shall develop and implementa comprehensive program for the acquisition of, design, and manufacture of salt iodization equipment, and transfer of the salt iodization technology to salt producers/manufacturers.

SECTION 5. The Technology and Livelihood Resource Centre (TLRC) shall:

a) Assist the DOST in the development and implementation of a comprehensive program for the acquisition of, design and manufacture of salt iodization machines and transfer of salt iodization technology to small and subsistence local salt producers/manufacturers;

b) Provide funding assistance to qualified small producers, especially if located in one of the priority provinces in support of the government's poverty alleviation and industry decentralization drive;

c) Develop a program of training entrepreneurs in setting up micro/cottage/small business enterprises to be located in its Technology and Livelihood Development Centre (TLDC) in the provinces;

d) Undertake an all-out information campaign to promote the use of iodized salt nationwide through its tri-media information program and in its business technology courses.

SECTION 6. The Cooperative Development Authority (CDA) shall provide assistance to the small and subsistence salt producers/manufacturers so that they may organize themselves into cooperatives and undertake salt iodization and marketing of iodized salt in the spirit of cooperativism. The organized cooperatives shall be registered in accordance with the CDA guidelines, rules, regulations and applicable laws.

SECTION 7. The Department of Environment and Natural Resources (DENR) shall provide assistance to the prospective salt producers/manufacturers in identifying suitable land areas appropriate for use as salt works/ farms. The conversion of such lands into salt farms shall require the concurrence of the landowner and the concerned agency/entity. The DENR shall ensure, through the Environmental Impact Statement (EIS) System, that proposed activities near the salt farms do not adversely affect the latter. The DENR shall also monitor the adoption of anti-pollution control measures by iodized salt producers/manufacturers.

SECTION 8. The Bureau of Customs of the Department of Finance (DOF) shall assist the DOH in monitoring salt importation by providing quarterly reports of entries, including names and addresses of importers/ consignees and quantity of shipment. It shall likewise inform the DOH on the quality and quantity of importation of the iodized salt.

SECTION 9. Any assistance to salt manufacturers/producers/traders/importers shall take into favorable consideration the size and capability of such salt producers as well as their faithful compliance with laws on health, labor and employment, environment and ecology.

RULE VII
ADVISORY BOARD

SECTION 1. Creation of the Salt Iodization Advisory Board – The Salt Iodization Advisory Board (SIAB) shall be composed of all members of the NNC Governing Board namely the Departments of Agriculture; Health; Social Welfare and Development; Education, Culture and Sports; Science and Technology; the Interior and Local Government; Labor and Employment; Trade and Industry; and Budget and Management; the National Economic and Development Authority; its three (3) private sector representatives, and a representative from the DENR, the medical profession and the salt manufacturers, as mandated by Section 8 of this Act. The Chairman of the NNC Governing Board shall chair the SIAB. The chairman shall convene the SIAB within one (1) month upon the approval of these IRR.

SECTION 2. Role – The SIAB shall function as the policy and coordinating body on the national salt iodization program and activities. It shall coordinate and monitor all activities concerning the salt iodization program from production and marketing, to public information campaign. It shall analyze the effectiveness of the salt iodization activities and then evaluate the progress of the program annually based on the reports submitted by DOH and other concerned agencies in the implementation of this Act. The SIAB shall submit an annual report every end of December to the Congress of the Philippines on the status of the salt iodization program and offer recommendations for its improvement.

RULE VIII
SANCTIONS

SECTION 1. The BFAD Director is hereby authorized to impose an administrative fine to existing salt producers/manufacturers/importers/traders based on the applicability of this Act. The provisions of this Act shall be immediately applicable to salt producers/manufacturers/importers/traders newly established or organized after the effectivity of the Act. The LGUs are authorized to impose administrative fine to food service establishments and outlets one year after the effectivity of the Act. The administrative fine shall be in the amount of not less than One Thousand Pesos (P1,000,00) but not more than One Hundred Thousand Pesos (P100,000.00), after notice and hearing of violation of any of the provisions of R.A. 8172 or its implementing rules and regulations.

In the imposition of the said administrative penalty, the imposable fine of One Thousand Pesos (P1,000.00) to Thirty Thousand Pesos (P30,000.00) shall be considered minimum penalty. Thirty One Thousand Pesos (P31,000.00) to Sixty Thousand Pesos (P60,000.00) as medium penalty, and Sixty One Thousand Pesos (P.61,000.00) to One Hundred Thousand Pesos ((P100,000.00) as maximum penalty: provided that the maximum fine shall be in addition to the revocation of the offender's License to Operate, and provided further that in all cases where the subject matter of the offence is a prohibited product, the Director shall order the recall and/or withdrawal of the product from the market.

SECTION 2. When the offence is committed with the following circumstances, the minimum penalty shall be imposed:

a) a history or record of satisfactory compliance with the rules and regulations prior to the commission of the offence, or absence of previous violation of R.A. 8172 or its IRR; and

b) lack of information on the part of the offender about the rules and regulations or requirements of the subject matter of the violation/offence.

SECTION 3. When the act or omission in violation of R.A. 8172 and its implementation rules and regulations is attended by a manifest intention to mislead, defraud or deceive the consuming public, the maximum fine and revocation of License to Operate shall be imposed.

SECTION 4. The medium penalty shall be imposed when the offence committed is not attended by any of the circumstances described in Section 2 and 3 hereof.

SECTION 5. The BFAD Director may delegate the conduct of administrative investigation of any violation of R.A. 8172 or its IRR to the head of the LGU: provided that the recommendation shall be subject to review and confirmation by the BFAD Director before the same shall be deemed final and executory. In such case, the LGU may be authorized by the BFAD Director to collect the fine that may be imposed provided that such fine collected shall be held in trust for the exclusive use by the investigating LGU in the implementation of this Act.

RULE IX
SEPARABILITY CLAUSE

If any provision of these Implementing Rules and Regulations is declared null and void, for any reason, the remaining provisions shall not be affected thereby and shall remain valid.

RULE X
EFFECTIVITY

These Implementing Rules and Regulations shall take effect thirty days after its publication in a newspaper of general circulation.

ANNEX 1

STANDARD FOR IODIZED SALT

1. **Scope**

This standard applies to iodized salt used as a condiment or an ingredient in the preparation of food in households, food service and food manufacturing establishments.

2. **Description**

Iodized salt is food-grade salt that contains the prescribed level of iodine . It shall be produced from refined or unrefined (crude) salt obtained from underground rock salt deposits or by evaporation of seawater or natural brine. The finished product shall be in the form or solid crystal or powder, white in color, without visible spots of clay, sand, gravel, or other foreign matters.

3. **Iodization process**

3.1 Salt may be iodized with potassium iodate (KIO_3) or potassium iodide (KI) by means of any of the following methods:

a) Dry mixing if salt is in powdered form
b) Drip feeding or spray mixing if salt is in crystal form
c) Submersion of salt crystals in iodated brine

4. **Essential composition and quality factors**

4.1 Purity requirements

To ensure the stability of iodine, salt to be iodized must conform with the following purity requirements:

Moisture max	4% for refined salt 7% for unrefined salt
NaCl, min	97% (dry basis)
Calcium and magnesium, max	2%
Water insoluble, max	0.2%
Heavy metal contaminants, max	
Arsenic as As	0.5 mg/Kg
Cadmium as Cd	0.5 mg/Kg
Lead as Pb	2.0 mg/Kg
Mercury as Hg	0.1 mg/Kg

4.2 Naturally present secondary products and contaminants in raw salt

Notwithstanding the purity requirements in section 4.1, the raw salt may contain natural secondary products, which are present in varying amounts depending on the origin and method of production of the salt, and which are composed mainly of calcium, potassium, magnesium and sodium sulphates, carbonates, bromides, and of calcium potassium magnesium chlorides as well. Natural contaminants may also be present in amounts varying with the origin and the method of production of the salt.

4.3 Iodine levels

In order to meet national needs, the prescribed levels of iodine (I_2)in iodized salt shall be as indicated below:

	Type of containers/Package	
Sampling Point	Bulk (>2kg)	Retail ($\leq$2kg)
Production Site	70-150 mg/kg	60-100 mg/kg
Port of Entry*	70-150 mg/kg	60-100 mg/kg
Retail Site	$\geq$ 50 mg/kg	$\geq$ 40 mg/kg

* For imported iodized salt; also at importer's /distributor's warehouse

5. **Food additives**

5.1 All additives used, including KIO_3, and KI, shall be of food-grade quality and shall conform to specifications prescribed by JEFCA or the Food Chemicals Codex. Permitted additives for iodized salt are listed below:

5.2 Anticacking Agents

	Maximum level in the final product
5.2.1 Coating agents; Carbonates, Calcium/magnesium, Magnesium oxide; Tricalcium phosphate; Silicon oxide, amorphous; Silicates of calcium, sodium or magnesium; Alumin of sodium or calcium	20 g/kg singly ort in combination (for 5.2.1 and 5.2.2)
5.2.2 Coating hydrophobic agents; aluminium, calcium, magnesium, potassium, or sodium salts of myristic, palmitic or stearic acid	
5.2.3 Crystal modifiers; ferrocyanides, calcium, potassium or sodium	10 mg/kg singly or in combination expressed as $[Fe(CN_6)]^3$
5.3 Emulsifiers	
Polysorbate 80	10 mg/kg
5.4 Processing aid	
Dimethylpolysiloxane	10 mg of residue/kg

6. **Packaging**

All iodized salt shall be packed in woven polypropylene bags, clean and unused jute bags, or other non-porous material with a lining of high density polyethylene to ensure the retention of appropriate iodine level at the time of consumption.

7. **Labelling**

7.1 Iodized salt for commercial distribution shall carry appropriate labeling in accordance with BDAD rules and regulations on labeling of prepackaged foods. Specifically, the following information shall be declared in every container of iodized salt whether in bulk or retail package:

7.1.1 For locally produced iodized salt

a) The name of the product, "IODIZED SALT", printed in bold capital letters
b) Name and address of manufacturer
c) Net weight (in metric units)
d) Iodine compound used
e) Chemical additives e.g. anticaking agents, emulsifiers
f) Open date marking e.g. "Best Before" or "Consume Before" Date
g) Lot Identification Code (Repackers must use manufactures's lot i.d. code)
h) Storage instruction: STORE IN COOL DRY PLACE

7.1.2 For imported iodized salt

a) Same as in 7.1.1 (a), (c) to (h)
b) Name and address of importer/local distributor
c) Country of origin

7.2 Labeling of Non-retail containers

In the case of non-retail containers of at least 25 kg of iodized salt, the labeling information required in section 7.1.1 (b), (d), (e) or in 7.1.2 (b) may not be declared if such bulk packages are intended for delivery to distributors/repackers or food manufacturers/institutional users, provided every shipment or delivery is accompanied by a document containing all the information in 7.1.1 or 7.1.2

8. **Storage, transport and display at retail**
In order to minimize avoidable losses of iodine, iodized salt shall not be exposed to any of the following conditions during storage, transport and display at retail outlets:
a) direct sunlight or near source of strong light
b) high temperature and humidity
c) contamination with moisture e.g. rain, flood, etc.
d) contamination with dust or filth from the environment

Reference

An Act Promoting Salt Iodization Nationwide and for Related Purposes (ASIN LAW) and its Implementing Rules and Regulations. Published by the Nutrition National Council. Printed in the Republic of the Philippines. 1996.

annex 7

List of participants: IDD Consultation, Geneva 1999

F. Azizi, Director
Endocrine Research Centre
Shahid Beheshti University
of Medical Sciences
and Health Services
P.O. Box 19395-4763
Teheran, Islamic Republic of Iran
Tel: 98-21-2409301-5
Fax: 98-21-2402463
E-mail: azizi@erc-iran.com

H. Bürgi, Chief
Department of Medicine
Burgerspital, Solothurn 4500
Switzerland
Tel: 41-32-622.0302
Fax: 41-32-621.2435
E-mail: buergi@smile.ch

Zu-Pei Chen, Director
Institute of Endocrinology/Chairman
National IDD Advisory Committee
to Ministry of Public Health
Tianjin Medical College
Tianjin 300070
People's Republic of China
Tel: 86-22-2352.5608
Fax: 86-22-2337.0618
E-mail: zpchen@public1.tpt.tj.cn

F. Delange, Executive Director
ICCIDD
153, Avenue de la Fauconnerie
1170 Brussels, Belgium
Tel: 32-2-675.8543
Fax: 32-2-675.1898
E-mail: fdelange@uld.ac.be

A. Duffiel
Professional Officer
Administrative Committee
on Coordination
Sub-Committee on Nutrition
c/o WHO, 20 Avenue Appia
1211 Geneva 27, Switzerland

J. Dunn
Professor of Medicine
Secretary of ICCIDD
University of Virginia
Health Sciences Center
P.O. Box 511
Charlottesville, VA 22908, USA
Tel: 1-804-924.5929
Fax: 1-804-296.9275
E-mail: jtd@avery.med.virginia.edu

B. Hetzel, Chairman
ICCIDD
139 Kermode Street
North Adelaide 5006, Australia
Tel: 61-8-8267.3768
Fax: 61-8-8204.7221
E-mail: iccidd@a011.aone.net.au

P. Jooste, Chief Scientist
National Research Programme
for Nutritional Intervention
Medical Research Council
P.O. Box 19070
Tygerberg 7505
South Africa
Tel: 27-21-938.0370
Fax: 27-21-938.0321
E-mail: pieter.jooste@mrc.ac.za

M.G. Karmarkar, Senior Adviser
ICCIDD
Centre for Community Medicine
All India Institute for Medical Sciences
Ansari Nagar
New Delhi 110029, India
Tel: 91-11-371.0726
Fax: 91-11-686.3522

G. Maberly
Professor of International Public Health and Director of PAMM
Department of International Health
Rollins School of Public Health
Emory University
1518 Clifton Road, NE
Atlanta, GA 30322, USA
Tel: 1-404-727.4553
Fax: 1-404-727.4590
E-mail: gmaberl@sph.emory.edu

C. Pandav, Regional Coordinator
ICCIDD
Centre for Community Medicine
All India Institute for Medical Sciences
Ansari Nagar
New Delhi 110029, India
Tel: 91-11-649.2693
Fax: 91-11-686.3522
E-mail: pandav@iccidd.ernet.in

E. Pretell, Head
Endocrine Service
Regional ICCIDD Coordinator for America
Cayetano Heredia Peruvian University
Avenue Cuba 523
Lima 11, Peru
Tel: 51-1-265.9118
Fax: 51-1-265.8094
E-mail: epretell@per.itete.com.pe

K. Sullivan, Assistant Professor
Department of Epidemiology
Emory University
1518 Clifton Road, NE
Atlanta, GA 30322, USA
Tel: 1-404-727.5846
Fax: 1-404-727.5369
E-mail: cdckms@sph.emory.edu

J.W. Schultink
Senior Adviser, Micronutrients
UNICEF
3 United Nations Plaza
New York, NY 10017, USA
Tel: 1-212-326.7000
Fax: 1-212-888-7465/7454
E-mail: wschultink@unicef.org

C. Todd, Regional Health Adviser
Delegation of the European Commission in Zimbabwe
P.O. Box 4252
Harare, Zimbabwe
Tel: 263-4-701914-5 ext. 203
Fax: 263-4-725360
E-mail:
charles.todd@delzwe.cec.eu.int

WHO Secretariat

H. Allen
Department of Nutrition
for Health and Development
World Health Organization
20 Avenue Appia
1211 Geneva 27, Switzerland
Tel: 41 22-791.3322
Fax: 41-22-791.4156
E-mail: allenh@who.ch

B. de Benoist
Department of Nutrition
for Health and Development
World Health Organization
20 Avenue Appia, 1211
Geneva 27, Switzerland
Tel: 41-22-791.3412
Fax: 41-22-791.4156
E-mail: debenoistb@who.ch

G. A. Clugston, Director
Department of Nutrition
for Health and Development
World Health Organization
20 Avenue Appia, 1211
Geneva 27, Switzerland
Tel: 41-22-791.3326
Fax: 41-22- 791.4156
E-mail: clugstong@who.ch

A. Verster, Director
Health Protection and Promotion
Regional Office of the
World Health Organization
for the Eastern Mediterranean
Nasr City, Cairo 11371, Egypt
Tel: 202-670-25-35
Fax: 202-670-24-92 or 202-670-24-94
E-mail: verstera@who.sci.eg