IODINE DEFICIENCY STATUS OF CHILDREN IN SRI LANKA 2000-2001

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FOREWARD

This study on the assessment of iodine deficiency disorders among primary school children in Sri Lanka was carried out by the Department of Nutrition, Medical Research Institute, Colombo under the able direction of Dr. Renuka Jayatissa. This study was carried out island-wide except in a few isolated areas in the North East where access was not possible.

This is a comprehensive study that should interest not only the medical professionals responsible for the implementation and monitoring of the salt iodisation programme legislated and implemented by the Ministry of Health but also the entire population. The findings of this study highlight the need to streamline the programme to achieve the expected benefits. Salt iodisation programme will be a permanent feature and the production process should be monitored strictly with no leeway. Also the minimum limits of iodisation should be stipulated in the gazette notification.

UNICEF assisted in establishing the laboratory facilities for estimation of urinary iodine levels an urine iodine at the MRI and provided the services of a Consultant to train the laboratory staff in the techniques. This has created the avenue for training the peripheral staff and creating laboratory units at least at provincial level to make the facility a permanent feature.

Whilst thanking UNICEF for the facilities provided, I trust the staff will continue this good work.

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I wish to place on record, my appreciation of those who assisted me in numerous ways to make this study, a success.

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CHAPTER 1
INTRODUCTION

A deficiency of iodine, which is among the body's essential trace elements, is both easy and inexpensive to prevent (WHO 1994). One teaspoon of iodine is all a person requires in a lifetime and yet its deficiency at critical stages of foetal life and early childhood remains the world's single most important and preventable cause of mental retardation.

While goitre has been recognised for thousands of years and cretinism for at least several hundred, their relationship to iodine deficiency was discovered only in 1813. The benefits of iodine were fully recognised in 1896 when the presence of iodine in the thyroid gland was demonstrated. Goitre is only the 'tip of the iceberg' and the introduction of the term "Iodine Deficiency Disorders" (IDD) which includes a spectrum of problems ranging from spontaneous abortions and stillbirths in pregnancy to psychomotor defects, impaired mental function, slowed cognitive development, muscular disorders in young children better describes the clinical situations that could arise as a result of iodine deficiency (WHO 1999).

Occurrence of iodine deficiency is shown to be associated with geographical characteristics of a country. This is well demonstrated by the high prevalence of iodine deficiency seen in countries in the vicinity of large mountain ranges e.g. Switzerland where there was a high prevalence of severe iodine deficiency in 1920s.

An estimated 1571 million people world-wide live in iodine-deficient environments and are thus at risk of IDD, 20 million of them are believed to be significantly mentally handicapped. As a result a large proportion of the severely deficient are women in their reproductive years whose babies are at high risk of irreversible mental retardation unless they receive adequate amounts of iodine (WHO 1994). It is estimated that 172 million people in the South East Asian region are victims of goitre while 599 million are at risk (WHO 2000).

Iodine is concentrated (as iodides) in the top-soil of the earth and absorbed by food crops. About 90% of daily needs of human’s are met from food and 10% from water. Sea fish, other seafood and seaweed are rich sources of iodine suitable for human consumption. Iodine is also

found in vegetables grown in soils containing adequate amounts of this trace element, and in milk products, eggs, poultry and meat from animals whose diet contained sufficient iodine. In regions subject to frequent flooding, the soil may be stripped of its iodine and the food crops, vegetables and fruits grown in the region are deficient in iodine (WHO 1994).

Based on studies of balance and excretion over a 24-hour period, a safe daily intake of iodine has been estimated to be between a minimum of 50μg and a maximum of at least 1000μg. A generally accepted desirable adult intake is 100-300μg/day. At all intake levels, a proportionate amount of iodine is excreted in the urine (WHO 1994).

Usefulness of salt iodization as a method of prevention of goitre was best demonstrated in Switzerland, where the salt iodization programme introduced in 1922 at a cost of approximately US$ 0.07 per inhabitant per year led to virtual elimination of this problem. From 1924 onwards, iodised salt was introduced in many other countries including parts of United States of America. The problem of iodine deficiency rapidly improved by reducing the goitre rates and cretinism quickly disappeared (WHO 1999).

CHAPTER 2
IODINE DEFICIENCY OF SRI LANKA

Sri Lanka is an island with a land area of approximately 65,654 square kilo-meters. The island stretches to a maximum length of 435 kilo-meters, and a width of 225 kilo-meters. It comprised a mountainous area in the south-central region ranging in elevation from about 3000 to 7000 ft. The coastal plain occupies the rest of the island, being narrower in the west and south but broadening out in the east and north. The climate of Sri Lanka is tropical. The annual average rainfall varies from below 1000mm over the North-west and South-east of the island to over 5000mm on the south-western slopes of the central hills (Sri Lanka 1999).

The mean annual temperature over Sri Lanka, is about 27.5^0 and 18^0C over the lowlands and the highlands in the central region respectively. Relative humidity varies generally from about 70% during the day to about 90-95% at night. In the driest areas in the North-west and South-east relative humidity drops to about 60%. The rivers flowing to the west, south and east being shorter than those flowing north, north-west or north-east on account of the lay of the land.

Historical overview

Endemic goitre[1] has not been mentioned in the Portuguese and Dutch writings on Ceylon, nor during the early British period. The first reports on the presence of goitre were those from Bennet (1843) and by Pridham (1849) who reported the presence of goitre in Galle area along the coastal belt, but did not refer to its presence elsewhere. Subsequent reports by Hirsh (1885) and Ballou (1894) also noted that goitre was not uncommon among the native women in Galle. Greenwald (1946,1950) summarises by stating that goitre in Ceylon is comparatively a recent disease and appears to have envisaged the possibility of an ever recurring leaching factor which could be continually in action depleting the iodine resources in the soils and thereby the drinking water and food plants springing from them, this making them iodine deficient (Greenwald 1953).

Studies on iodine deficiency in Sri Lanka (Ceylon)

[1] Endemic Goitre is the condition affects more than 5% of people living in any circumscribed area.

The first island wide survey to study the problem of iodine deficiency was carried out among the rural population by the Nutrition Department of the Medical Research Institute (MRI) during the years 1947 - 49. This study showed that goitre was endemic in the south west sector of Ceylon in the wet zone. The study was carried out in a random sample of 39 villages selected at random all over Ceylon and all residents of the villages were included in the study (Mahadeva & Shanmuganathan 1967). Grading of goitre was not undertaken during this survey. The endemic goitre belt was found to extend throughout the Western, Sabaragamuwa, Central, Southern and part of Uva province. Females were more affected that the males. There was almost no goitre in the Northern, Eastern and North Western provinces. The highest incidence was found in the region between the Kelani and the Kalu rivers. Almost no goitres were found in the northern, eastern, and north-western provinces. It showed that the mean annual escape of water per square mile of a river basin (the yield factor) was to be directly proportional to the intensity of endemic goitre in that basin.

Even though the findings were published many years later in 1967, the results of the study made the Government of Ceylon to request the World Health Organisation for assistance in deciding whether goitre constituted a public health problem in Sri Lanka. In 1950, a study to asses goitre status was carried out by Wilson who studied 722 school children in 10 different rural areas of the country. The goitre prevalence was 22.5% in the wet zone and 6.1% in the dry zone and was found to be prevalent in the south-west region of the country. A higher prevalence was seen among the females(Wilson 1954).

Following the study by Wilson , a recommendation was made to provide potassium iodide tables to pregnant women attending the maternity clinics and for adolescent girls in schools, in the high prevalence areas. Several years after the implementation of this programme, in 1963, a second survey was carried out by the same group of researchers from the MRI, in nine villages included in the previous survey (Mahadeva & Shanmuganathan 1967). This study showed a significant increase in the problem of goitre specially among females.

All these studies indicated that that the goitre belt in Sri Lanka was confined to the south-west region of the island extending over the whole of the Western, Sabaragamuwa, Central and Southern provinces and part of Uva province, which constitute the wet zone of the country,

with a very high annual rainfall of 100-200 inches. Over 70% of the population of the island reside in this zone (Mahadeva 1967). The high annual rainfall in this area is believed to leech the soil of its iodine content and environment iodine deficiency results (Stanbury and Hetzel 1980).

Subramaniam and Deo (1966) carried out a rapid clinical survey and investigated iodine metabolism in endemic goitre in order to establish its aetiology and indicated the environment iodine deficiency. Serum PBI^{127} levels were within normal limits and absence of cretins and deaf-mutes showed the mild nature of iodine deficiency. It was suggested the control measures required to combat it.

Recent studies on the prevalence of goitre include the survey carried out in 1986, by Fernando et al (1989) in 17 of 24 districts including 59,158 school children and the study done by the MRI in 1987 - 89 among 1,641 pregnant women in the Kalutara district carried out during the period 1987-89. The overall goitre prevalence among school children in the age group 5-18 years ranged from 6.5% to 30.2% and it was reported that it was more in inland (21%) than in coastal (13%) areas (Table 1). Goitre prevalence among the pregnant women in Kalutara district was 63% in 1987-89 (MRI 1990).

Iodine content of food and water

Assessment of iodine content of drinking water was undertaken as a part of the study carried out in 1963 showed that the iodine level varied from 2.2 ug/l to 10.1ug/l . The samples from the Western, Sabaragamuwa, Southern, North Western, Central and Uva provinces had mean iodine levels in water of less than 10 μg/l while the Eastern, North Central and Northern provinces had higher values of iodine content in water. On three samples the iodine content was low, 1.4-2.7μg/l. One water sample draining from indigenous rocks of dry zone, had very high iodine content of 61.0μg/l (Mahadeva & Shanmuganathan 1967). Wilson (1954) also reported that iodine content of drinking water is low in the wet areas of Ceylon.

Information of iodine content of foods consumed by Sri Lankans is available from one study which showed that the iodine content of the food consumed by residents in endemic and non-endemic areas provided an intake of 300-350μg and 850μg per person per day respectively.

Even after allowing for extreme losses amounting to 38% which may occur during cooking, the daily intake of iodine in endemic areas and non-endemic areas were 186-215μg and 530μg per person per day respectively (Mahadeva et al 1968). The main findings from these studies are summarised in Table 1.

Interventions undertaken to control iodine deficiency

The first reported intervention to control iodine deficiency was implemented in 1951 on the recommendation of Dr. Wilson, where a pilot project for supplying iodide salt to a test area in Gampola district commenced in 1961. This intervention was unsuccessful due to consumer resistance. Several years later, in 1990, a project for the iodation of all domestic salt was initiated in the Kalutara district (MRI 1990).

Salt production, distribution and consumption

Salt is manufactured in Sri Lanka by solar evaporation using sea water as raw material. The salt so produced has very low iodine content. There are two major salt producing regions in Sri Lanka at Hambantota and Puttalam. The main salt producing factory is Lanka Salt Ltd. Hambantota. It produces about 80,000 metric tons of salt annually. Around 60,000 metric tons of salt (two third) of the production of salt is sold for small-scale salt manufactures to carry out the iodisation and for industrial purpose. The total salt production in the country is around 135,000 tons. In addition, Sri Lanka imports salt approximately 30% of its requirements from India.

The manufacturers are responsible for the distribution of salt to retail traders throughout the country. It is difficult to determine individual salt consumption accurately because of the culinary practices related to dissolving the kitchen salt in water and then decanting off the clear supernatant liquid as needed. By considering the results of the dietary surveys carried out by the MRI, the figure of 10 grammes per head per day is taken as a consumption value.

Since IDD control activities were initiated, the capacity of the salt industry to iodate salt has been strengthened and iodisation plants have been installed and made operational. During the period 1992-1995, UNICEF provided seven iodisation plants and 2,000 kg of potassium iodate to the National Salt Corporation of which four plants have been installed at Lanka Salt Ltd. and

one at Putallam for the small salt producers. Total requirement of potassium iodate is 1.5 metric tons per year and the estimated annual expenditure is Rupees 1,500,000.

Over 280 small-scale private salt producers account for approximately 30,000 metric tons annually (one third of the production of total salt) by continuous spraying after drying and cooling and before packaging. Salt is packed in 500g packets in opaque thick plastic bags and stored in master polythene bags. At retail level, salt is sold in 500, 1000g opaque plastic bags with thickness of 100gauge.

National salt iodization programme

The decision to implement a universal salt iodization programme was made in 1995, on the basis of reported studies that indicated iodine deficiency as an important problem in Sri Lanka. The relevant legislation was adopted in 1995 under the FOOD ACT, 26 of 1980. This required minimum level of 50ppm iodine in salt at factory level and 25ppm at consumer level. Potassium iodate was designated the sole source of iodine. The sale of non-iodised salt for human consumption was banned to ensure accessibility of iodised salt to each and every consumer.

Under the Section 32 of the Food Act, monitoring of iodised salt is a role of the department of Health. Public Health Inspectors (PHI) are supposed to monitor the salt at retail and household levels by using a simple rapid test kits. The five laboratories in the country carried out the quantitative estimation (titration method) of iodine levels in salt.

The programme of universal salt iodization has been in existence in Sri Lanka for the past few years. In addition to close monitoring of the programme to ensure its effectiveness, it is necessary to assess the impact of this programme on the problem of iodine deficiency. Hence a study was carried out with the following objectives:

1. To estimate the prevalence of goitre among primary school children.
2. To determine the urinary iodine levels among school children.
3. To assess the levels of iodine in the salt consumed at the household level.
4. To assess the level of iodine in the drinking water.
5. To assess the level of iodine in the salt at retail level
6. To determine the knowledge and practices on iodised salt among the retail shop owners.

Table 1

Summary features of iodine studies carried out in Sri Lanka from 1947 - 1999

Study	Study period	Study subjects	Sample size	Results
Mahadeva & Shanmuganathan 1967	1947-49	Males and females in the 31 wet zone villages	20,333 males & 20,972 females	The presence of visible goitre was 0.0-0.6% among males and 0.0 to 6.6% among females.
Mahadeva & Shanmuganathan 1967	1963	9 out of 31 villages that had been surveyed in 1947.	3304 males and 5268 females	The presence of visible goitre was 0.0-2.6% among males and 7.0 to 15.0% among females.
		pregnant women from 17 antenatal clinics	2870	The incidence varied from 0.4% to 34.8%.
		Foods from same area, other areas and imported		Food of people in endemic and non-endemic areas is about 300-350μg and 850μg per person per day respectively
Wilson 1954	1950	Rural school children in 10 different parts	722 (312 boys and 405 girls)	Goitre prevalence was 22-55% in wet zone and 6-12% in dry zone and prevalent in south-west region of the country. More in females than in males.
		Adults in rural maternity hospital wards and outdoor dispensaries		Few goitres were seen in men.
		Rural drinking water	6	Three samples the iodine content was low, 1.4-2.7μg/l. One water sample draining from igneous rocks of dry zone, had very high iodine content of 61.0μg/l.
		Manioc sample	6	None of the changes were greater than an ordinary mixed diet.
Deo & Subramaniam 1971	1966	School children aged 8-16 years in endemic zone		Goitre prevalence was 12-54%. Mean urinary iodide value was 20.15 μg/g creatinine. Raised $PB^{131}I$ values in

		and control area (Jaffna)		endemic goitre were detected.
		Adults	143 males and 151 females.	Goitre prevalence was 28.6% in males and 43% in females.
		School children from Horana and Jaffna		Very high thyroidal uptakes of I^{131}, 70.1% to 83.4% in males and 83.5% to 90.1% in females in Horana as opposed to 40.8% in males and 47.3% in females in Jaffna, indicative of environment iodine deficiency. Serum PBI^{127} levels were within normal limits and absence of cretins and deaf-mutes showed the mild nature of iodine deficiency.
MRI 1990	1987/88	Pregnant women in endemic zone	1235	Goitre prevalence was 65.5%
Fernando et al 1989	1986/87 National	School children, 17 of 24 districts.	59,158 children	An overall goitre prevalence of 14.4% (range 6.5% to 30.2%). The goitre rate was higher in rural (21%) versus urban areas (16%), among girls than among boys (23% versus 14%), and in inland (21%) than in coastal (13%) areas. The magnitude of IDD varied by district, from 6.3% in Matale to 30.8% in Kalutara.

CHAPTER 3
STUDY METHODOLOGY

This study used a cross sectional study design and included 4 components.

1. School based study among children aged 8-10 years
2. Estimation of iodine content in the salt at retail outlets
3. Estimation of iodine content in drinking water
4. Assessment of knowledge and practices related to salt iodisation programme among retail traders.

3.1. School based study among children aged 8-10 years

The study population was identified as school children aged 8-10 years. The required sample size for each province was calculated on the basis of the number required to included in the sample to assess the urine iodine level. This was 300 children in 8-10 year old age group giving a total sample size of 2700 for all 9 provinces. The sampling method adopted was that recommended by UNICEF (1999). This requires inclusion of 30 schools from each province. A multi-stage stratified sampling technique was used to identify the sample. During the first stage the proportionate stratification was done to identify the number of schools in the urban and rural areas in each province according to the population of children in selected age group. In the second stage, required number of schools were identified using simple random sampling. During the third stage of sampling, all classes with children in year 4 or 5 classes were listed out and one class was randomly selected from each school. All children in each selected class were included in the assessment of goitre status. Informed written consent was obtained from the parents through a letter from the investigator forward through the class teacher. Details of sample size calculation and identification of the sample are given in Annex-1.

This component of the study included the following:

- obtaining information on age and sex and other identifying information
- clinical examination for goitre
- estimation of iodine in a sample of urine
- assessment of iodine content of a sample of salt obtaining from the household

All children who had obtained the consent of their parents and were present on the day of the study were identified as participants. A structured format was developed to obtain identification data, age and sex of children in the selected classes. The information was obtained from the attendance register and marked on the format by a member of the study team (Annex-2).

3.1.1. Clinical examination for goitre

A group of 10 public health inspectors were trained as field investigators to assess the goitre status of the study group. A consultant physician conducted theoretical and practical training for assessment of goitre. All children in the selected classes were assessed for the presence/absence goitre.

Grading of goitre was done according to the following system (WHO/UNICEF/ICCIDD 1992).

Grade 0 - Thyroid not palpable not visible,

Grade 1 - Thyroid palpable but not visible with neck in normal position. Moves up wards in the neck as the subject swallows.

Grade 2 - Goitre visible with neck in normal position. Consistent with enlarged thyroid when the neck is palpated.

3.1.2. Measurement of iodine in iodine

Sample of urine for estimating urinary iodine were obtained from 10 children, selected randomly from each selected class in each province (Annex -1). A total of 300 urine samples was collected from each province.

The following steps were adopted in the collection and transport of urine samples.

1. All selected children were made to wash their hands with soap and water under the supervision of the study team.
2. Each child was provided with disposable paper-cup with wide mouth and requested them to collect the urine sample, by urinating directly into the cup. They were informed that it will be adequate to provide a sample of urine, to fill half the cup provided.
3. Members of the study team wearing disposable gloves, transferred approximately 5 ml of the urine specimen from the cup to a tight fitting screw-capped plastic container. The remaining urine and the cups were disposed appropriately.

4. The urine samples were labelled with identification data i.e. province number, school number and the serial number of the child (in that order).
5. All 10 samples were stored in the large plastic container and this package was marked with the province number and school identification number and then transported for storage.
6. The samples were transported to the Divisional Drug Stores and stored at 4-8^{0}C. They were transported to the laboratory of the Nutrition Department of Medical Research Institute (MRI) twice a week with cold packs and stored at -20^0 till taken for analysis.

Facilities for estimating iodine content in urine were established at the laboratory of the Nutrition Department of Medical Research Institute (MRI). The following steps followed in carrying out the analysis of urinary iodine levels. The equipment and chemicals necessary for estimating urinary iodine levels were made available by UNICEF. The method to be used in assessing iodine concentration was the modified microplate method, which is the simplified method adopted from Pino Method (Ohashi et al 2000).

A Consultant from the Department of Biochemistry of Dhaka University in Bangladesh provided assistance in establishing the technique in the laboratory. The assay evaluation was done to cover all the aspects in accordance with those recommended by Ohashi et al (2000). These included: calibration curve and calculation, detection limit of the assay, inter and intra assay coefficient of variance (CV), recovery, cross contamination between wells in the plate. The temperature of freezers, refrigerators and ovens were maintained.

All four laboratory technologists were trained in the technique and for reverse pipetting to minimise variations. During the training automatic pipettes were calibrated and records were maintained to minimise the pipetting errors. During the assessing urinary iodine levels, all technologists were instructed to follow procedures to minimise contamination. They were: soaking all new glassware with concentrated Nitric acid for 24 hours, washing them 20 times with double distilled water and oven dried, final rinsing done with reagent grade water (Resistivity 18.2 MΩ.cm), after the assay, all used glassware to be washed in tap water and soaked overnight with teepol (BDH-analar) and washed 20 times with double distilled water, final rinse with reagent grade water, oven dried and wrapped, avoidance of smoking, application

of cosmetics and other biochemical tests inside the laboratory during the period of assay, overcoats and shoes were changed whenever one enters into the laboratory, all team-members to wash their hands prior to the assay each time, wipe the laboratory benches daily with 0.05% thiosulphate prior to starting the assay, kept the laboratory temperature at 25^0c, to check and maintain records daily and to use new microplates and pipette tips, for every new assay.

All samples were analysed by the 4 trained MLTs under the supervision of the Consultant Chemical Pathologist. Internal quality control analysis was carried out throughout by using samples with known iodine values. External quality control was carried out in collaboration with the Laboratory of University Paediatrics hospital, Brussels, Belgium. The details are given in Annex-3.

The urine samples and quality control samples were stored at -20^0C. They were kept at 4^0C temperature day before the analysis. The urine samples were tested on first arrived - first assessed basis. When the test were performed the results were entered into the computer data sheet with the labelling details.

3.1.3. Estimation of iodine content of salt at household level

All children from the selected class from each school were requested to bring a sample of salt from home, in a polythene pack. The level of iodine in the salt samples was determined with two rapid field test kits i.e. MBI (India) and Iodina (Indonesia) depending on the availability of the kits at the time of data collection. MBI kits were used in 3 provinces and Iodina kits were used for the other provinces. MBI kit had a colour gradient indicating five categories and the number of parts per million (ppm) of iodine could be assessed by colour matching. The Iodina kit has only 2 colours indicating the presence /absence of iodine.

A spoonful of salt to be tested was spread on a white paper and a drop of the test solution on the surface of the salt sample was discharged and the colour change observed. The salt samples were classified according to their iodine levels.

3.1.4. Pilot study

Prior to the conduct of the study at field level, a pilot study was carried out in Horana Divisional Director of Health Services (DDHS) area in the Kalutara district. This area was selected for the pilot study because the highest prevalence of goitre in the 1989 survey was reported from this area. During the pilot phase, all components of the planned study were implemented and appropriate modifications made to improve the feasibility of the study and to improve validity of data.

3.1.5. Data collection at field level

The field investigators, all of whom have previous experience in field research activities were responsible for all components of the study. In addition to the training in assessment of goitre status investigators were trained in procedures in collection and transport of urine samples, testing the salt samples for their iodine content.

Permission was obtained from Education authority and Provincial Directors of Health Services for the study. Five teams each team comprising of 2 field investigators, one of whom was trained in goitre assessment were responsible for data collection. All selected schools were informed about the study. The consent forms were distributed to all children in the selected classes prior to the study to obtain the consent of the parents/guardians. The schools were informed the date of the visit and the students from the selected class were requested to bring salt samples on that day. All field work was completed during a 5 months period, September - January 2001.

3.1.6. Collection of data in Northern and Eastern provinces:

Only 5 schools from Northern and Eastern province were covered by the team of field investigators from the MRI. Divisional Senior Public Health Inspectors (SPHID) from these two provinces were trained in the procedures to be used in the study. This training included both the theoretical and practical aspects. They undertook the collection of the required member of urine samples and transferring them to the MRI laboratory under the specified conditions. The estimation of iodine in salt at household levels was assessed using the rapid test kits. Assessment of goitre was not carried out in the Northern province and in the Eastern province, only 5 schools were included in this component of study.

3.1.7. Ensuring validity of data

One field investigator in each team was responsible for obtaining relevant information from the schools and the other carried out assessment of goitre status. Three Medical Officers were trained in goitre assessment and each school was visited by one medical officer who supervised the goitre assessment. The results of the assessment made by the field investigators were not available for the medical officers at the time of the examination. o validate the findings on goitre status made by the field investigators grading done by the survey teams were verified by three medical officers. For the validation test, 2-3 schools were randomly selected each day, each of which was studied independently by 5 field teams. All children selected from each school were examined for goitre by Medical Officers. This led to re-examination of approximately 50% of all children from the study sample.

Stringent procedures were adopted to assess validity of the urinary iodine estimation in the MRI laboratory as described in Annex -4. Internal and external quality control methods were performed.

3.2. Estimation of iodine content in salt at retail outlets

When the field investigators visited a school, they were advice to visit 2 shops that sold salt at retail. In each shop, the field investigators purchased one packet of all brands that were available in the shop at the time of the visit. Those salt packets were transported to the MRI laboratory for analysis every week. The iodine level in each salt packet was assessed by titration method on a 'first arrived, first tested basis'. Details of the method used in this analysis are given in annex - 5.

3.3. Estimation of iodine content in drinking water

The field investigators were instructed to collect drinking water samples in the locality of the school from all the available sources such as taps, well, deep well, tube well, streams etc. Water samples were transported to MRI laboratory using the same procedures adopted for samples of urine.

3.4. Assessment of knowledge and practices related to salt iodisation programme among retail traders

When the field investigators completed the data collection in the schools, they were asked to visit two retail shops close to the school, within one kilometer radius. The shop owners were interviewed using a pre-tested and validated questionnaire (Annexe-6) to collect the following information:

- place of purchase of salt
- type of salt sold
- storage and handling of salt
- Knowledge and practices related to iodine and iodine deficiency disorders.

3.5. Data analysis

The data entry and analysis was carried out using the EPI/INFO package.

3.6. Ethical considerations

Ethical clearance was obtained from the ethical committee of Medical Research Institute and permission obtained from the relevant Educational and health authorities. Written consent was obtained from parents or guardian of children who attended the study. Confidentiality of information obtained during the study was ensured. The findings of the study were informed to Provincial Directors to strengthen the salt monitoring programmes. All principals of the schools were send educational leaflets on iodine deficiency to improve the knowledge on iodine. The final report was submitted to Deputy Director General of Public Health Services, Department of Health Services for further action.

CHAPTER 4
PREVALENCE OF GOITRE

A total of 8241 children aged 8-10 years from 9 provinces were identified as the study population. Of them, 4204 (51.0%) were males and 4037 (49.0%) were females (Table 2). The percentage distribution of males and females in the study population were comparable with the national figures (Ministry of Health 1998). The mean age of children were 9.8 (SD=0.94) years.

Table 2

Sex distribution of the study population by provinces

Province*	**Male (%)**	**Female (%)**	**Total (%)**
Western	413 (9.8)	593 (14.7)	1006 (12.2)
Southern	463 (11.0)	393 (9.7)	856 (10.4)
Uva	467 (11.1)	459 (11.4)	926 (11.2)
Eastern	427 (10.2)	349 (8.6)	776 (9.4)
North Central	448 (10.7)	430 (10.7)	878 (10.7)
Central	531 (12.6)	342 (8.5)	873 (10.6)
Sabaragamuwa	567 (13.5)	508 (12.6)	1075 (13.0)
North Western	470 (11.2)	490 (12.1)	960 (11.6)
Northern	418 (9.9)	473 (11.7)	891 (10.8)
Sri Lanka	**4204 (51.0)**	**4037 (49.0)**	**8241 (100.0)**

In general, there were more males in the study population, compared to females. However, the proportion of female children were higher than male in the Western, Uva, North western and Northern province.

Prevalence of goitre by provinces

Of the total population, only 6733 (81.7% of the study population) were included in the study of goitre status. Among this group, 20.1% had Grade 1 goitre and 0.8% had Grade2 goitre, giving a total goitre rate (TGR) of 20.9% (Table 3) .

Table 3

Prevalence of goitre by provinces

Province*	Total examined	Prevalence of goitre (%)			Total goitre rate (grade 1+2)
		Grade 0	Grade 1	Grade 2	
Western	1006	83.7	15.4	0.9	16.3
Southern	856	82.9	15.7	1.4	17.1
Uva	926	74.0	24.3	1.7	26.0
Eastern	159	74.8	24.5	0.6	25.2
North Central	878	73.8	25.4	0.8	26.2
Central	873	75.7	24.1	0.2	24.3
Sabaragamuwa	1075	80.6	19.1	0.4	19.4
North Western	960	82.8	16.9	0.3	17.2
Sri Lanka	**6733**	**79.1**	**20.1**	**0.8**	**20.9**

The total goitre prevalence between provinces varied between provinces with the highest prevalence noted in the North Central Province (26.2%) and the lowest in the Western Province (16.3%). Grade 2 goitre rate was low, ranging from 0.2-1.7%. The high prevalence in the North Central Province is of special significance as this province has been considered as a non-endemic area. The highest rate of grade 2 goitre (1.7%) was detected in Uva province.

Prevalence of goitre by sex

Table 4 indicates that within each province, the prevalence of both Grade1 and Grade2 i.e. total goitre rate was higher among females (24.5%) than among males (17.5%). The highest total goitre prevalence among female children was in the Eastern province (32.9%). This observation has to be interpreted with caution due to the small number of students included in the assessment. The sex difference in the prevalence of Grade 1 goitre was most marked in the Central province, i.e. 19.6% and 31.6% among males and females respectively. The highest prevalence of Grade 2 goitre was seen among the females in the Uva province (3.3%).

Table 4

Goitre prevalence in children of 8-10 years by sex and provinces

Province*	Total examined		Prevalence of goitre (%)						Total goitre rate (grade 1+2) (%)	
			Grade 0		Grade 1		Grade 2			
	M**	F**	M**	F**	M**	F**	M**	F**	M**	F**
Western	413	593	83.8	83.6	15.3	15.5	1.0	0.8	16.2	16.4
Southern	463	393	86.0	79.4	13.2	18.6	0.9	2.0	14.0	20.6
Uva	467	459	78.2	69.7	21.6	27.0	0.2	3.3	21.8	30.3
Eastern	83	76	81.9	67.1	18.1	31.6	0.0	1.3	18.1	32.9
North Central	448	430	77.0	70.5	22.5	28.4	0.4	1.2	23.0	29.5
Central	531	342	80.4	68.4	19.4	31.3	0.2	0.3	19.6	31.6
Sabaragamuwa	567	508	85.2	75.4	14.6	24.0	0.2	0.6	14.8	24.6
North Western	470	490	86.8	79.0	13.0	20.6	0.2	0.4	13.2	21.0
Sri Lanka	**3442**	**3291**	**82.5**	**75.5**	**17.1**	**23.2**	**0.4**	**1.2**	**17.5**	**24.5**

(M** = Male children, F*** = Female children)

CHAPTER 5
URINE IODINE LEVELS

According to the sample size calculation , it was necessary to collect 300 urine samples per province. i.e. a total of 2700. However, it was possible to obtain only 2630 (.....% of the expected number) due to limitations in obtaining samples from Northern and Eastern provinces .

Urinary iodine levels by province

The "adequate" urinary iodine levels are considered to be within the range 100-200μg/L (Delange et al 2001). The median urinary iodine levels were above accepted cut-off point of 100μg/L (WHO 1994) in 8 provinces except in one (Uva) province (Table 5) with the highest median urinary iodine levels in North Central province (231.3μg/L).

Table 5

The levels of urine iodine by provinces

Province*	Total examined	Median urinary iodine concentration (μg/L)	25th -75th percentiles of urinary iodine values (μg/L)
Western	300	151.4	93.1-237.7
Southern	300	122.4	74.3-178.8
Uva	300	96.2	61.8-149.0
Eastern	274	139.5	74.1-246.5
North Central	300	231.3	53.2-328.2
Central	299	122.5	76.6-190.6
Sabaragamuwa	289	136.1	76.8-205.2
Northwestern	300	180.7	106.6-314.4
Northern	228	194.4	117.7-303.5
Sri Lanka	**2630**	**145.3**	**84.6-240.2**

Study of the **frequency distribution of urinary iodine levels by province** shows that 35.4% of the children had urine iodine levels in the 'adequate' range with 30.6% with lower values and 34.0% with higher values (Table 6). Of those who had lower values, only a small percentage (1.4%) had very low values of <20μg/L, this percentage ranging from a high value of 4.6% in the Eastern province to a low value of 0.3% in the Southern province.

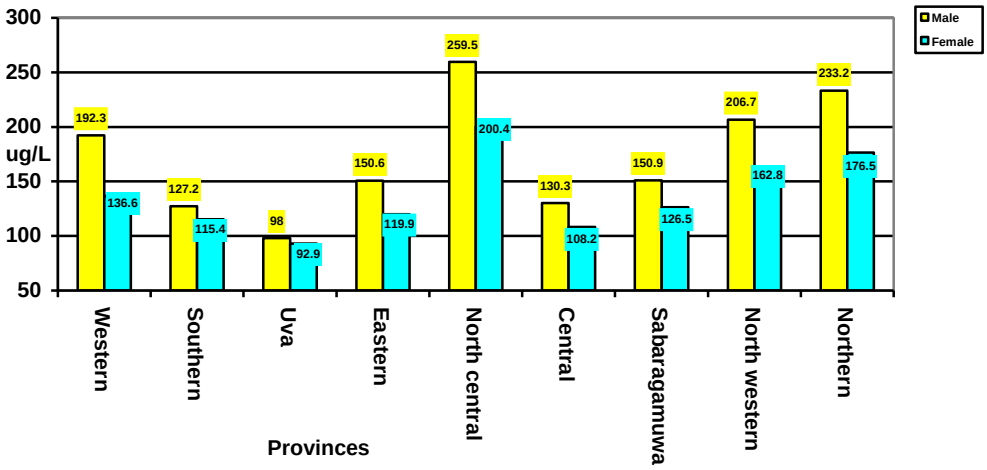
The group that had iodine levels of above 300μg/L indicating a possible excessive iodine intake, the percentages ranged from 4.7% in the Southern province and 32% in the North Central province. It must be noted that of the 300 urine samples studied from the North Central province, 59.3% had values higher than the 'adequate' value, compared to 14% in the Uva province. The wide variation in the distribution of urinary iodine levels by province is an important observation made in this study which needs further investigation.

Table 6

Frequency distribution of urine iodine levels by provinces

Province*	**Total examined**	**Percentage of urine iodine levels (μg/L)**					
		Deficiency			**No deficiency**		
		< 20	**20-49.9**	**50-99.9**	**100-199.9**	**200-299.9**	**>=300**
		Severe	**Moderate**	**Mild**	**Ideal**	**More than adequate**	**Excessive iodine intake**
Western	300	0.7	7.3	18.7	36.7	23.7	13.0
Southern	300	0.3	9.3	30.3	39.3	16.0	4.7
Uva	300	2.3	**14.3**	**35.3**	34.0	9.0	5.0
Eastern	280	**4.6**	6.4	23.2	32.9	13.2	19.6
North Central	300	0.3	0.7	7.3	32.3	**27.3**	**32.0**
Central	300	0.7	9.3	28.0	37.3	15.3	9.3
Sabaragamuwa	300	1.3	9.7	22.3	40.7	13.0	13.0
North Western	300	1.7	2.7	18.3	31.3	20.0	26.0
Northern	250	0.4	3.6	14.0	33.2	22.8	26.0
Sri Lanka	**2630**	**1.4**	**7.1**	**22.1**	**35.4**	**17.8**	**16.3**

Figure 2
Urine iodine values of males and females in provinces



Urinary iodine levels by sex by province

Median urinary iodine levels among males was 161.4 µg/L and was higher than among females, 133.9 µg/L (Figure 2). The lowest urinary iodine values were detected in females in Uva province and the highest in males in North Central province, 92.9µg/L and 259.5 µg/L respectively. It is important to note that in 3 provinces i.e. North Central, North Western and Northern provinces, the median urinary levels in males were above 200µg/L.

CHAPTER 6

IODINE CONTENT OF SALT

Iodine content of salt was determined at household level and at retail level.

Estimation of iodine levels in salt samples from households

Each school child who participated in the goitre assessment was requested to bring a sample of salt from his/her house and test kits were used to determine the level of iodination. A majority of children i.e. 75% brought samples of salt from 'home' . Almost all samples had some amount of iodine according to the results of rapid test kit. For a sample of salt to be considered as 'adequately iodinated' the colour has to change to purple indicating an iodine content of at 25 mg/kg. . According to this specification, only 49.5% of the samples were 'adequately iodinated' (Table 7). The lowest percentage of samples with adequate iodination was seen in the North Western province, i.e. 37.4% and highest in Western province, i.e. 65%.

Table 7

Adequate iodination of salt (mg/kg) at household level by provinces

Province	No.	Rapid test kit positive (%)
Western	575	65.0
Southern	624	59.1
Uva	641	53.0
Eastern	632	55.5
North Central	660	37.4
Central	662	37.0
Sabaragamuwa	883	48.9
North Western	692	38.0
Northern	814	54.6
Sri Lanka	**6181**	**49.5**

Estimation of iodine level in salt samples obtained from retail traders

There were a total of ..... salt packets belonging to 165 brands, purchased from 398 retail outlets all over the country. They were tested to determine the level of iodine using the titration method. The number of samples of salt obtained per brand varied widely, from 51 samples of one brand to ... in another. Only those 'brands from which there were five or more samples were included in the analysis of iodine levels by brand. Table 8 presents the findings. The important observation from this analysis is the wide variation in the iodine content seen 'between brands' as well as 'within brands'.

The iodine content of salt samples within a given province depends on the number of 'brands' of salt packets assessed, number of packets per brand and the iodine content in each brand. As shown in the Table 9, the median iodine content of salt did not show much variation , with a high value of 38.5 ppm in the Western province to a low value of 26.3 ppm in the Uva province. However, it is important to note the extremely wide variation in the iodine content observed at national level (5.3 -418.9 ppm) as well as within each province specially in the Central and Western and North Central provinces. Such variation is to be expected in keeping with the observations made in Table 8.

Table 8

Iodine content of salt samples at retail level measured by titration method by provinces

Province	**No.**	**Median iodine content (ppm)**	**Range**
Western	122	38.5	6.6 – 349.4
Southern	100	30.8	10.6 – 138.8
Uva	70	26.3	6.3 – 137.3
Eastern	16	37.2	15.8 – 55.8
North Central	87	23.8	7.4 – 283.5
Central	95	26.7	5.3 – 418.9
Sabaragamuwa	92	34.7	8.7 – 120.6
North Western	96	33.7	9.5 – 74.1
Sri Lanka	**678**	**30.7**	**5.3 – 418.9**

Table 9 shows that 41.1% of the samples had iodine levels within the permitted range, i.e. 25-40ppm. It was observed that 18.6% of salt samples had iodine values higher than the permitted range (above 50 ppm) and 66.9% had lower values. Of the samples with very low iodine values, i.e. less than 25ppm, the highest percentage was seen in the North Central province (52.9%) with Central (47.4%), Southern (43.0%) and Uva (44.3%) provinces also having relatively high percentages.

Table 9

Frequency distribution of iodine level in salt at retail levels by provinces

Province*	**Total examined**	**Frequency distribution of samples exposure as % according to salt iodisation level (ppm)**				
		< 25	**25-40**	**40.1-50**	**50-100**	**>100**
Western	122	26.2	26.2	19.7	**26.2**	1.6
Southern	100	43.0	20.0	17.0	18.0	2.0
Uva	70	44.3	35.7	12.9	5.7	1.4
Eastern	16	18.8	**37.5**	**37.5**	6.3	0.0
North Central	87	**52.9**	26.4	8.0	10.3	2.3
Central	95	47.4	18.9	12.6	18.9	2.1
Sabaragamuwa	92	31.5	30.4	14.1	21.7	2.2
North Western	96	45.8	31.3	9.4	10.4	**3.1**
Sri Lanka	**678**	**40.3**	**26.8**	**14.3**	**16.5**	**2.1**

The levels of iodine in the different brands of salt were assessed. This analysis is limited to 25 brands of salt, where there were more than 5 samples per brand.

Table 10

Iodine content of salts (ppm) by brands

Code number of main brands (No. of samples)	**Iodisation level (ppm)**				
	<25	**25-40**	**40.1-50**	**50-100**	**>100**
1 (51)	5.9	13.7	33.3	47.1	0.0
2 (19)	63.2	31.6	0.0	5.3	0.0
3 (23)	30.4	60.9	8.7	0.0	0.0
4 (22)	68.2	22.7	4.5	4.5	0.0
5 (7)	14.3	57.1	14.3	14.3	0.0
6 (5)	0.0	60.0	20.0	20.0	0.0
7 (4)	75.0	25.0	0.0	0.0	0.0
8 (5)	**80.0**	0.0	0.0	20.0	0.0
9 (11)	27.3	45.5	27.3	0.0	0.0
10 (11)	9.1	**63.6**	18.2	9.1	0.0
11 (10)	20.0	20.0	10.0	40.0	10.0
12 (16)	0.0	37.5	31.3	31.3	0.0
13 (14)	57.1	28.6	7.1	7.1	0.0
14 (8)	37.5	25.0	0.0	37.5	0.0
15 (17)	5.9	11.8	**41.2**	35.3	5.9
16 (10)	20.0	0.0	10.0	60.0	10.0
17 (9)	77.8	0.0	11.1	11.1	0.0
18 (11)	9.1	45.5	0.0	27.3	**18.2**
19 (73)	72.6	21.9	2.7	1.4	1.4
20 (11)	63.6	27.3	9.1	0.0	0.0
21 (28)	75.0	10.7	7.1	7.1	0.0
22 (10)	80.0	10.0	0.0	10.0	0.0
23 (8)	**87.5**	0.0	12.5	0.0	0.0
24 (5)	0.0	20.0	0.0	**80.0**	0.0
25 (6)	50.0	0.0	33.3	0.0	16.7

Compliance with requirements imposed through the Food Act CHECK

The salt packets obtained from the retail outlets were studied to assess their compliance with the criteria specified under the food act (Sri Lanka Gazette 1993). Table 11 presents the findings. It was observed that in 40.3% of salt samples, salt was in the form of rock salt, 36.8% were dirty requiring washing prior to cooking.

Table 11

Compliance with requirements under the Food (iodisation of salts) regulations 1993

Area	No.	%
Appearance of salt in the sample		
• Crystalised solid in granules (1-10mm)	232	34.3
• Powder	171	25.3
• Rock salts (>10mm)	274	40.5
Cleanliness of the salt		
• Pure white in colour and clean	428	63.2
• Brown and dirt	249	36.8
Weight of the packet		
• 250gm	4	0.6
• 400gm	267	43.3
• 500gm	4	0.6
• 800gm	15	2.4
• 900gm	2	0.3
• 1000gm	324	52.6
Absent of labelling requirements in the salt packet in any language:		
• No washing	164	24.4
• Not to expose to sunlight	189	28.1
• Name of the manufacture	2	0.3
• label as iodised salt	7	1.0
• Expiry date	25	3.7
• Manufacturer date	623	92.7

Regarding the labelling requirements, the date of manufacture was indicated on 92.7% of packets while the place of manufacture was given only in 0.3%. The expiry date was given in 3.7% of packets. Only 1% of the packets were labelled as iodized salt. Instructions related to keeping salt away from sunlight (28%) and avoiding washing of salt (24%) were given only in some packets.

Table 12

Monitoring of salts at retail level by provinces

Province	Testing of salts by PHIs during last 6 months		Total number of retailers (%)
	Yes (%)	No (%)	
Western	**12 (20.7)**	46 (79.3)	58 (14.6)
Southern	20 (33.3)	40 (66.7)	60 (15.1)
Uva	23 (41.8)	32 (58.2)	55 (13.8)
Eastern	6 (60.0)	4 (40.0)	10 (2.5)
North Central	20 (37.7)	32 (61.5)	52 (13.1)
Central	20 (37.7)	33 (62.3)	53 (13.3)
Sabaragamuwa	19 (35.8)	34 (64.2)	53 (13.3)
North Western	18 (31.6)	39 (68.4)	57 (14.3)
Sri Lanka	**138 (34.7)**	**260 (65.3)**	**398**

Only 138 (34.7%) retail outlets indicated that the salt packets in their outlets had been tested by Public Health Inspectors (PHIs) during the previous 6 months (Table 12). Coverage of monitoring was lowest in the Western province and highest in Uva province.

CHAPTER 7

IODINE CONTENT OF DRINKING WATER

Samples of water were collected from the locality of the school from varied sources, such as taps, wells, tanks, tube wells etc. These samples were transported to the MRI laboratory using the same procedure as used for samples of urine and the assessment of iodine levels was carried out using the same laboratory technique. It must be noted that the number of samples of water per province was relatively low, hence the limitations in drawing conclusions. Samples were not available from the Northern, Eastern and Uva provinces due to logistic problems.

Table 13

Level of iodine (μg/L) in drinking water by provinces

Province	**No.**	**Median iodine levels (range)**
Western	6	6.4 (4.3-10.2)
Southern	3	13.4 (12.5-18.9)
North Central	7	60.9 (14.0-173.3)
Central	14	15.4 (3.1-48.2)
Sabaragamuwa	6	19.6 (14.5-41.8)
North Western	23	42.5 (6.8-251.4)
Sri Lanka	**59**	**49.5 (3.1-251.4)**

As shown in Table 13, the lowest iodine values were observed in samples from the Western province where the sources varied from taps to well (4.3-10.2μg/L) and the highest values in samples from the North Central province. The iodine levels varied according to the source. It was lowest in tap water (14μg/L) and highest in water obtained from tube wells (173.3μg/L).

CHAPTER 8

KNOWLEDGE AND PRACTICES OF RETAIL SALT TRADERS

A total of 398 retail traders from 8 provinces (except in Northern province) were interviewed. A majority of respondents (66.1%) had heard of 'goitre'. As shown in Table 14, varying proportions knew about other iodine deficiency disorders.

Table 14

Knowledge of iodine deficiency among salt retailers

Response	Freq	%
Knowledge on IDD		
Goitre	263	66.1
Cretin	3	0.8
Mental abnormality	21	5.3
Other causes	123	30.9
Not Known	20	5.0
Know on iodide salt		
Yes	378	95.0
No	20	5.0
Source of knowledge on iodine salt		
Health personnel	115	28.9
Media	229	57.5
Neighbour	9	2.3
Own child	1	0.3
Mobile van people	12	5.0
Other sources	12	5.0
Not know	20	5.0
Results of use of iodide salt		
Not known	147	36.9
Awareness of legislation		
Yes	290	72.9
No	108	27.1
Details of legislation		
Know	235	59.0
Not known	163	40.5

Most retailers (70.9%) purchased salt from distributing vehicles and 20.1% purchased from wholesalers in the neighbourhood. The retailers purchased their salt at varying intervals, every month (62.6%), once in 3 months (31.9%) and once in 6 months (5.5%). Almost all (98.8%) of them had no difficulty in buying iodised salt and had adequate stores for the last the 6 months

A majority of retailers (95%) knew about iodised salt, many of them (57%) having obtained their knowledge from mass media (57.5%), others from health personnel (28.9%) and from others sources (8.6%). A majority of the respondents (72.9%) knew about salt legislation in the country. Table 15 shows the observation made by the field investigators on the quality of salt packets stored, in the retail shops .

Table 15

Observation of the field investigators on quality of salt

Area	No.	%
Labelling for iodination		
Yes	394	99.0
No	4	1.0
Storage of salt in the shop		
Store room	11	2.8
Inside the shop	340	85.4
outside the shop (expose to sun)	47	11.8
Type of salt available in the shops		
Large granules	261	65.6
Small crystals	132	33.2
Powder	242	60.8
The method of keeping salt in the shops		
Open sac	18	4.5
Closed sac	9	2.3
Sealed packets	371	93.2
Availability of salt in the shop		
open sac	18	4.5
close sac	9	2.3
sealed packets	371	93.2

Almost all (99%) packets of salt in the retail shops were labelled as iodised salt. It was noted that in 11.8% of the outlets, salt packets were stored outside the shop and exposed to the sun.

CHAPTER 9

MAIN FINDINGS OF THE STUDY

The iodine deficiency status in Sri Lanka , according to the WHO classification (criteria) is presented in Table 11, based on the findings of the study. Taking the median urinary iodine levels as the indicator, iodine status in 7 out of 9 provinces could be considered as satisfactory. The median urinary iodine levels in the Uva province indicated ' mild iodine deficiency' while the levels in the North Central province indicated ' more than adequate' levels.

Table 11

Iodine deficiency status in Sri Lanka according to the WHO classification

Province*	**Indicators**		
	Goitre	**Median urinary iodine (μg/L)**	**Household iodide salt**
			% adequately iodised salt (=>25ppm)
Western	16.3 Mild	151.4 Ideal	65.0 Inadequate
Southern	17.1 Mild	122.4 Ideal	59.0 Inadequate
Uva	25.9 Moderate	96.2 Mild	52.7 Inadequate
Eastern	25.6 Moderate	139.5 Ideal	55.3 Inadequate
North Central	26.2 Moderate	231.5 More than adequate	37.4 Inadequate
Central	24.2 Moderate	122.5 Ideal	37.1 Inadequate
Sabaragamuwa	19.4 Mild	135.9 Ideal	48.7 Inadequate
Northwestern	17.3 Mild	181.0 Ideal	38.0 Inadequate
Northern	-	194.4 Ideal	54.5 Inadequate
Sri Lanka	**20.8 Moderate**	**145.3 Ideal**	**49.5 Inadequate**

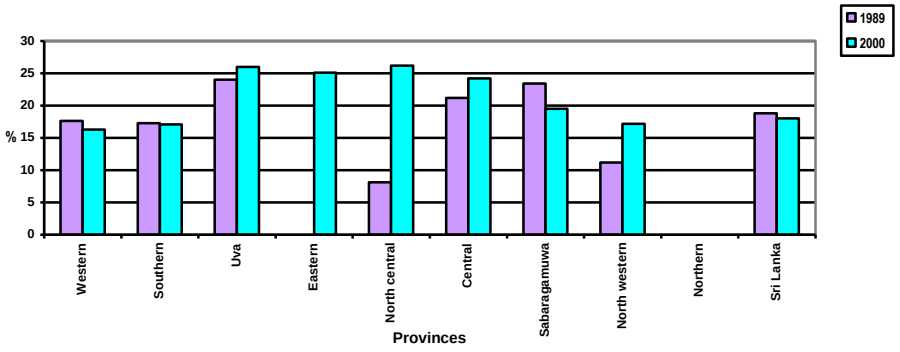
The median urinary iodine levels were above the cut-off point of 100μg/L in all provinces except Uva. It must be noted that 59.3% of the study population in North Central province had median urinary iodine levels >200μg/L, a much higher level. In contrast, the total goitre rate in the NCP is among the highest in Sri Lanka, indicating the need for further studies on the mechanism of occurrence of goitre in the NCP.

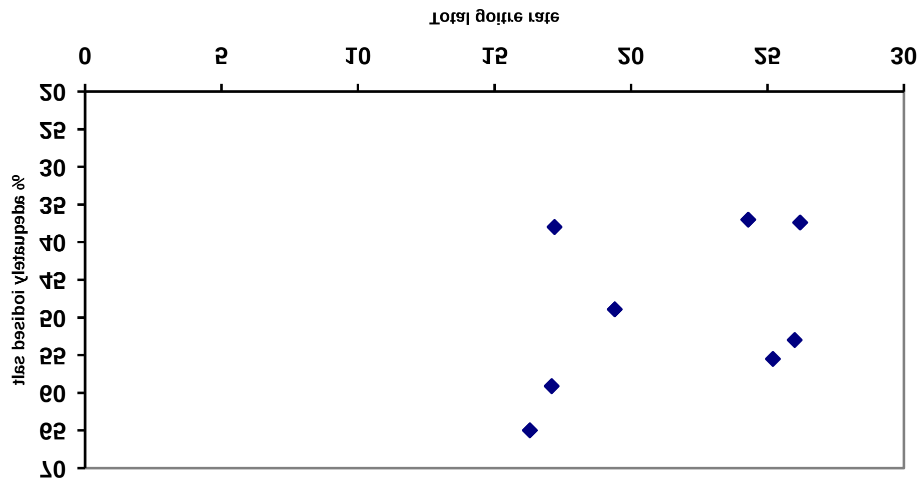
It is interesting to note that the iodine status of 7 provinces was satisfactory in spite of the fact that the proportion of households with intake of salt with adequate levels of iodine was inadequate.

Another important observation is the wide variation in the iodine content of the different brands of salt available, both between brands and within a given brand. This identifies the need for an in depth study on the process of iodination used in different settings where this process takes place. Inadequate coverage in the monitoring of retail outlets has also to be considered in this connection.

When goitre rates observed in this study are compared with the study by Fernando et al 1989, there is a decline in the goitre prevalence rates in the Western, Southern and Sabaragamuwa provinces with a marginal increase in the Central and Uva provinces. (Figure ....1). However, in the provinces of dry zone (North Central, North Western province) an increase in the prevalence has been observed.

Figure 1
Comparison of goitre rates in 1989 and 2000/1





Correlation between total goitre rate and iodised salt by Province

Correlation between urinary iodine and total goitre
rate by Province
Median urinary iodine
50
100
150
200
250
Total goitre rate
10
12
14
16
18
20
22
24
26
28

Correlation between total goitre rate and iodised salt by Province
Median urinary iodine
0
50
100
150
200
250
10
15
20
25
30
35
40
45
50
55
60
65
70
Total goitre rate %

CHAPTER 10
CONCLUSIONS AND RECOMMENDATION

1. Sri Lanka has achieved the goal in eliminating IDD as a public health problem as indicated by urinary iodine levels except in Uva province. Urinary iodine levels have been assessed for the fist time in this present study, hence it is not possible to draw conclusions regarding the effectiveness of salt iodization programme based on the iodine status. Thus, it is important to develop a surveillance system to monitor urinary iodine levels and other indicators as necessary, so that it will be possible to take timely decisions regarding the future changes in the iodization programme.

Consideration must be given to review the specifications for iodine content of iodized salt as recommended by ICCIDD/UNICEF/WHO in 1995 and making appropriate modifications in the legal enactment.

- *Alert the health workers as the importance of monitoring iodine level both high and low values.*

2. Median urinary iodine levels in the Uva province indicated mild iodine deficiency even after 5 years of universal salt iodization. Consideration should be given to improved monitoring of the implementation of the iodization programme in the province and establishing a more stringent surveillance system, if necessary including a neonatal screening programme. .

3. The wide variation in the iodine content in the salt samples indicates the need for improving the quality of salt iodination and the need for of regular monitoring of the process of iodination and the monitoring at the level of manufacture and at retail level.

It is recommended that following action be considered:

- Create awareness among the salt manufacturers . Such awareness sessions should be supplemented by field visits to the sites where salt iodination takes place to provide guidance on the correct procedures for iodization.
- Ensure regular quality control of iodine concentration in salt at the point of production for each batch by using titration method. Preparation of guidelines and forms for monitoring and assessment of iodised salt will facilitate this activity.

- Establish laboratories in provinces for salt iodine test
- Establish a national quality control system in collaboration with MRI laboratory.
    - ⇒ *Conducting workshops for laboratory technicians to achieve uniformity in their assessment methods.*
    - ⇒ *Distribution of quality control samples to provincial laboratories to test the uniformity of the analysis.*
- Periodic monitoring of salt iodine levels in retail shops and households should be established and supervised adequately. This activity should be supported by preparation of guidelines and training of peripheral health staff on monitoring

4. The high urinary iodine levels noted in the North Central province along with a high total goitre rate indicates the need for an in depth study involving environmental studies.

References

1. World Health Organisation 1999, Progress towards the elimination of iodine deficiency disorders (IDD), WHO/NHD/99.4.
2. World Health Organisation 1994, Iodine and health eliminating iodine deficiency disorders safely through salt iodisation, WHO/NUT/94.4, Geneva.
3. World Health Organisation 2000, Nutrition in South-East Asia, Regional Office for South-East Asia, New Delhi.
4. Sri Lanka 1999, Statistical Abstract of the Democratic Socialist Republic of Sri Lanka, Department of census and statistics, Ministry of finance and planning.
5. Stanbury JB & Hetzel BS 1980, Endemic Goitre and Endemic cretinism, Iodine nutrition in health and disease. John Wiley and Sons.
6. Greenwald I 1953, Some notes on the history of goitre in Ceylon, The Ceylon Medical Journal.
7. Wilson DC 1954, Goitre in Ceylon and Nigeria, Br. J. Nutr., 8(2), 90-9.
8. Mahadeva K, Seneviratne DA, Jayatilleke DB, Shanmuganathan SS, Premachandra P and Nagarajah M 1968, Further studies on the problem of goitre in Ceylon, Br. J. Nutr., 22, 527-34.
9. Deo MG, Subramanian TAV 1971, Iodine metabolism in children and women with goitre in Ceylon, Br. J. Nutr., 25, 97-105.
10. Wickramasinghe SYDC, Welgama SP and Buthpitiya AG 1982, Simple goitre in the Central Province, Kandy
11. (WHO) World Health Organisation 1994, Indicators for assessing iodine deficiency disorders and their control through salt iodizaton, WHO/NUT/94.6, WHO, UNICEF, ICCIDD, Geneva: 1-55.
12. Ohashi T; Yamaki M; Pandav CS; Karmarkar; Irie M; 2000, Simple microplate method for determination of urinary iodine, Clinical Chemistry, 46(4):529-36.
13. Delange F; Benoist de B; Burgi H; ICCIDD 2001, At what median urinary iodine concentration is a population iodine suffcient? IDD News Letter, ICCIDD, 17(1):10-1.

ANNEXES

ANNEX - 1

DETERMINATION OF SAMPLE SIZE

Sample size for urine iodine estimation was calculated by taking the following factors into consideration:

a) Estimates of iodine deficiency were made on school children in the age group 8-10 years.

b) Estimates were required at provincial level.

c) The prevalence of iodine deficiency (p) in each province was 0.10

d) $q = 1 - p$

e) The error (d) was willing to make was $\pm$ 0.05

f) The α error was 0.05 ($z_{1-\alpha/2} = 1.96$)

The required sample size for each province was calculated using the following formula,

$$N = \frac{z^2 * p * q}{d^2}$$

Based on the above, the minimum sample required from each province was 138[4]. As a cluster sampling design was to be used, a design effect was estimated to be 2.0. Therefore, the sample size for each province,

$$N = 138 * 2.0$$
$$= 276$$

Assuming a non-response rate of approximately 10%, the required sample size for each province was 300 children in 8-10 year old age group. Therefore, for 9 provinces the total sample size was 2700 children.

Method of selection of sample:

The recently recommended sampling methodology was adopted (UNICEF 1999).

1. Target age group was 8-10 years. To represent those age group, year 4 and 5 children was selected.
2. Using the 1998 school census data, the populations of year 4 and 5 of all schools within each province were cumulated separately by sector (urban and rural).

3. Number of schools from each sector in the province was selected by stratifying proportionately on urban and rural sector school children populations.
4. The cumulated urban and rural year 4 and 5 population was listed out.
5. It was divided by number of schools per sector to obtain a sampling site interval.
6. Thirty random numbers were generated in the computer.
7. The school including these numbers in its cumulative population was identified as selected schools.
8. This procedure was repeated in each of the 9 provinces, giving the required total of 270 schools.
9. The series of year 4 or 5 classes were listed out and one class was randomly selected from each school. When there was less than 15 children in one class year 4 and 5 were amalgamated.
10. The 270 schools were plotted on a map and a sequence for the fieldwork developed for the study team.
11. Each team was allocated the schools and five schools were completed per day as each team studied one school per day due to difficulties in transport and the distance between clusters.
12. Each team was given the plotted map with allocated schools. Teams moved from one province to the other.
13. All the children in selected classes were included into the study after taking the consent of parents or guardians.
14. The children who were present on the day of visit to the school were listed out according to the attendance register and 10 children were selected randomly using the given random numbers.
15. When there were girls and boys in a same class, equal number of them were selected (5 from each group).
16. Casual urine samples were collected from 10 selected.

ANNEX -2

DATA COLLECTION FORMAT

School based survey on iodine deficiency

Date

Province School No.

Code number of field investigator

School Name (- ''

(Sample labelling = province number/school number/serial number)

Serial number	Child's Name	Birth day	Male /female 1 - male 2 - female	Goitre ^0 1 2 &	Salt sample 1-yes 2-No	Colour change with test kit 0-1 25-2 50-3 75-4 100-5	Urine sample 1-Yes 2-Not relevant

ANNEX -3

VALIDATION OF BIOCHEMICAL ESTIMATION

The following methods were adopted to validate the urinary iodine estimation in the MRI laboratory.

1. All the steps, which were given above were adopted to minimise the contamination.
2. Iodine content of the each urine sample was determined by each investigator in duplicate. All the samples, which came across the borderline of the cut off values the samples were repeated until it fell into definite group. If the values had not fallen into a group even after repeating for 6 times the mean values were taken.
3. For every assay, seven standards for different concentrations in duplicate were run simultaneously.
4. Millipore water (reagent grade water = Resistivity 18.2 MΩ.cm) was used as a blank and two blank samples were run per plate.
5. Standards were prepared using reagent grade water (Resistivity 18.2 MΩ.cm).
6. All the instruments (weighing balance, pipettes) were calibrated every month. Temperature of refrigerator's was checked for adequate performance daily.
7. Seven standards were included in duplicates with each plate and a calibration graph was drawn for each assay.
8. The samples, which gave the value of less than 10μg/L were repeated once and mean values were obtained.
9. The values, which fall into non-linear range were repeated by performing doubling dilutions until it fell into linear range. The final values were obtained by the multiplication with the dilution factor.

Internal quality assurance programme

Internal quality assurance programme of validity of urinary iodine analysis was performed in two ways.

1. A 24-hour urine sample from an individual was collected and preserved in a refrigerator. Each investigator determined the iodine content of 20 specimens from the above sample.

2. Then low, medium and high quality control samples were prepared diluting the above sample with millipore water.
3. Each investigator took 3 specimens from 3 different values of the above sample in duplicate every time she measured iodine in urine samples.
4. Three quality control samples in 3 different values (low, medium and high) were brought from the laboratory of Belgium and three samples in duplicate were run per plate.
10. When internal quality control values came out of range the samples, which were covered in that group were repeated.
11. The samples with known values were transported to study areas to check any changes during the transport and the results are shown in the table below. There was no significant change of urine iodine values during the transport.

Results of internal quality control programme

(Transportation of the known value of samples to study areas)

Pre transport urine iodine values (ug/l)	Post transport urine iodine values (ug/l)
159.8	156.4
80.4	84.2
270.7	266.3
155.3	163.5
66.2	68.9
211.3	233.2
16.7	6.9
29.4	35.5
24.4	35.9
344.7	301.7
57.3	68.2

T=0.081, df=10, P=0.94

External quality assurance programme

Five unknown samples in different concentrations were brought from the laboratory of Belgium and each investigator performed 5 samples from the above specimens in duplicates at every time she measured iodine in urine.

Results of external quality control programme

Target values of unknown samples (μg/L)	Mean (SD) values taken after analysis at MRI laboratory
58	51.4 (10.8)
37	41.7 (8.7)
72	71.6 (7.6)
126	115.2 (11.9)
94	90.0 (9.9)

T=1.293, df=4, P=0.27

They was no significant change to the ones which measured at laboratory of paediatrics, University hospital for children, Avenue J.J. Crocq 15, B-1020 Brussels, Belgium.

ANNEX -4

Assessment of knowledge and practices related to salt iodisation programme among retail traders

1' 1'1' From where do you buy your requirement of salt @ (Check all that apply)

1'2' Specify approximate distance in km from the place of procurement).

		Distance (km)
1' From another shop in the same town/village	1	
2' From another shop in nearby town	2	
3' From the Wholesale shop in District	3	
4' From the local weekly fare	4	
5' Others: (Specify) ……	5	

2' How often do you buy salt ? (Check the one that usually apply)

1' Less than once a month	1
2' Once a month	2
3' Once in 2-3 months	3
4' Once in 6 months or less often	4

3' Salts available in shops (Observation by Interviewer)

1. Polythene sacs (50-70 kg)	
2' Jute bags (50-70 kg)	
3' Small polythene packs (1/2 kg, 1 kg, 5 kg)	

4' 4'1' What type of salt do you sell @

4'2' What is the price per kg@

Iodised Salt		Price per kg (Rs. Cts)
1 Large crystal salt	1	
2. Small crystal salt	2	
3' Powdered or highly refined salt	3	
4' Others: Specify…….	4	

5. Where do you store salt @

	As told	As Observed
1) Warehouse	1	1
2) Inside the shop	2	2
3) Outside the shop	3	3
4) Others: Specify…….	4	4

6 ' How do you store salt @

	As told	As observed
1) Open as a mound	1	1
2) Covered in bags	2	2
3) Packets/wooden box	3	3

7' What are the ill effects of iodine deficiency @

1) Goitre	1
2) Cretinism	2
3) Mental retardation	3
4) Don't know	4
5 Others: Specify……	5

8' 1' Have you heard about iodised salt ?

1) Yes	1
2) No	2

8' 2' If yes @ from whom (Check all that apply; please do not suggest answers)

1) Health worker	1
2) Radio $ TV $ Papers $ Schools	2
3) Neighbors	3
4) Own child	4
5) Another shop keeper	5
6) Others: Specify……..	6

9' What are the benefits of consuming iodised salt @

^ Do not suggest answers, write the response verbatim &

1 ----------

2 ----------

10. 1 Are you aware of any regulations regarding the sale of salt @

Yes	Z 1
No	2

10.2 Can you describe the key elements of these regulations ? (Write the answer verbatim also)

1 …….

2…….

11. Have you ever had difficulty obtaining iodised salt ?

Yes	Z 1
No	2

12. If you normally stock iodised salt, when was the last time you did not have iodised salt to sell @

1) Always have stock on hand	1

2)	Stock out within past month	2
3)	Stock out within past 6 months	3
4)	Stock out more than 1 year ago	5

13' Has salt been sampled from your shop in last 6 months

Yes	1
No	2

13'2 By Whom @

1' Public Health Inspector	1
2' Others: Specify……	2