EVALUATION OF THE IODINE DEFICIENCY DISORDERS CONTROL PROGRAM IN LESOTHO

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LIST OF SYMBOLS AND ABBREVIATIONS

AIDS	= Acquired Immuno-Deficiency Syndrome
%	= Percent
dl	= Deciliter
DIT	= Di-iodotyrosine
EMICS	= End of Decade Multiple Indicator Cluster Survey
FNCO	= Food and Nutrition Coordinating Office (in Lesotho)
GDP	= Gross Domestic Product
GNP	= Gross National Product
HIV	= Human Immuno-Deficiency Virus
ICCIDD	= International Council for Control of Iodine Deficiency Disorders
IDD	= Iodine Deficiency Disorders
IEC	= Information, Education and Communication
IIH	= iodine induced hyperthyroidism
IQ	= Intelligence Quotient
KI	= Potassium iodide
KIO3	= Potassium iodate
l	= litre
LHDA	= Lesotho Highlands Development Authority
LHWP	= Lesotho Highlands Water Project
LNVAC	= Lesotho National Vulnerability Assessment Committee
MI	= Micronutrient Initiatives
MIT	=Mono-iodotyrosine
mg	= milligrams
n	= sample size
NaI	= Sodium iodide
NCHS	= National centre for Health Statistics (Ohio)
NGOs	= Non-Governmental Organizations
NUL	= National University of Lesotho

PAMM	= Program Against Micronutrient Malnutrition
PEM	= Protein Energy Malnutrition
ppm	= Parts per million
RDA	= Recommended Daily Allowance
SCN	=Thiocyanate
T3	= Tri-iodothyronine
T4	= Thyroxine
Tg	=Thyroglobulin
TSH	= Thyroid Stimulating Hormone
TGR	= Total Goitre Rate
μg	= Micrograms
UNICEF	= United Nations Children's Fund
US$	= United States dollars
USA	= United States of America
VGR	= Visible Goitre Rate
VTO	= 5-Venyl-2 thio-oxazoliodone
WFP	= World Food Program
WHA	= World Health Assembly
WHO	= World Health Organization

Glossary

Colloid: Constituent of the thyroid gland in which thyroid hormone storage takes place.

Creatinine: A product of metabolism in muscle, which is excreted in the urine at about the same level from day to day.

Cretinism: A condition associated with severe iodine deficiency and goitre commonly characterized by mental deficiency, deaf mutism, squint, disorders of stance and gait, stunted growth and hyperthyroidism.

Deaf-mutism: State of being both deaf and dumb.

Endemic: Occurrence of a disease confined to a community or defined population in which the prevalence of the condition exceeds a critical level, for example, 5 percent prevalence in endemic goitre.

Foetus: The unborn offspring, the child in the womb after the third month of pregnancy.

Gait: Manner of walking.

Goitre: Enlarged thyroid gland.

Goitrogens: Chemical substances in the diet which cause goitre due to action on the thyroid gland in blocking thyroid hormone synthesis or increasing kidney excretion of iodide. Their effect can usually be overcome by increasing iodine intake.

Hormone: Specialized chemical secretions of endocrine glands, which are released directly into the blood, and exert specific effects on their target organs.

Hyperplasia: Increased number of cells due to stimulation.

Hyperthyroidism: A condition due to elevated levels of thyroid hormones, which produce a rapid heart rate and other features of a nervous state (trembling, excessive sweating, irritability and weight loss).

Hypothyroidism: The result of a lowered level of circulating thyroid hormone slowing mental and physical functions.

Iodine: A non-metallic element belonging to the halogen group. It is a black crystalline substance having a density of about five. It melts at 114 degrees Centigrade and boils at a slightly higher temperature, giving off a characteristic violet vapour. Its atomic number is 53 and atomic weight is 126.92.

Iodine deficiency disorders (IDD): The effects of iodine deficiency, which show up during every stage of life.

Iodisation (of salt): The general term covering fortification of common salt with potassium iodate or potassium iodide.

Iodised oil: An organic compound of iodised ethyl esters of fatty acids of various kinds of oil. Soya bean and walnut oil have also been used to make iodised oil (Lipiodol & Oriodol). Only oils containing unsaturated fatty acids can be iodised, and administered via injection or oral dosage.

Iodophors: Iodine containing antiseptics used in the dairy industry.

Lipiodol: Brand name of iodised poppy seed oil capsules used for the oral treatment of severe iodine deficiency

Myxedematous: An oedema (swelling), which occurs due to poor thyroid functioning.

Neonatal hypothyroidism: Condition in the newborn with thyroid hormone deficiency.

Nutrient: Substance that supplies the body with the elements necessary for normal functioning.

Perinatal (mortality rate): Number of foetal deaths after the 28^{th} week of pregnancy, plus the number of deaths of infants under seven days of age, per 1000 live births.

Phalanx: Digital bone of a finger.

Prevalence (rate): Number of persons with the same disease at the same time per population at risk.

Prophylaxis: An intervention aimed at preventing the occurrence of a disease.

Squint: Inability of the eyes to look in the same direction together.

Stance: Position of body when standing.

Still birth: Birth of a dead foetus.

Stunting: Shortness due to retarded growth.

Thyocyanate: Chemicals known to have goitrogenic potential.

Thyroid: An endocrine gland, which secretes a hormone, thyroxine. It is located at the base of the neck and extends on both sides of the midline

Thyroxine: A hormone, which contains iodine and is synthesized and secreted by the thyroid gland. It plays a vital role in the normal growth and development of the human brain in early life and in metabolic processes.

Thyroid stimulating hormone: A hormone, which comes from the pituitary gland at the base of the brain and controls thyroid activity.

Triodothyronine: One of the thyroid hormones, which utilizes 3 iodine molecules.

CHAPTER 1: INTRODUCTION

1.1 BACKGROUND INFORMATION

Lesotho is a small mountainous country completely surrounded by the Republic of South Africa. It covers an area of approximately 30,350sq km of which 75 percent is mountainous and only 13 percent is arable (EMICS, 2000). The total population is estimated at 2.2 million with a growth rate of 2.6 percent (Bureau of statistics, 1996). The country is divided into ten administrative districts (Appendix 1) and ecologically divided into four zones, mainly on the basis of altitude, namely; Mountains, Lowlands, Foothills and Senqu river valley (Appendix 2). All of the areas in the country have an altitude of more than 1,500 metres above sea level, reaching nearly 3,500 at their highest points (Wolde-Gebriel, 1993). The Lowlands consist of areas below 1,800 metres above sea level, cover approximately 17 percent of Lesotho's surface area and have a high population density. The Foothills lie at altitude between 1,800 and 2,000 metres above sea level and make up 15 percent of the surface area of Lesotho, holding 20 percent of the population. The Mountains cover about 59 percent of the country with altitudes above 2,286 metres above sea level and hold less than one third of the country's population. The Senqu river valley zone penetrates deep into the Mountains and comprises about 9 percent of the land area with altitudes similar to those of the Lowlands. Climatic conditions are variable because of the topography of the country: the Mountains have cool summers and very cold winters often accompanied by snow, while the Lowlands have warmer summers with occasional heavy rainfall between October and April and dry but cold winters.

Economically, Lesotho is heavily dependent on South Africa, with no important natural resources other than water. The Lesotho Highlands Development Authority (LHDA) currently stores water in two dams (with a capacity of 1,950million-m^3 and 950 million-m^3) (LHWP, 2001). The water is transferred by gravitational flow via tunnels to South Africa, where it is sold. Lesotho's economy relies mainly on agriculture (which contributes only 11% of the gross domestic production), light manufacturing and remittances from labourers working on the South African mines (WFP, 2001). Due to the economic situation of South Africa's mining sector in terms of low gold prices, mine closures and use of local employees, fewer migrant workers are being employed and many are being made redundant and have to return to Lesotho (Gibbons, 1998). Over 30 percent of Basotho are landless, and most of those with land have only average only one field measuring one hectare. The scarcity of arable land has led to over cultivation of available land and further degradation. Erratic weather, including heavy rainfall, frost, hailstorms and even a tornado, have also severely affected agricultural production and food security at household level (LNVAC, 2002).

While agriculture provides employment for about 50 percent of the domestic labour force, its share of gross domestic production fell from 50 percent in 1973 to 11 percent in 1996 (LNVAC, 2002). The country is classified as a least developed, low income and food deficient. It is ranked 134th out of 174 countries assessed on food availability (WFP, 2001). The gross national product (GNP) is 770 United States Dollars (US$) and the gross domestic product (GDP) is US$354. The proportion of households defined as poor has increased significantly since 1990 and is now at 68 percent (Gay & Hall, 2001). On the basis of income per member, 32 percent of households in the Mountains and 20 percent in the Lowlands are the poorest.

The literacy rate in Lesotho is 82 percent (Gay & Hall, 2001). The government initiated free primary education in 2000 and this increased the number of children attending primary school from 67 percent (in 1999) to 89 percent (Ministry of education, 2002). More girls attend school than do boys because boys usually herd animals (more than 20% in the Mountains and less than 10% in the other ecological zones) instead of going to school (Gay & Hall, 2001). The general health of the country is poor with the increasing incidence of intestinal and respiratory diseases correlating directly with the non-availability of health facilities and clean water (Gibbons, 1998). According to hospital rates, low birth weight is 10 percent (EMICS, 2000). Infant and child mortality rates are 102 to 122 and 148 to 156 per 1000 live births respectively, while maternal mortality rate is 2.2 deaths per 1000 pregnancies *(EMICS, 2000)*. The most recent available data suggest that over one quarter of adults aged 15 to 49 years are infected with Human Immuno-deficiency Virus (HIV), with 31 percent being cases of Acquired Immuno- deficiency Syndrome (AIDS), which is a serious threat to the economy of the country (Maw, 2000). The rates of malnutrition among children and women have increased in the last decade. Recent data estimates that the prevalence of stunting, wasting and underweight is 30.7 percent, 3.2 percent and 15.4 percent respectively in children under the age of five (FNCO, 2002). These prevalence rates are higher in the Mountains than in the Lowlands. Micronutrient malnutrition is also a problem in the country, especially the deficiency of vitamin A (Wolde-Gebriel, 1993) iodine (Wolde-Gebriel, 1993; Sebotsa *et al.*, 2003) and iron (Wolde-Gebriel, 1993; Mabeleng, 2002).

1.2 IODINE DEFICIENCY

Iodine is an essential element for human survival (WHO, 1994). It is sparsely distributed over the earth and is an essential substrate for the synthesis of thyroid hormones (Delange, 1994). When the physiologic requirements of iodine are not met in a given population, a series of functional and developmental abnormalities occur. These abnormalities, termed iodine deficiency disorders (IDD), occur in different life stages and include abortions, stillbirths, congenital abnormalities, cretinism, goitre and impaired mental function. Some of these disorders, such as thyroid enlargement (goitre), are the result of compensation mechanisms of the thyroid (Peterson, 2000).

Goitre is the most visible form of IDD but in its most extreme form, iodine deficiency results in cretinism (WHO/UNICEF/ICCIDD, 2001). Severe iodine deficiency (iodine intake below 20μg/l) is accompanied by the occurrence of an abnormally high number of individuals referred to as endemic cretins, who exhibit a variety of anomalies of both intellectual and physical development (Glinoer & Delange, 2000). Cretins suffer from growth retardation or dwarfism, are severely mentally retarded and the majority are deaf mute (WHO, 1995). The prevalence of endemic cretinism may reach 5 to 15 percent in a population and this represents a veritable medical and social scourge (Glinoer & Delange, 2000).

The effect of IDD on mental development does not, however, always lead to severe mental retardation or cretinism. It may lead to the more subtle degrees of brain damage and reduced cognitive capacity, which affect the entire population and are of much greater public health importance (WHO/UNICEF/ICCIDD, 2001). A meta-analysis of 18 studies, which were conducted in areas with severe endemic goitre, indicated that iodine deficiency was responsible for an intelligent quotient (IQ) loss of 13.5 points (Bleichrodt & Born, 1994). The neurointellectual deficits are, however, not limited to remote areas with severe iodine deficiency and endemic cretinism but also exist in mild to moderate iodine deficiency (Glinoer & Delange, 2000). A summary of a series of studies conducted in areas with moderate or mild iodine deficiency, mainly in Southern Europe, showed neuro-pshycointellectual deficits in infants and school children. These deficits included: lower pshychomotor and mental development; low perceptual integrative motor ability; lower verbal IQ, perception, and attentive functions; lower velocity of motor response to visual stimuli, and lower learning capacity. All these deficits have grave consequences for the intellectual development of the children and for development of their communities and their countries (WHO, 1995). The potential impact of iodine deficiency on the intellectual development of large segments of the population is therefore of particular concern, especially when all of the adverse effects of iodine deficiency can be easily prevented by long-term, sustainable iodine prophylaxis (Li *et al*, 2001).

Iodine is essential during foetal development and babies born to iodine deficient mothers can be impaired irreversibly (UNICEF, 1995). The chances of miscarriage, stillbirth or pre-maturity rise significantly if a pregnant woman is iodine deficient. If born alive to an iodine deficient mother, a child may exhibit some or all of the defects associated with IDD, including compromised growth and development, clumsiness, torpor, muscular rigidity, immature skeletal development and other disabilities. Iodine deficiency also causes hypothyroidism, poor eye-hand coordination, partial paralysis and lassitude. Iodine deficient people cannot produce and learn as much as they should, with disastrous effects on economic development (WHO, 1995). Apparently, not only are humans affected, bur also domestic animals, and livestock productivity is also dramatically reduced (Pachauri, 1997, p. 140). These grave consequences of iodine deficiency make it an unnecessary and preventable burden on the public, which needs to be eradicated. The elimination of IDD is therefore a critical development issue, and should be given the highest priority by governments and international agencies (WHO/UNICEF/ICCIDD, 2001).

1.2.1 THE GLOBAL BURDEN OF IDD

Iodine occurs in fairly constant amounts in ocean water but is distributed very unevenly in the earth's crust (Dunn & Van der Haar, 1990, p.10). It was originally present in all soils, however rainfall, glaciations, exposure to wind and floods has leached the soils of iodine, especially in the mountainous areas and in flood plains (Peterson, 2000). Although some iodine is returned to the soil by rain, this is insufficient and soils remain iodine deficient. Foods and animals grown on such soils are iodine deficient. Iodine deficiency, therefore, presents a danger in a wide range of geographical areas, anywhere that rain or floods, ancient glaciers, deforestation or erosion have robbed the soil of iodine (UNICEF, 1995). It also exists where people do not eat a diet rich in seafood or where food is grown or animals are raised on iodine poor soil.

In 1991, the World Health Organization (WHO) estimated that 20 percent of people throughout the world lived in areas in which iodine intake was inadequate (WHO, 1995). Subsequently it was estimated that 18 percent of children aged 6 to 11 years in developing countries have goitre, with the prevalence in the least developed countries estimated to be 28 percent (Van Der Haar, 1997). The United Nations Children Fund (UNICEF) also estimated that 43 million people worldwide are suffering from varying degrees of brain damage (UNICEF, 1998). There are an estimated 11 million overt cretins and some 760 million people have goitres. According to recent information on global IDD status, IDD are a public health problem in 130 out of 191 countries worldwide (Brahmbhatt *et al.*, 2001). In Africa alone iodine deficiency affects about 150 million people in 40 countries. IDD have also been identified as a problem of public health significance in all the Eastern, Central and Southern African (ECSA) countries, with the exception of Mauritius and Seychelles (Kavishe, 1994, p.232). These estimates of obviously affected people have placed iodine deficiency among the most extensive nutritional problems in the world.

1.2.2 IDD IN LESOTHO

In Lesotho goitre surveys were conducted as early as 1960, as indicated on Table 1. A national study conducted by Munoz and Anderson (1962) showed the total goitre rate of 41 percent and visible goitre rate of 14 percent in school children aged 6 to 13 years. Thyroid function was assessed by measuring serum protein bound iodine where 26.1 percent were below 4 µg/100ml, indicating that about a quarter of subjects had low serum T4 levels. In 1962 a study conducted in the district of Qachas'nek indicated a total goitre rate of 27.8 percent in school children (Salhus, 1962). The multistage cluster survey conducted in the Mountain and Senqu river valley zones indicated TGR of 46.5 percent and VGR of 22.5 percent in clinic attendants aged 12 years and over (Slobodian, 1987). The second national study was conducted by Todd (1988) and indicated a prevalence rate of 45 percent in women of childbearing age and 21 percent in school children between the ages of 6 and 12 years. The median urinary iodine concentrations in the Mountains and Lowlands were 35µg/l and 55µg/l respectively. Out of 1708 children, deaf-mute, partial deaf, speech problems and mental retardation associated with iodine deficiency were observed in 29 children. It was also indicated in this 1988 report that, according to the central hospital (in Maseru) records, thyroidectomy was performed on 88 patients between 1980 and 1987.

The 1993 National Micronutrient survey conducted in four zones: Mountain (Highlands), Sengu river valley, Foothills and the Lowlands indicated a TGR of 39.4 percent and the VGR of 14.6 percent in women of childbearing age (Wolde-Gebriel, 1993). The total goitre rate in school children aged 6 to 16 years was 42.5 percent and the visible goitre rate was 15.3 percent. Goitre was more prevalent in the Mountain zone than in the rest of the zones. The T4 values were lower than the lower cut-off point of 64.4 nmol/l in 29.5 percent of the subjects while the TSH value was above the upper limit of 4.0 µIU/ml in 9.7 percent of the subjects. A study conducted at Mohale Dam catchment area indicated a prevalence of 17.5 percent in children between ages 10 and 14 and a urinary iodine excretion of 13µg/l (Jooste *et al.*, 1997b). The prevalence of goitre was recently found to be 4.9 percent, indicating the absence of IDD, and the median urinary iodine concentration was 26.3μg/l, which indicated moderate iodine deficiency in a study conducted in 1999 (Sebotsa *et al.*, 2003).

Table1. Summary of the previous goitre surveys in Lesotho.

YEAR	POPULATION	SAMPLE SIZE (n)	TGR (%)	VGR (%)	INVESTIGATOR
1956-1960	Primary school children (6-13 years) (country-wide)	13284	41.1	14.3	Munoz and Anderson (1962)
1962	Primary school children (6-13 years) (Qachasnek district)	885	27.8	-	Salhus (1962)
1976	Women (15-49 years) (multistage, cluster sampling; country-wide)	992	-	5.3	Anon (1976)
1987	Clinic attendants over 12 years old (Mountain districts and Senqu river valley)	948	46.5	22.5	Slobodian (1987)
1987	Women (15-49)(multistage, cluster sampling; country-wide)	952	-	4.7	Douglass (1988)
1988	School children (6-12 years) Women (15-49 years) (country-wide)	1708 1550	21 45	- 13	Todd (1988)
1993	School children (6-15 years) Women (15-49) (country-wide)	990 1050	42.5 39.4	15.3 14.6	Wolde-Gebriel (1993)
1997	School age children (5-15 years) (Mohale dam catchment area)	286	17.5	0.7	Jooste *et al.* (1997b)
2000	School age children (8-12 years) (country-wide)	4071	4.9	-	Sebotsa *et al.* (2003)

1.2.3 IDD PREVENTION AND CONTROL

All the frightening consequences of IDD, such as abortion, still birth and mental retardation can be prevented by ensuring that everyone, especially women of childbearing age and young children, consumes an adequate amount of iodine (WHO, 1995). A large series of investigations conducted in areas with moderate iodine deficiency, which have demonstrated the presence of definite abnormalities in the psychoneuromotor and intellectual development of children and adults is the main reason for ensuring that IDD is controlled in populations. The goal of eliminating IDD as a public health problem by the year 2000 was therefore accepted as one of the priorities in the field of nutrition by the United Nations Systems in 1990 (Hetzel, 1994, p.27). This goal was further endorsed by the World Summit for Children in the same year.

Iodine deficiency results mainly from geological rather than social and economic conditions (Hetzel, 1994, p.5; Mannar & Dunn, 1995, p.3). The deficiency of iodine cannot be eliminated by changing diet habits or by eating specific kinds of foods grown in the same area. Rather, the correction has to be achieved by supplying iodine from an external source. The correction of iodine deficiency can be done in two ways; either by periodic supplementation of deficient populations with iodised oil capsules or other preparations or by fortifying commonly eaten food with iodine. While both strategies are effective, the iodisation of salt is the common, long term and sustainable solution that will ensure that iodine reaches the entire population.

Mannar and Dunn (1995, p.4) have also stated that if iodised salt containing the required concentration of iodine is widely available and consumed in a community, there will, in a year's time, be no further birth of cretins or children with subnormal mental and physical development which can be attributed to iodine deficiency. Children will be active and perform better in school and further enlargement of thyroid in adults will be prevented. Recognizing this unique opportunity, there has been international commitment to ensure universal iodisation of all salt for human and animal consumption by 1995.

Apart from salt, iodised oil is considered as the best alternative method, especially in the most remote areas of developing countries (Isa *et al.*, 2000). The most current studies showed that a single dose of iodised oil given to individuals in populations affected by endemic goitre has reduced the prevalence of the disease, corrected iodine deficiency and normalized the thyroid function. Iodised oil programs have also conclusively been shown to be effective in preventing and treating endemic goitre and preventing endemic cretinism and the alterations of psychomotor intellectual development, which are frequently encountered in non-cretinious individuals (Delange, 1996). For example short-term success in reducing goitre rates was achieved in England in efficacy studies with iodised oil (Tonglet *et al.*, 1992); in school children and pregnant mothers in Malaysia (Isa *et al.*, 2000), and in school children in Switzerland (Zimmermann, 2000a).

Water is another vehicle for iodine supplementation. The experiences in adding iodine to central drinking water have been largely successful in correcting iodine deficiency in countries such as Malaysia (Foo *et al.*, 1998) and China (Delange, 1998). In Sudan, a pilot trial to fortify sugar with iodine was successful in reducing goitre rates and in improving thyroid hormone status (Eltom et al., 1995). Other foodstuffs such as bread and tea have also been suggested as means of food fortification with iodine (Peterson, 2000). Direct supplementation can also be done using iodide tablets or solutions (Dunn, 1996).

The persisting mild to severe IDD in Lesotho called for immediate action. An IDD control program was initiated in 1991 by the Micronutrient Task Force (multisectoral body dealing with micronutrient activities in the country) to eliminate IDD in the country (Ministry of Health, 1991). Two interventions were identified as the major components of the IDD control program: salt iodisation and iodised oil capsule supplementation. These interventions were selected based on the fact that salt is widely used on a regular basis in the country and therefore would serve as the best vehicle to carry iodine to the whole population. It was also considered that the process of developing the legislation on universal salt iodisation and making it legal would take a long time. Therefore, iodised oil capsule supplementation was proposed as a short-term intervention in Lesotho.

The legislation on universal salt iodisation was drafted in 1994 as a long-term intervention (Appendix 3). It states that food grade salt or other salt intended for both human and animal consumption, which is exported to Lesotho, must be iodised with potassium iodate (KIO_3) and contain not less than 40ppm and not more than 60ppm of iodine on entering the country. Exemptions from these regulations include salt intended for use in the manufacture of compound foodstuffs and salt used for experimental purposes. This legislation was made law in 1999 and promulgated in March 2000. Almost all of the salt entering the country comes from South Africa where legislation does not include mandatory iodisation of salt meant for animal consumption (Appendix 4). Studies in Lesotho have however shown an increase in the use of iodised salt despite the fact that there is no universal salt iodisation in South Africa. These impressive results on the use of iodised salt in Lesotho were attributed to the awareness campaigns which staterted in 1994. Communities were made aware of IDD and the importance of using salt labeled "iodised salt". The awareness campaigns were done through community gatherings, media, local newspapers, posters and pamphlets. The salt meant for animal consumption is coarse salt packed in 20kg bags or more. For this reason legislation in Lesotho allows Customs and Excise officials to do random check tests of the salt at entry points and Health Inspectors at retail level. The IDD Control Task Force was formed to ensure enforcement of the legislation in 2000. However, due to logistical problems facing the Task Force, enforcement is no longer being done. There has been no monitoring and evaluation of salt iodisation since the promulgation of the universal salt iodisation legislation in the country.

Iodised oil capsules were distributed as a short-term intervention from 1995 to 1998. The first supplementation with iodised oil capsules, each containing 200mg of iodine, which is internationally regarded as adequate to be effective for a year (Tonglet *et al.*, 1992), was done from February 1995 to May 1996. The second supplementation with capsules containing the same dosage of iodine was done from January 1997 to February 1998. Supplementation was done at schools and clinics to all people aged between 2 and 49 years.

During the implementation of the control program it was considered that many programs in the past have failed because they introduced iodine supplementation measures without educating the target groups or other involved parties about the importance of IDD and its correction. Therefore, education was seen as a corner stone of the IDD control program in the country to make all interested parties aware of IDD and its correction. In 1994, awareness campaigns (through public gatherings, local radios and newspapers, pamphlets, posters and workshops) were started. Members of the Micronutrient Task Force and IDD control Task Force were all involved in ensuring adequate awareness at all levels. However, after 2000 the campaigns have not been effective due to the logistical problems of both task forces.

In a recent (1999) study conducted in Lesotho (Sebotsa *et al.*, 2003), the two interventions (salt iodisation and iodised oil capsule supplementation) were found to be effective in decreasing the prevalence of goitre and increasing urinary iodine excretion in school children. All the ten districts and ecological zones were included in this recent study. The sampling frame consisted of list of primary schools categorized by ecological zones in each district. Stratified sampling was used to select five schools from all ecological zones in each district. The prevalence of goitre was 4.9 percent, indicating the absence of IDD, and the median urinary concentration was 26.3 micrograms per litre (μg/l), which indicated moderate iodine deficiency. Compared to the previous studies, which indicated mild to severe IDD, this 1999 study showed a great improvement in the control of IDD in the country.

1.3 STATEMENT OF THE PROBLEM

Although there was an improvement in controlling IDD in Lesotho, the 1999 study indicated that IDD are still a public health problem in need of correction (Sebotsa *et al.*, 2003). The country is therefore faced with a challenge to institute sustainable systems supported by essential technical and financial inputs to ensure that IDD is eliminated and will never recur in future. The last supplementation with iodised oil took place in 1998 because iodised oil capsules are very expensive and are usually used as a short-term intervention. For this reason, salt iodisation (iodine concentration between 40 and 60 ppm) is the only current IDD control program in Lesotho.

Endemic goitre has, however, been seen to persist in some countries with mandatory salt iodisation. For example IDD is still prevalent in Indonesia, despite an IDD control program having been in place for approximately 20 years (Muslimatun *et al.*, 1998). This indicates that neither voluntary nor mandatory iodisation of table salt will automatically guarantee success in eradicating iodine deficiency and endemic goitre (Jooste *et al.*, 1997a). The key issue to ensure success in eradication of IDD as a public health measure lies in the effective implementation and subsequent monitoring of the iodisation program and its effects (WHO/UNICEF/ICCIDD, 2001). Regular monitoring (on a quarterly basis) of the iodine content of salt at various points (production level, entry points, retail level and household level) needs to be undertaken to ensure distribution of adequately iodised salt to the entire population (Hess *et al.*, 2001). In addition, periodic evaluation is necessary to ensure that overall goals and objectives of the program are being met. A reasonable period for evaluation is three years after the introduction of the iodisation program (Dunn & Van der Haar, 1990, p.51).

In Lesotho, the salt iodisation program has neither been monitored nor evaluated since the 1999 study and the launching of the universal salt iodisation legislation in 2000. There is therefore a need for regular monitoring and a three-yearly evaluation of the salt iodisation program in the country to ensure its effectiveness and sustainability. Monitoring and evaluation of this current IDD control program in Lesotho is also needed to guarantee success in the eradication of IDD in the country; to ensure that the legislation is being enforced, and to see that the objectives, which include elimination of IDD have been met. Such monitoring and evaluation will also ensure that the IDD control program is sustainable for elimination of IDD in Lesotho in the decades to come. According to Dunn and Van der Haar (1990, p.50), a successful program must provide adequate surveillance of the biological impact of iodisation, by periodic surveys of goitre and urinary iodine, and by constant monitoring of the iodine level in iodised salt.

The present study was therefore undertaken as the first monitoring and evaluation tool and was guided by the following questions:

1 Is all salt, imported to Lesotho iodised to the legal requirements?
2 What is the iodisation level of different brands of salt available in Lesotho?
3 What is the coverage of adequately iodised salt in Lesotho?
4 How effective is salt iodisation with regard to the iodine status of the population?
5 Has IDD been eliminated as a public health problem in Lesotho?
6 Is the elimination of IDD in Lesotho sustainable?

1.4 THE SIGNIFICANCE OF THE STUDY

It has been stated that once implemented, an iodisation program needs constant monitoring with prompt corrections of problems as they develop (WHO/UNICEF/ICCIDD, 1994). Monitoring and evaluation are essential for an iodisation program particularly because there is a need to ensure that iodine deficiency is corrected. Therefore, as the first evaluation and monitoring, the present study could be used by the policy makers in the government of Lesotho to check whether the IDD elimination program is working as planned and will provide information needed to take corrective action if necessary. It could be used as a tool to plan for a more effective and sustainable salt iodisation program in the country.

The study would provide information on the iodine content of salt at entry point, retail level and household level and coverage in the household use of adequately iodised salt. It would also provide information on the effectiveness of salt iodisation in relation to the urinary iodine concentration, thyroid size and the prevalence of goitre. Sustainability of the salt iodisation program, which is important for all the programs, will also be indicated by the study. The information obtained from the study could be used to assess a need for further studies and as a tool for ongoing periodic monitoring and evaluation in the future.

1.5 AIM AND OBJECTIVES

1.5.1 AIM

To evaluate the salt iodisation program in Lesotho in terms of process, impact and sustainability indicators.

1.5.2 OBJECTIVES

1. To determine the iodine content of salt at entry points and at retail level in each district, ecological zone and at national level.
2. To determine the iodine content of different brands and types of salt available in the country.
3. To determine the iodine content and coverage in the use of adequately iodised salt at household level.
4. To assess the urinary iodine concentration of primary school children (8-12 years) and women of childbearing age (15-30 years) in each district, ecological zone and at national level.
5. To assess the thyroid size of primary school children (8-12 years) and women of child bearing age (15-30 years) in each district, ecological zone and at national level.
6. To determine the prevalence of iodine deficiency and of goitre in each district, ecological zone and at national level in primary school children (8-12 years) and women of child bearing age (15-30 years).
7. To assess the sustainability of the IDD elimination as a public health problem in Lesotho.

1.6 STRUCTURE OF THE THESIS

The thesis is divided into six chapters. Chapter one is the introduction of the thesis. It outlines the motivation for the study by giving an overview of the problem that is to be addressed. In addition, the specific aim and the objectives of the study have been outlined. The second chapter is devoted to the review of the literature on IDD information. Iodine deficiency disorders, their magnitude, control and the indicators used in their assessment are discussed. The background information on evaluation and monitoring, as well as sustainability of an IDD control program, is also included in the literature review. The methods and techniques that were applied during data collection are described in Chapter three. Special attention is given to the definitions of variables, standardization of techniques, sample population, study procedure, analysis of data and problems encountered during the study. Results of this study are presented in Chapter four. The results are discussed and interpreted in Chapter five. The final Chapter consists of conclusions that can be drawn from the results of the study in addition to recommendations based on the results. The cited literature is given in the references. Examples of information sheets, maps, legislation, palpation procedure and biochemical methods of analysis used in this study are given as appendices and the thesis is concluded with a short summary of the study.

CHAPTER 2: LITERATURE REVIEW

2.1 INTRODUCTION

IDD is a collective term for a range of disabilities caused by an inadequate dietary supply of iodine in a population. The most outstanding abnormalities include stillbirths, increased infant and child mortality, growth abnormalities, and above all, effects on brain development (Cobra *et al*, 1997; Delange *et al*, 1997). Proper supplementation with iodine completely prevents these consequences and salt iodisation is the preferred approach for supplementation in iodine deficient populations.

Once the presence of IDD is established a program to deal with its prevention and elimination must be developed. Education and communication are the integral components of the IDD control program, and should have as targets politicians and decision makers, health workers, workers in the salt trade and, most importantly, the community itself. A successful program must provide adequate surveillance of the biological impact of iodisation, by periodic evaluation (survey of goitre and urinary iodine concentration) and by constant monitoring of the iodine level in iodised salt. Monitoring and evaluation of the effects of implementation are crucial to the long-term success of an IDD control program. Failure to provide for adequate periodic evaluation and long term monitoring has caused many initially successful programs to fail.

In this chapter, an overview of the physiology of iodine is given. This includes iodine absorption, metabolism, utilization, excretion and the recommended daily intake. The effects of iodine deficiency in the different life stages are discussed following an overview of the physiology of iodine. In this section IDD in the neonates, infants, childhood, adolescence and adults is given based on available literature. The prevalence of IDD is included in this chapter to indicate how widespread the problem is. Given the magnitude of the problem it was important to highlight the interventions in place to control and prevent IDD internationally. Therefore the disadvantages and advantages of possible vehicles, which carry iodine to the population, are discussed with more emphasis on salt iodisation, which is regarded as the most effective and sustainable solution. Monitoring and evaluation of the iodisation program are highlighted with an overview of the indicators used. The last section discusses the sustainability of the program, which is important to ensure that iodine deficiency does not recur in the population.

2.2 THE PHYSIOLOGY OF IODINE

Iodine is a trace element present in the body in minute amounts (15-20mg, i.e., 0.02 X 10^{-3} % of body weight) (Delange, 2000b, p.295). The importance of iodine as an essential element arises from the fact that it is a constituent of the thyroid hormones. Its only confirmed role is in the synthesis of the thyroid hormones. Thyroid hormones in turn act by regulating the metabolic pattern of most cells of the organism (Delange, 2000). They also play a determining role in the process of early growth and development of most organs, especially that of the brain, which occurs in humans during the foetal and early postnatal life. Consequently, iodine deficiency, if severe enough, will impair thyroid hormogenesis (Delange, 2000b, p.296).

The stomach and the upper small intestine rapidly absorb iodine as either one of two chemical forms: iodide or iodate (Hetzel, 1989, p.24). The ingested iodine is believed to be absorbed efficiently (about 90%) (Hurrel, 1997). Iodate is reduced to iodide, which is transported in the blood to the thyroid gland, where an active transport mechanism pumps it into the thyroid cell (Hetzel, 1989, p.27). About 60µg of iodine needs to be trapped per day to maintain an adequate thyroxine level (Hetzel, 1994, p.7). The efficiency of the trapping mechanism is regulated with the help of a thyroid-stimulating hormone (TSH) depending on the availability of iodine and the gland's activity. This trapping mechanism maintains a gradient of 100:1 between the thyroid cells and the extra-cellular fluid. In iodine deficiency this gradient may exceed 400:1 in order to maintain the output of thyroxine. In the gland, iodide is oxidized to iodine, which is bound to tyrosine to form mono-iodotyrosine (MIT) and di-iodotyrosine (DIT) (Hetzel, 1989, p.25). These are coupled to form tri-iodothyronine (T3) and thyroxine (T4) in the thyroid epithelial cells. Thyroxine is then stored in colloid follicles bound to thyroglobulin. When needed, TSH will stimulate the proteolysis of thyroglobulin in the thyroid cells to release thyroxine into the blood.

A feedback system regulates iodine metabolism by using the hypothalamic hormone and the thyrotropin-releasing hormone (TRH), which modulate the secretion of TSH from the hypothalamus (Hetzel, 1989, p.29). The level of T4 in the blood regulates metabolism. Decreasing T4 levels lead to increasing TSH levels, which serve to increase thyroid iodine uptake as well as the production and release of more T4 and T3 into the bloodstream. At high TSH levels the thyroid will preferentially produce the biologically more active T3. Conversely, as thyroid hormone levels rise, TSH secretion falls. Sustained high TSH levels stimulate an increase in the size and number of follicular cells, an increase in vascularization, and consequently thyroid hypertrophy. When this reaches a prevalence of 5 percent of a defined population it is called endemic goitre (Hurrel, 1997). This proportion of 5 percent was chosen because a higher prevalence usually implies an environmental factor, whereas a lower prevalence is common even when all known environmental factors are controlled (Delange, 2000).

The thyroid cells, however, use 33 percent of the absorbed iodine for the synthesis of T4 and T3 and the remaining 67 percent is predominantly excreted in the urine (Lutz & Przytulski, 1997, p.137). This makes urinary iodine content a good marker of current iodine status. Iodine can be found in muscle, thyroid gland, skin and skeleton, but the greatest concentration is in the thyroid gland in the neck. In iodine sufficient population, the body of a healthy human contains 15 to 20mg of iodine of which 70 to 80 percent is in the thyroid gland, which weighs only 15 to 25g (Hetzel, 1989, p.24; Hetzel, 1994, p.7).

The dietary recommendations for iodine around the world were reviewed by Thomson (2002). The recommended daily intake of iodine according to WHO/UNICEF/ICCIDD (2001) is indicated in Table 2. However, the recently released series of reports presenting the dietary reference values for the nutrients by Americans and Canadians (Trumbo *et al.*, 2001) show slightly different values. In each case recommendations have been set relatively high in order to provide an extra margin of safety and to meet increased demands that may be imposed by natural goitrogens under certain conditions (Thomson, 2002). An iodine intake of 150μg per day has been suggested as sufficient for all adults and adolescents (Anderson, 2000, p.140) and *is* very similar in most countries (Thomson, 2002). In contrast recommendations for pregnancy and lactation vary considerably from country to country ranging from 200 to 260μg per day. Similarly the recommendations for infants range from 50 to 130μg per day. This perhaps also reflects an uncertainty in the requirements for infants, resulting in higher values being recommended as a precaution. More data are required on iodine status and requirement of iodine in infants and also in children, so that it is not necessary to extrapolate the recommended intakes from adult values.

Table 2. The Recommended Daily Intake of iodine (WHO/UNICEF/ICCIDD, 2001).

Life stage group	**Daily intake**
Preschool children (0 to 59 months)	90 μg
Schoolchildren (6 to 12 years)	120 μg
Adults (above 12 years)	150 μg
Pregnant and lactating women	200 μg

Allergy to iodine is a theoretical but almost non-existent possibility (Delange, 1998). It has been reported that high intake of iodine substantiated by urinary iodine of 1 000 to 10 000 μg/l, could have adverse effects in susceptible individuals and in patients with preexisting abnormalities of the thyroid gland (WHO, 1994). In general, consumption of iodine that exceeds the recommended dosage by as much as ten times is well tolerated by most people (Todd, 1998). However some people respond adversely to levels close to the recommended intake. The effects of high iodine intake on thyroid function are variable and depend chiefly on the health of the thyroid gland (WHO, 1994; Stanbury *et al.*, 1998; Lee *et al.*, 1999). The side effects include; a transient phenomenon known as Wolff-Chaikoff effect, thyroiditis, iodine-induced hyperthyroidism (IIH), iodine induced hypothyroidism, iodine induced autoimmunity both of the Hashimoto and of the Graves types, and an increase in the incidence of papillary cancers (Koutras, 1996). Skin rashes and acne have also occasionally been attributed to iodised salt but such reports are extremely rare and these conditions are unlikely to occur following salt iodisation (WHO, 1994). Anderson (2000, p.140) states that iodine intake has a rather wide margin of safety. Up to 1 mg of iodine per day is generally safe and many people tolerate much higher amounts without apparent damage (Dunn, 2000). However in some cases goitre is seen as a possible consequence of long-term iodine intake well in excess of physiological need (Zhao *et al.*, 2000).

Unlike other nutrients such as Iron, Calcium or Vitamins, Iodine does not occur naturally in specific foods (except for marine products). It is rather present in the soil and is ingested through foods grown on that soil (Hetzel, 1994, p.6; WHO, 1994). For this reason, the iodine content of the water in wells and lakes gives an idea of the availability of iodine in the soil and this is further reflected in the iodine content of foodstuffs, such as vegetables and animal products coming from that region (Lamberg, 1993; UNICEF, 1998). Seafood is therefore the richest source because of the high iodine content of the oceans. Iodine also enters the food chain through the use of iodophors as disinfectants, colouring agents and dough conditioners. These sources add significant iodine to the food supply (Lamberg, 1993; Anderson, 2000, p.139).

The intake of iodine is affected by lack of iodine in the environment and diet. Where the soil is lacking in iodine, locally produced food provides inadequate dietary iodine and unless the source of iodine is supplied from outside, people consuming these diets develop the deficiency (Van Der Haar, 1997; UNICEF, 1998). The iodine content of plants grown in iodine deficient soils may be as low as 10μg per kilogram compared to 100μg per kilogram dry weight in plants in a non iodine deficient soil (Hetzel, 1994, p.6). An insufficient dietary supply of iodine is the main cause of endemic goitre and cretinism. Therefore a low dietary intake of iodine is of concern in vegetarians (Davidsson, 1999) and vegans not consuming iodine supplements, seaweed and other related products rich in iodine (Lightowler & Davies, 1998). The indirect evidence of greater deficiency problems regarding vegetarian diets compared with meat containing mixed diets, might be seen in the fact that iodine deficiency is usually most prevalent in rural populations which primarily consume plant foods (Sullivan *et al.*, 1997).

Certain geographical areas have low iodine levels in soil and water and consequently in the crops grown in these areas (Filteau *et al.*, 1994). The areas with low iodine levels are usually mountainous because the soils lowest in iodine are those that were covered longest by the quaternary glaciers and snow and when these melted, most of the iodine leached out of the ground beneath. Iodine deficiency also occurs in lowlands far from the oceans and those affected by regular flooding and heavy winds (Koutras *et al.*, 1980, p.185). Because low levels of environmental iodine and associated dietary intakes of iodine exist in specific geo-ecological areas or zones, IDD is generally localized in those zones. Within countries the levels of IDD therefore vary significantly from area to area (WHO, 1993).

Although entirely preventable, iodine deficiency disorders still prevail because of various socioeconomic, cultural and political limitations to adequate programs of iodine supplementation (Thilly *et al.*, 1980, p.157). There is also evidence that poor overall nutritional status leads to higher goitre prevalence than would be predicted from iodine status alone (Filteau *et al.*, 1994). Other forms of malnutrition, notably protein energy malnutrition (PEM) and vitamin A deficiency, may have secondary effects on iodine nutritional status (Beard *et al.*, 1990). Severe PEM affects thyroidal function and metabolism of thyroid function. Retinal and retinoic acid inhibit the synthesis of thyroglobulin and thyroperoxidase in response to TSH (Namba *et al.*, 1993). Therefore it is possible that vitamin A deficiency might induce very large goitres by decreasing this regulatory mechanism and thus enhancing stimulation of the thyroid during iodine deficiency when TSH levels are elevated (Filteau *et al.*, 1994). Selenium is present in the enzymes of the thyroid (Glutathionine peroxidase and Superoxidase dismutase) responsible for the detoxification of toxic derivatives of oxygen (0_2 or H_20_2) (Delange, 1994). It is also a component of the iodothyronine 5'deiodinases, which is responsible for the peripheral conversion of T4 to more biologically active T3. Selenium deficiency therefore results in Glutathionine peroxidase deficit and consequently in accumulation of H_20_2. Excess H_20_2 could induce thyroid cell destruction and finally thyroid fibrosis resulting in thyroid failure. Additionally, selenium deficiency prevents the conversion of T4 to T3 in the liver (Aurthur *et al.*, 1993) and it also increases thyroid size in iodine deficient animals (Beckett *et al.*, 1993). Iron deficiency impairs the therapeutic response to iodine supplementation, possibly mediated via decreased T4 to T3 conversion or through decreased thyroxiperidase activity impairing iodide organification (Zimmerman *et al.*, 2002b).

While IDD is primarily caused by insufficient dietary intake of iodine, other substances referred to as goitrogens have been suggested to interfere with the proper functioning of thyroid hormone synthesis and utilization (Peterson, 2000). Goitrogens and are considered to be important only when iodine intake is low. Goitrogenic factors in the diet or environment other than iodine deficiency can play a role in the etiology of IDD (Delange, 1994). The role of these substances had to be considered as endemic goitre has been found in regions with no iodine deficiency.

Goitrogens are substances occurring naturally in foods and can cause goitre by blocking thyroidal absorption or utilization of iodine (Lutz & Pruzytulski, 1997, p.146). The best known of these substances are sulphur containing thionamides derived from vegetables of the Cruciferae family, particularly the Brassica genus such as cabbage, turnips, brussels sprouts, sweet potatoes, rapeseeds, peanuts and soybeans. Their anti-thyroidal action is related to the presence of thioglucosides which after digestion, release thiocyanate (SCN) and isothiocyanate (Delange, 1994). The SCN ion has a molecular volume and charge similar to that of iodide and competes with iodide for uptake into the thyroid (Thilly *et al.*, 1993). Both SCN and isothiocyanate are however inactivated by cooking. Some studies suggest that local water may contain goitrogenic substances from geologic origin or possibly from Escherichia Coli pollution in the water (Delange, 1994).

Another important group of goitrogens is the cyanoglucosides. This has been found in several staples like cassava, maize, bamboo shoots, sweet potatoes and lima beans. After ingestion these glucosides release cyanade, which is detoxified by conversion to SCN (Delange, 1994). In Zaire and some other African regions cassava is a staple food from which during the processing SCN is liberated. The determining factor involved in the goitrogenic action of cassava is the balance between dietary supplies of iodine and SCN (Delange, 1994), therefore the effects of SCN can be eliminated by increasing the supply of iodine (Lamberg, 1993).

The goitrogenic effects of some other thionamides, such as 5-vinyl-2-thio-oxazolione (VTO, goitrin) and flavonoids inhibit the activity of thyroperoxidase in the oxidation of iodine and the formation of tyrosine dimmers. These goitrogens depend on a block in the thyroidal synthesis of hormones and are possibly only partially eliminated by more iodine. VTO occurs in the seeds of various Brassica. Goitrin in milk has been linked to endemic goitre and iodine deficiency in Finland (Delange, 1994; Lamberg, 1993). VTO and flavonoids are eliminated by intake of more iodine (Delange, 1994).

2.3 THE EFFECTS OF IODINE DEFICIENCY

According to the WHO (1995), the effects of iodine deficiency begin before birth and have various results throughout the life cycle (Table 3). The various effects of iodine deficiency impose human, social and economic costs on individuals and communities (Hetzel, 1994, p.19) and this leads to poverty. The human and social costs arise from the obvious disabilities of mental deficiency and deaf mutism. These effects have economic implications such as reduced work output in the household and in the labour market, the costs of medical and institutional care and higher educational costs from increased absenteeism and grade repetition. The more subtle effects on mental status cause poor levels of school performance by children and hence produce long-term effects over the whole life span. Reproductive failure is the outstanding manifestation of iodine deficiency in animals and this is a major problem in countries such as Lesotho where most households depend on farming. Poverty hinders households to access and use adequate and quality food and health care. Therefore several heads of states have emphasized that poverty eradication be given the first priority and be included in the national development policy. The effects of IDD, which may lead to poverty are very costly to manage, while the cost of salt iodisation for IDD elimination is very low (Mannar, 1994, p.92*)*.

Table 3. Iodine deficiency disorders at various stages of life (WHO, 1995)

Life stages	**IDD**
Foetal life and infancy	Abortions, stillbirth, congenital anomalies, increased infant mortality, psychomotor defects, cretinism in various degrees
Childhood and adolescence	Goitre, retarded physical development, impaired mental development, impaired intellectual performance
Adulthood	Goitre, hypothyroidism, impaired mental function

2.3.1 IODINE DEFICIENCY IN THE FOETUS AND IN NEONATES

The effects of iodine deficiency on the foetus and neonate include increased perinatal and infant mortality (Cobra *et al.*, 1997). In the foetus iodine deficiency is associated with greater incidence of stillbirths, abortions and congenital abnormalities (Hetzel, 1994, p.10). This is because, during pregnancy, maternal thyroid hormones are of great importance for normal development of the central nervous system of the foetus (Versloot *et al.*, 1998). In mild iodine deficiency, the foetus can compensate when the maternal hypothyroxinaemia is not severe, but with the declining maternal T4 level in severe iodine deficiency, foetal hypothyroidism ensues with its attendant irreversible neurological deficits (neurological cretinism) (Hetzel, 1994, p.11). This condition occurs with an iodine intake of below 25μg per day in contrast to a normal intake of 100 to 150μg per day.

Hormonal changes and metabolic demands during pregnancy result in profound alterations in the biochemical parameters of thyroid function (Glinoer & Delange, 2000). In iodine deficiency, the serum levels of free T4 decrease steadily during gestation (Delange, 2000a). Although the median values remain within the normal range, one-third of the pregnant women have free T4 values near or below the lower limit of the normal range in mild iodine deficiency. This is in contrast with the thyroid status during pregnancy in conditions of normal iodine intake, which is characterized by only a slight (15%) decrease in free T4 by the end of gestation. It is therefore clear that foetal T4 production is diminished at a time when it is of eminent importance for the normal development of many organs, especially the brain (Versloot *et al.*, 1998).

An important issue for thyroid function and regulation in the foetus is the concept that thyroid hormones are transferred from mother to foetus, both before and probably after the onset of foetal thyroid function (Glinoer & Delange, 2000). Iodide readily crosses the placenta and the concentration of iodide in the foetal blood increases throughout the gestation until it is approximately 75 percent of that in the maternal blood (Gorman, 1999). T4 is already found in the first-trimester coelomic fluid from the 6^{th} week of gestational age, long before the onset of foetal thyroid function, which occurs at the 24^{th} week of gestation (Delange, 2000). Whether thyroid hormone is needed during the first trimester is less certain, and if it is, it must be supplied, by the mother since it is not secreted by the foetus until the second trimester (Robert & Utiger, 1999). However, during the second and third trimester, the thyroid hormone is supplied by both the mother and the foetus, but mostly by the mother (Delange, 2000a, p.77). The first phase of maximum growth velocity of developing brain structures, occurring during the second trimester, corresponds to a phase during which the supply of thyroid hormones to the growing foetus is almost exclusively of maternal origin (Glinoer & Delange, 2000). Therefore, severe maternal hypothyroxinemia, occurring during the second trimester of gestation, results in dramatic and irreversible neurological deficits in the offspring, while when maternal hypothyroxinemia occurs later, it results in much less severe, and also partially reversible, foetal brain damage. As a significant degree of neurological development occurs within weeks of conception, it is imperative that women have adequate iodine stores during the first trimester of pregnancy (WHO/UNICEF/ICCIDD, 1993).

Another major effect of foetal iodine deficiency is endemic cretinism. Its commonest form is the neurological type, which is not reversed by administration of iodine or thyroid hormones (Hurrel, 1997). Endemic cretinism results from an insufficient supply of thyroid hormones to the developing brain (Delange, 2000b). Thyroid hormone action is exerted through the binding of T3 to nuclear receptors, which regulate the expression of specific genes in different brain regions following a precise development schedule. During foetal and early postnatal life T3 bound to nuclear receptors is primarily dependant on its local production from T4 via type II deiodinase. In humans, T4 can be found in the first trimester coelomic fluid from 6 weeks of gestational age (Delange, 2000b). Nuclear T3 receptors are present in the brain of 10-weeks-old foetus, when foetal thyroid function may begin, and increase more than six fold by 12 weeks and tenfold by 16 weeks. Foetal plasma T4 is low but detectable up to the 24th week of gestation. After the onset of foetal thyroid function, T4 increases steadily, reaching adult values by 36 weeks. However, transfer of maternal T4 continues until birth, when it still represents 20 percent to 50 percent of cord serum T4. Maternal hypothyroiximia can therefore result in impaired neurointellectulal development in the offspring. Data from Papua New Guinea indicate a relationship between the level of maternal T4 and the outcome of pregnancies both current and in the recent past, including mortality and the occurrence of cretinism (Pharoah, 1993). There were proportionally more perinatal deaths and cretins among the offspring of women who showed the lowest levels of serum T4. Several observations clearly demonstrated that myxedematous endemic cretinism also results from severe thyroid failure occurring during foetal or early postnatal life. Screening of all pregnant women for hypothyroidism, preferably in the first trimester, has therefore been proposed and once it is decided upon, its practicability, sensitivity and specificity should also be considered (Prop *et al.*, 1999).

Neonates are more sensitive to iodine deficiency than adults (Glinoer, 1997). A sign of iodine deficiency during this period is neonatal hypothyroidism. This is associated with a defect in the production of thyroid hormones due to the absence of the thyroid, a small, misplaced thyroid or a defect in the biochemical machinery in the thyroid (Hetzel, 1994, p.13). Elevated serum TSH in the neonates therefore indicates insufficient supply of thyroid hormones to the developing brain (Delange, 1998).

The importance of the state of thyroid function in the neonate relates to the fact that at birth the brain of the human infant has only reached about one-third of its full size and continues to grow rapidly until the end of the second year of life (Hetzel, 1994, p.14). Thyroid hormones in the neonate play a critical role in growth and maturation of all organs, especially the brain. Consequently, hypothyroidism during foetal and postnatal life not only affects postnatal growth but also brain development, resulting in irreversible mental retardation (Delange, 1998). If there is adequate iodine intake, neonatal hypothyroidism occurs at the rate of 1 in 4, 000 births (0.025%), and if iodine intake is inadequate, then the rate may increase to 1 percent or even up to 10 percent of births which indicates a massive threat to brain development (Stanbury & Pinchera, 1994, p.81). If infants with congenital hypothyroidism are not identified and treated very soon after birth, when they become dependent on their own thyroid secretion, they will become permanently mentally retarded (Robert & Utiger, 1999). The hypothyroidism persists into infancy and childhood if the deficiency is not corrected, and retardation of physical and mental development results.

2.3.2 IODINE DEFICIENCY IN CHILDHOOD AND IN ADOLESCENCE

The most obvious sign of IDD during this period is thyroid enlargement, goitre (Peterson, 2000). The prevalence increases with age, reaching a maximum after the first decade and studies have shown that girls have a higher prevalence than boys (Delange, 1994). In the Langloof area in South Africa, the prevalence of goitre ranged from 14.3 percent to 30.2 percent in the four communities indicating mild to severe IDD (Jooste *et al.*, 1997a). The most affected children were those from the low socio-economic strata, and it was indicated that this is because low socio-economic status is associated with high prevalence of protein energy malnutrition (PEM), which affects thyroidal function and metabolism of thyroid function (Beard *et al.*, 1990). For example, in Lesotho the prevalence of goitre was higher in school children with low socio-economic status than in those who enjoyed a better socio-economic status (Wolde-Gebriel, 1993). This observation was similar to those of other international studies (Pardede *et al.*, 1998; Hollowell *et al.*, 1998; Jooste *et al.*, 1997b).

There is increasing evidence of impaired mental function in apparently normal children living in iodine deficient areas (Hetzel, 1994, p.15). Euthyroid schoolchildren born and living in iodine deficient environments were reported to exhibit subtle or even overt neuropsycho-intellectual deficits when compared with controls from non-iodine deficient environments, living in the same ethnic, demographic, nutritional and socio-economic system. Low verbal IQ, perception and attentive function have also been reported with moderate iodine deficiency (Delange, 1994). A comprehensive review of the relation between iodine deficiency and intellectual performance outcomes in school children concludes that children who grow up in an iodine deficient environment accumulate a cognitive deficit of at least 10 IQ points in comparison with their peers from iodine sufficient areas (WHO, 1995; Shrestha & West, 1996). Hetzel (1989, p.90) indicated that low maternal thyroxine levels during pregnancy significantly affected the children's dexterity even when tested at the age of 10 to 12 years.

Recent studies in Indonesia and in an iodine deficient area in Spain, using a wide range of psychological tests, have shown that mental development of children from iodine deficient areas lags behind that of children from iodine replete areas (Pardede *et al.*, 1998). The difference in psychomotor development becomes apparent after the age of two and a half years. It was also found in Indonesia that cognitive performance of school children had a direct relationship with iodine status. Similar findings were observed in Kwazulu Natal (South Africa) where goitrous subjects scored on average 5.2 percent lower than those without goitre in their Zulu exam papers (Benade *et al.*, 1997). In a study conducted in the rural area of Bangladesh, the euthyroid group had better scores in reading and spelling and mathematics than did the hypothyroid group (Huda *et al.*, 1999).

2.3.3 IODINE DEFICIENCY IN ADULTS

In adults, a widespread prevalence of goitre is related to iodine deficiency. A high degree of apathy has also been noted in populations living in iodine deficient areas in Northern India and this may even affect domestic animals such as dogs (Hetzel, 1994, p.16). Fertility is decreased in women with hypothyroidism, and among those who do become pregnant, the frequency of pre-eclampsia and preterm delivery is increased (Robert & Utiger, 1999). It is also apparent that reduced mental function due to brain hypothyroidism is widely prevalent in iodine deficient communities and has an effect on their capacity for initiative and decision-making (Hetzel, 1994, p.19). The mental slowness and apathy could have serious consequences for development in poor countries by affecting literacy or other development programs and motivation for improving living conditions (Filteau *et al.*, 1994). This indicates that iodine deficiency can be a major obstacle to the human and social development of communities living in an iodine deficient environment.

2.3.4 IODINE INDUCED HYPERTHYROIDISM (IIH)

IIH is the most important side effect, which may occur primarily in older people with long-standing nodular goitre, and it is recognized not to be a problem in younger subjects (Bartalena *et al*, 1996; Todd & Dunn, 1998; Stanbury *et al.*, 1998). It may occur in a population that has been long exposed to iodine deficiency and where severely iodine deficient populations rapidly and excessively increase their iodine intake (Stanbury *et al.*, 1998; Zhao *et al.*, 2000). This happens even when the total amount of iodine intake is within the usually accepted range of

100µg to 200µg per day (WHO, 1996). IIH also occurs in patients with thyroid nodules that are "autonomous" or "overactive" (Lee *et al.*, 1999). Autonomous nodules produce thyroid hormone in direct correlation with iodine intake without regard to thyroid hormone levels. These nodules produce excess thyroid hormone because they lack feedback controls and do not shut down like normal thyroid tissue does in the face of high iodine intakes. The symptoms of IIH include: anxiety, palpitations, weight loss, muscle weakness, fatigue, diarrhoea, sweating, and hot sensations (Todd, 1998). IIH may also cause elevation in basal heart rate, anatomical changes in heart muscle, and demineralisation of bone (Stanbury *et al.*, 1998) and more serious cardiac effects such as atrial fibrillation, angina and heart failure (Todd, 1998).

IIH has also been reported when persons are exposed to an incremental increase in iodine intake from iodine supplements given prophylactically for iodine deficiency or when administered in various iodine-containing pharmaceuticals (Phillips, 1997) and may return to normal, when the iodine is withdrawn (Stranbury *et al.*, 1998). For example in Kivu, Zaire, there was a striking increase in urinary iodine in 191 goitrous patients, 14 had clear thyrotoxicosis and 15 had suppressed TSH with normal serum T3 and T4 after the introduction of salt containing up to 148ppm of iodine (Bourdoux *et al.*, 1996). Introduction of iodised salt in Zimbabwe doubled the incidence of IIH during the first two years of the program (Todd *et al.*, 1995). The reason for the development of IIH after supplementation is that iodine deficiency increases thyrocyte proliferation and mutation rates (Dremier *et al.*, 1996). Possible consequences are the development of hyper-functioning autonomous nodules in the thyroid and hyperthyroidism. There are many reports, however, of successful use of iodised salt prophylactically and it has been used by a normal population, as a purifier without mention of IIH. The frequency with which IIH occurs depends on a number of factors (Stanbury *et al.*, 1998). They include the severity of iodine deficiency that existed before prophylactic iodine was introduced, the magnitude of the incremental rise in iodine intake, the frequency of autonomous elements in the thyroid, the age groups examined, the skills and instruments used in ascertainment and when or at what intervals the disorder is investigated.

2.4 THE PREVALENCE OF IDD

Iodine deficiency has been called the world's most significant cause of mental retardation (WHO/UNICEF/ICCIDD, 1994). It is both easy and inexpensive to prevent but nevertheless continues to be a significant public health problem in many countries (WHO, 1994).

Iodine deficiency has been identified as a global public health problem with over a billion people at risk worldwide (WHO/UNICEF/ICCIDD, 1994). In 1990, 28 percent of the world's population (1,572 million people) was believed to be at risk of IDD and 12 percent (655 million people) were affected by goitre (WHO/UNICEF/ICCIDD, 1994). A recent WHO/UNICEF/ICCIDD report (1996), states that at least 1,570 billion people (or 29% of the world's population) live in areas of iodine deficiency and need some form of iodine supplementation. It is estimated that more than one billion people concentrated primarily in less developed countries are unable to consume adequate levels of iodine (Maberly, 1998). In 1999, WHO estimated that of its 191 Member States, 130 had a significant IDD problem and 13% of the world's population, which is approximately 740 million people, were affected by goitre (WHO/UNICEF/ICCIDD, 2001). The global estimates of the number of subjects affected by some of the IDD conditions are shown on Table 4.

Table 4. The recent 1999 magnitude of IDD by WHO Region (WHO/UNICEF/ICCIDD, 2001).

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**

* Based on United Nations (UN) Population

In Lesotho, the prevalence of goitre was documented more than 40 years ago when severe IDD was reported (Munoz & Anderson, 1962). In 1993, mild to severe IDD was attributed to a lack of iodine in soil and water and the use of food containing goitrogens such as cabbage (Wolde-Gebriel, 1993). A recent study conducted in 1999 indicated mild IDD and showed that IDD is still a public health problem in the country (Sebotsa *et al.*, 2003).

2.5 IDD CONTROL PROGRAMS

IDD is among the easiest and cheapest of all disorders to prevent (WHO/UNICEF/ICCIDD, 2001). The planning of a global strategy for prevention and control of IDD has been taken up by the United Nations, Administrative Committee on Coordination; Subcommittee on Nutrition (ACC/SCN) (Mannar & Dunn, 1995, p.5). In October 1985 the ACC/SCN requested the WHO to prepare an international support program for IDD control. Similarly, the 39th World Health Assembly (WHA), which was held in Geneva in 1986, passed a resolution urging all member nations to give high priority to the prevention and control of IDD. Therefore, the International Council for Control of Iodine Deficiency Disorders (ICCIDD) was formed in 1986 to function as an expert consultative group, on the assessment and control of IDD, operating with the WHO and UNICEF on a global, regional and national level. ICCIDD has also formed regional working groups in Africa, South East Asia and the Middle East for developing regional strategies for IDD control. Much progress has been achieved since the creation of the ICCIDD. The world Summit for Children, held in New York in September 1990, called for virtual elimination of IDD by the year 2000. Similarly the International Conference on Nutrition (ICN) held in December 1992 called on governments, Non-Governmental Organisations (NGOs), the private sector, other expert groups and the community, to ensure and legislate for the fortification of foods or water with iodine where iodine deficiency is a significant health problem.

The effectiveness of iodised salt on thyroid size depends on age, stage of goitre and the duration of the prophylaxis. Studies have indicated that if iodised salt containing the required amount of iodine is widely available and consumed in a population, goitres in primary school children and young adults begin to shrink and even disappear altogether (Mannar, 1994, p.90).

Further enlargement of the thyroid in adults is prevented but the established goitres in adults do not decrease in size. Furthermore, it has been stated that the correction of iodine deficiency through the implementation of iodised salt consumption prevents goitre in children born after iodine prophylaxis and is able to prevent further increase in thyroid size in older children, but fails to include a quick regression of the thyroid enlargement in children previously exposed to iodine deficiency (Aghini-Lomard *et al.*, 1997). Goitre rates remained enlarged one year after iodisation became compulsory at a higher iodine concentration than occurred with optional iodisation in South Africa (Jooste *et al.*, 2000). Unlike salt, the effects of iodised oil on the thyroid are observed within a short period. A significant decrease of goitre was observed in goitrous patients a few months after the administration of iodised oil (Tonglet *et al.*, 1992). Similarly in a study in an endemic goitre area in Peninsular Malaysia, there was a reduction of thyroid size of school children and pregnant women after 6 and 12 months of supplementation with iodised oil (Isa *et al.*, 2000). However, this depends on the dose of iodised oil as was observed by Benmiloud et al. (1994) where administration of a single dose of 480mg iodised oil to school children aged 6 to 11 years did not result in decreased thyroid volume as measured by ultrasonography after 395 days but significantly decreased at a higher dose of 960mg. Iodisations of water, sugar, bread and other foodstuffs have also been successful in reducing goitre rates.

The IDD control programs include both fortification of food with iodine and iodine supplementation (iodised oil and direct iodine supplements). There are several possible vehicles for iodine fortification, but salt iodisation has been the preferred approach for iodine deficient populations.

2.5.1 FORTIFICATION AND SUPPLEMENTATION WITH IODINE

In principle, virtually any food can be used for fortification with iodine (Dunn, 1994, p.115). The problem with using other foodstuffs rather than salt as vehicles is that their intake is not essential and frequently they are not consumed by those most vulnerable to iodine deficiency. Therefore, it is not often that other foodstuffs deserve serious consideration as primary vehicles for correcting iodine deficiency. Iodine has been added to tea, bread, sugar and candy. For example, in Sudan, a pilot trial to fortify sugar with iodine was successful in increasing urinary iodine concentration, in reducing goitre rates and improving thyroid hormone status (Eltom *et al.* 1995). Although they are effective, each of these foodstuffs may lead to mal-distribution in the diets of a community, and therefore wide variations in iodine intake may result (Dunn, 1994, p.115).

Water, like salt, is a dietary necessity, and must be consumed daily. A study in Malaysia indicated that in spite of the availability of adequately iodized salt, iodine intake was insufficient to meet pre-pubertal children's physiological needs (Foo *et al.*, 1998). Iodine repletion was achieved only with the fortification of a hostel's water supply. It was then concluded in this study that in remote societies that consume little food from outside, use salt only in cooking, and share a common water source, iodisation of the community water supply may be the only strategy that will effectively rid these societies of the scourge of iodine deficiency. In a semi-arid area of Inking, China, iodisation of irrigation water normalized iodine deficiency and reduced infant mortality at an estimated cost of US$0.05 per capita per year (Delong, 1998). Therefore, water is another physiologically ideal vehicle for introducing iodine. Its big drawback when compared to salt, is that sources of drinking water are ubiquitous and therefore, very difficult to control (Dunn, 1994, p.113). In addition, goitre and thyroid abnormalities were associated with iodine excess from the water in several studies conducted among the population living in plain areas in China (Zhao *et al.*, 2000) and among the Peace Corps who used water purified by iodine based filters in Niger, West Africa (Khan *et al.*, 1998). It was also indicated in Mali that iodisation of well water is very costly and only viable in certain parts of the country where there are adequate water supplies (WHO, 1998). Nevertheless, under favourable circumstances, water iodisation is a reasonable method for the correction of iodine deficiency and the monitoring of iodine status of populations is important (Zhao *et al.*, 1999).

In areas where iodised salt is not available, administration of iodised oil has been proposed as an emergency prophylactic and therapeutic approach (Benmiloud *et al.*, 1994). This leads to eradication of goitre and cretinism in a population. The most current studies showed that a single dose of iodised oil given to individuals in populations affected by endemic goitre reduced the prevalence of disease, corrected iodine deficiency and normalized thyroid function (Delange, 1996; Isa *et al.*, 2000). For example, Pongpaew *et al.* (1998) indicated an increase in the weight and height of school children in an endemic area of iodine deficiency disorders after one year of iodine supplementation. There was a reduction in the thyroid volume and an increase in urinary iodine excretion in school children and pregnant mothers in Malaysia after oral iodised oil supplementation (Isa *et al.*, 2000). In a study conducted in Danané Health District in Côte d' Ivoire, children were given capsules containing 200mg iodine and the goitre rate fell from 42 to 38 percent at 30 weeks and 17 percent at 50 weeks and urinary iodine excretion remained significantly increased above baseline for the entire year (Zimmermann *et al.*, 2000a). Iodised oil capsules containing 200mg of iodine contributed to a decrease in the prevalence of goitre in primary school children in Lesotho (Sebotsa *et al.*, 2003). The major advantage of iodised oil administration is that it can be implemented immediately, and does not involve the complexities of altering salt production and trade.

Iodised oil can be given either by intramuscular injection or orally (via dispenser or oil capsules). The duration of effectiveness of injected iodised oil exceeds that of oral iodised oil by far and may thus appear to be a most convenient and effective method for iodised oil administration (Furnee, 1997). However, injections under field conditions in developing countries have the potential risk of communicable diseases such as hepatitis and HIV and dependence on trained manpower (Isa *et al.*, 2000). Taking iodised oil orally eliminates many of the disadvantages of injections, but there are several factors, which affect its effectiveness (Furnee, 1997). For example, the presence of intestinal parasite reduces duration, boys and girls between age 8 and 10 have different duration of effectiveness; fat children retain more iodine from an oral dose of iodised oil than children with little fat; goitrous subjects retain more iodine than non-goitrous subjects; goitrogen (e.g. cassava and cabbage) consumption reduces the duration, and seasonality influences the duration of this prophylaxis measure. Although the cost of providing iodised oil depends on the distribution dose, interval and delivery strategy, iodised oil supplementation costs more than salt iodisation. The cost of iodisation is in the range of US$0.02 to US$0.10 per person per year Mannar, 1994, p.92) while the total annual cost of an oil supplementation program is estimated at US$ 0.50 per person per year (Jamison *et al.*, 1993, p.3). Another drawback of iodised oil supplementation is the need to make direct contact with every targeted person at the appropriate distribution interval (Peterson, 2000).

In circumstances in which iodised salt or other alternatives are not readily available, iodine supplements in the form of tablets or drops can successfully correct iodine deficiency. An oral potassium iodide (KI) solution was found to be effective for the prophylaxis of iodine deficiency if given as a dose of 30mg monthly or 8mg biweekly (Todd & Dunn, 1998). Subjects can also receive oral iodine directly in the form of Lugol's solution, which is widely available as an antiseptic and contains free iodine 50grams per litre (Todd & Dunn, 1998), and is commonly found even in small rural hospitals in developing countries (Dunn & Van Der Haar, 1990, p.59). The great advantages of Lugol's iodine are its wide availability and low cost. It also provides a supply of iodine that is closer to physiological needs. However, effective use of Lugol's iodine requires responsible people to distribute it and to see that the correct dose is given at the proper intervals (Dunn & Van Der Haar, 1990, p.40) because large doses can be toxic to the gastro-intestine (Todd & Dunn, 1998). This control is difficult to maintain in most public health programs in developing countries (Dunn, 1994, p.114).

Mannar and Dunn (1995, p.3) indicate that of all the possible vehicles iodised salt has become the most commonly accepted for the following reasons:

- "It is one of the few commodities that comes close to being universally consumed by almost all sections of a community irrespective of economic level. It is consumed at approximately the same level, throughout the year in a given region by all normal adults. Thus a micronutrient like iodine, when introduced through salt, will be administered to each individual at a uniform dosage throughout the year.
- Compared to other food commodities whose production is widely dispersed, the production of salt is generally limited to a few centres. In many remote areas of the world, salt is one of the few commodities that come from outside the area, thereby lending itself to processing on an economical scale and under controlled conditions. By adding a fixed dosage of a micronutrient like iodine to salt at centralized locations, a

majority of the population all over a region or country will ingest the nutrient in physiological amounts continuously with no additional effort.

- The mixing of an iodine compound with salt is a simple operation and produces no adverse chemical reactions. The equipment required is uncomplicated, easy to operate and maintain.
- A major portion of salt produced in the world is derived from seawater. Seawater contains iodine in addition to salt. However, when seawater evaporates, much of the iodine either remains in solution or is lost by evaporation. Only a small portion of the iodine is retained in the salt. Iodisation, therefore, restores a natural constituent of sea salt.
- The addition of iodine to salt (usually as potassium or sodium iodide or iodate) does not impart any colour, taste or odour to the salt. In fact iodised salt is indistinguishable from uniodised salt.
- The cost of iodisation is low: normally in the range of 2 to 7 US cents per kilogram, which is less than 5 percent of the retail price of salt in most countries."

2.5.2 SALT IODISATION

The idea of using salt as a vehicle for the addition of iodine to the diet began in Switzerland in the 1920s (UNICEF, 1998). This followed the pioneering studies of Dr David Marine in Akron, Ohio, USA in the preceding decade, which showed that administration of iodide tablets over several days twice a year produced a dramatic decrease of goitre in adolescents. The salt industry then found that it was relatively easy to add iodine at a final stage in the processing of salt before packing. The concept gained ground and soon most salt companies in the USA, Australia and European countries started iodising salt (Mannar, 1994, p.93). Since 1990, worldwide production and availability of iodised salt has increased greatly; production of iodised salt has increased from less than 10 percent to more than 50 percent in South-east Asia and India, more than 70 percent in China and Africa and more than 80 percent in Latin America (Maberly, 1998). In 1994, a total of 48 developing countries with IDD had no significant salt iodisation programs, but recently most of them have iodised more than half their salt. It is also reported that following the firm commitment at the World Summit for children in 1990 to achieve sustainable elimination of IDD by the year 2000, extremely successful programs of salt iodisation were implemented in several affected countries and the percent of the world population at risk of IDD has dropped from 28.9 percent in 1994 to 13.7 percent in 1997 (WHO, 1997).

In nearly all countries where iodine deficiency occurs, it is now recognized that the most effective way to achieve the virtual elimination of IDD is through universal salt iodisation (WHO/UNICEF/ICCIDD, 2001). The effectiveness of iodised salt prophylaxis to correct iodine deficiency and reduce goitre prevalence has been reported in several international studies. For example, the prevalence of goitre was shown to have drastically decreased and the median urinary iodine levels were equal or above the cut-off point of 100μg/l in all countries in a seven-country study in Africa (Botswana, Cameroon, Democratic Republic of Congo, Kenya, Nigeria, Tanzania, Zambia and Zimbabwe) after the introduction of iodised salt (WHO/UNOCEF/ICCIDD, 1996). Universal salt iodisation involves the iodisation of all human and livestock salt, including salt used in the food industry. Adequate iodisation of all salt will deliver iodine in the required quantities to the population on a continuous and self-sustaining basis.

2.5.2.1 The recommended iodine levels in salt

There is no universal specification for the level of iodisation in salt (PAMM/MI/ICCIDD, 1995, p.30). The level depends on the average daily salt consumption, the severity of iodine deficiency, and expected iodine evaporation losses during transport, storage, and cooking (Peterson, 2000). These factors must be considered to determine the recommended level at production, and the practical amounts used should be decided upon by the appropriate national authorities (PAMM/MI/ICCIDD, 1995, p.30). Very high urinary iodine levels and IIH were observed in countries such as Zimbabwe (Todd *et al.*, 1995) and Zaire (Bourdoux *et al.*, 1996) where salt was iodised at higher levels and distributed in small plastic consumer packs minimising iodine loses. This resulted in the recommendation that iodine concentration in salt at the point of production should be within the range of 20 to 40 ppm of iodine in order to provide 150μg of iodine per person per day (WHO/UNICEF/ICCIDD, 2001). This recommendation is based on typical circumstances, where iodine lost from salt is 20 percent from production site to household and another 20 percent is lost during cooking, and average salt intake is 10 grams per person per day. However, in some instances the quality of iodised salt is poor, or salt is incorrectly packaged, or the salt deteriorates due to excessive long-term exposure to moisture, heat and contaminants. This results in iodine losses from point of production to consumption in excess of 50 percent. Additionally salt consumption is sometimes less than 10 grams per person per day. As a result, actual iodine consumption may fall well below recommended levels.

2.5.2.2 Salt iodisation techniques

Salt can be fortified with KI or KIO_3. However, in tropical humid conditions the evaporation of iodide is substantial (Peterson, 2000). In such settings KIO_3 provides a less soluble, more stable alternative and performs better in salt with impurities. Iodine is added as KIO_3 to salt after refining and drying and before packaging (Mannar & Dunn, 1995, p.27). At its simplest level, a predetermined amount of iodine can be added to an appropriate amount of salt and mixed by hand. This procedure is tedious and does not give even distribution of iodine within the salt (Dunn & Van Der Haar, 1990, p.34). However, it requires no machinery and has been used in remote villages, particularly in Thailand. To be effective it requires proper instruction and supervision, frequent checks on the completeness of mixing and adequate supplies of iodine. Occasionally this method is attractive as a pilot project to demonstrate the feasibility of salt iodisation on a limited scale. Most salt is iodised mechanically. The equipment required consists of relatively simple measuring devices, feeders and mixers (Mannar, 1994, p.95). The salt is moved on a conveyor belt and iodine is introduced at an appropriate point in a predetermined amount (Dunn & Van Der Haar, 1990, p.34) using the following techniques:

(i) Dry mixing: KIO_3 is mixed with an anti-caking agent like calcium carbonate, tricalcium phosphate, or magnesium carbonate in a ratio of 1:9 (Mannar & Dunn, 1995, p.27). One part of this stock mixture is then mixed with 10 parts of salt to form the "premix", which is introduced onto a screw conveyor and mixing takes place as the material moves through. This process is suitable for fine and even-grained salt with a grain size of less than 2mm, otherwise KIO_3, having a finer particle size and being heavier than salt, will settle at the bottom of the container. The success of the dry method depends on the uniformity of the premix and on the consistency of mixing (PAMM/MI/ICCIDD, 1995, p.30).

(ii) Drip-feed addition: This process is commonly used for iodisation of salt crystals. A liquid solution of iodine is dripped at a constant rate from a bottle suspended above the salt that is moving on conveyor belts (Dunn & Van Der Haar, 1990, p.35). The drip feed system is simple and cheap and is often used for iodizing moist crude salt crystals and even refined powder salt (Mannar & Dunn, 1995, p.27). However, when the particle size of the salt is very fine (<2mm), the drip feed system is not suitable because it does not disperse the iodate solution with sufficient uniformity. Its success depends on a steady, uninterrupted flow of salt and a uniform spray solution (PAMM/MI/ICCIDD, 1995, p.30). Evaporation of the iodate solution and obstruction from crusting in the spray nozzle may impair the mixing process.

(iii) Spray mixing: KIO_3 is dissolved in water to make a 4 percent solution (PAMM/MI/ICCIDD, 1995, p.30). The salt on a conveyor belt is then iodised by a fine spray of this iodate solution at a predetermined pressure (Dunn & Van Der Haar, 1990, p.35). The spray system atomizes the iodate solution and disperses it uniformly on the salt crystals, thus ensuring much more uniform mixing.

(iv) Submersion process: A saturated solution of salt and iodine are placed in contact, then the salt is dried, leaving it iodised (Dunn & Van Der Haar, 1990, p.35).

The choice of salt and an ideal iodisation method depends upon the conditions prevailing in a particular location (Mannar & Dunn, 1995, p.38). Less developed countries' programs are frequently hampered by salt of uneven purity, humidity, and unreliable packing material and for them the preferred method will usually be crushing the salt and iodizing it by spray mixing with potassium iodate.

2.5.2.3 Factors affecting the efficacy of iodised salt

Prophylaxis with iodised salt has been mostly used (Maberly, 1994). There is no doubt about the efficacy of iodised salt but it depends on several factors, which include the amount of iodine required, daily salt consumption, iodine concentration in salt, duration of prophylaxis, handling and distribution of salt and goitrogenic factors.

In 1952 an expert group of the World Health Organizations decided that the intake of 100μg to 150μg should be regarded as normal (WHO, 1994). This amount should be adequate for correcting iodine deficiency, for compensating for possible temporarily increased demands of iodine and for preventing the effects of environmental goitrogens. However, the current recommended daily iodine intake for pre-school children to pregnant and lactating woman is 90μg to 200μg (WHO/UNICEF/ICCIDD, 2001). This quantity amounts to a pinhead a month or a teaspoonful for a lifetime (Mannar, 1994, p.89).

The concentration of iodine in salt should be adjusted according to the consumption of table salt (Lamberg, 1993), which varies greatly among populations, from about 2 to 20 grams per day (Dunn, 2000). For example salt consumption in Lesotho is 3 to 10 grams per day (Bureau of Statistics, 2001). However, the usual consumption levels worldwide are within the 5 to 15 grams per day range for both children and adults (WHO, 1994). For people eating 10grams of salt per day, this provides 150μg to 200μg of iodine (Dunn, 2000).

Iodine concentration in salt also varies greatly. For example, in Latin America and Africa, the concentration of 30 to 100 milligrams per kilogram is used and in Europe between 10 and 50 milligrams per kilogram is used (Lamberg, 1993). In South Africa and in Lesotho it is 40 to 60ppm at the site of production (Appendix 3 & 4). The iodine concentration in salt at the point of production should be within the range of 20 to 40mg of iodine per kg of salt (WHO/UNICEF/ICCIDD, 2001). The level of iodisation, however, has to be carefully fixed depending upon the daily consumption of salt by the population, the nature of the salt to be iodised and the loss of iodine during storage and transportation.

The duration of prophylaxis is also important and it has been indicated that, generally, it may take two generations or more before the goitre has disappeared in all age groups (Lindberg *et al.*, 1989). The goitre rate of more than 30 percent in Tanzania was attributed to insufficient time since the introduction of iodised salt (Sundqvist *et al.*, 1998). Similarly, in South Africa one of the reasons for the lack of change in the goitre grades of children in the Langkloof area was insufficient time of exposure to compulsory salt iodisation (Jooste *et al.*, 2000). However, a study in Lesotho indicated that public awareness on the use of iodised salt, which started in 1994, contributed to a decrease of goitre and an increase in urinary iodine concentration (Sebotsa *et al.*, 2003).

Very important is the handling and distribution of iodised salt. In the past, KI has been added to the salt but KIO_3 is more stable and is presently usually recommended (Bürgi *et al.*, 2001). Both KI and KIO_3 are heavier than the sodium chloride, and therefore they gradually settle to the bottom of the container when iodised salt is stored for a long time. Distribution in small packages is therefore advantageous (Lamberg, 1993). Even though KIO_3 is considered stable, studies have confirmed that some iodine is lost when iodised salt is heated or boiled in a solution (Chauhan *et al.*, 1992). The stability of iodine in iodised salt is affected by moisture content of the salt, impurities in the salt, humidity of the atmosphere, light and heat, acidity or alkalinity of the mixture and the form in which iodine is present (Ranganathan & Rao, 1986; Stewart *et al*, 1996). It is difficult to iodise salt containing more moisture, and in salt with 5 percent moisture iodisation is not uniform and the loss of iodine is also higher than with dry salt. When the humidity for salt storage is higher than 76 percent, the salt absorbs the moisture and the iodide or iodate may migrate to the bottom of the bag. When the humidity is lower than 76 percent, the salt will release surface moisture, which may also result in some loss of iodine. Some cations (AL, MG, Ca) have a powerful hygroscopic effect as their salt undergoes slight hydrolysis with the production of hydrogen ions (acidity) and consequent oxidation by atmospheric oxygen. Traces of ions of ferric iron and nitrate have a direct, but very destructive effect on iodide and the ferric and nitrate ions also have catalytic action. Potassium and sulphate ions have a stabilizing effect because they inhibit water absorption by the salt.

Goitrogenic factors in the diet or environment, other than iodine deficiency, can play a role in the etiology of IDD (Delange, 1994; Jooste *et al.*, 1999). The role of these substances had to be considered as endemic goitre has been found in regions with no iodine deficiency. They cause goitre by blocking thyroidal absorption or utilization of iodine (Lutz & Pruzytulsk, 1997, p.138). Many substances have been proposed as potential goitrogens of public health importance but it has been difficult to confirm or reject these hypotheses or to estimate the importance of a goitrogenic effect in any one population (Peterson, 2000).

2.5.2.4 Salt iodisation legislations and enforcement

Critical to any national IDD elimination program requiring salt iodisation are policies, laws and agreements requiring all edible salt to be iodised, effective inspection and enforcement systems, and political advocacy and scientific support from community leaders (Maberly, 1998). First the government must be convinced that iodine deficiency is important and that iodised salt is the corrective measure and then a law should be drafted. While specifics of the law may vary according to characteristics of an individual country, the following will usually be an important component: 'All salt for human and animal consumption in the country must be iodised'. The law should clearly designate one governmental unit as responsible for IDD control. While the law should decree salt iodisation it should not neglect the technical specifications. It should require periodic reporting by the IDD control unit to appropriate government agencies, and should specify enforcement procedures and penalties for non-compliance (Mannar & Dunn, 1995, p.89).

A national law on universal salt iodisation can only be introduced meaningfully when all salt producers have been able to build their capacity to comply with the specifications (Van Der Haar, 1997). Small-scale producers require support in obtaining technology and establishing quality assurance before they can comply. Enforcement of the regulation has proved critical to ensuring the quality of iodised salt, especially in countries such as Bolivia, where there are multiple small producers (Mannar & Dunn, 1995, p.82).

Several countries have developed legislations with varying iodine forms and concentrations. For example, the legislation in Europe allows for voluntary (in fourteen countries) or compulsory (in six countries) iodisation of salt with different iodine forms where the preferred addition is KI at a concentration ranging from 7.5ppm to 50ppm (Bürgi, 1992). Germany uses exclusively KIO_3 at a concentration of 15 to 25ppm and France has opted for sodium iodide (NaI) at a maximal concentration of 15ppm. In India, legislation considers the loss of iodine in transit and mandates the level of iodine in salt to be 30ppm at the manufacturing level and 15ppm at the consumer level (Prakash, 1997, p.13).

In Africa KIO_3 is used at concentrations ranging from 25ppm to 100ppm (WHO, 1998) and the Sub-Saharan African countries with tropical and sub-tropical climates generally use KIO_3 at levels varying between 50ppm to 100ppm (Jooste *et al.*, 1995). The current revised legislation (1995) in South Africa, from where Lesotho gets almost all of its salt, requires iodisation using KIO_3 at a level between 40 to 60ppm (Appendix 3). Similarly legislation in Lesotho (Appendix 4) states that all salt imported or marketed for animal or human consumption must be iodised with KIO_3 and contain between 40 to 60ppm of iodine when entering the country.

2.5.2.5 Constraints hampering salt iodisation programs

While salt iodisation appears to be the main candidate for iodine fortification, there are several potential challenges related to getting the iodine into salt, making iodine stay on salt, ensuring the use of iodised salt and knowing whether these things occur (Peterson, 2000). A review of the salt production and distribution systems in various developing countries shows common patterns and constraints in implementing salt iodisation programs (Mannar & Dunn, 1995, p.47). These similarities provide a basis to assess, plan and implement new programs or strengthen existing programs. Some of the common constraints are as follows:

- Inadequate awareness on the part of policy makers, the salt industry and the general public of the magnitude of the problem and its alleviation through salt iodisation.
- Multiplicity of salt production sites and diversity of types of salt in the market.
- Primitive methods of salt production, leading to poor salt quality, which contributes to moisture absorption and leaching of iodine from the salt.

- Inadequate packaging, aggravating iodine losses during transport, handling and storage.
- Erratic salt distribution patterns with inadequate distribution of iodised salt in areas where transportation is deficient.
- Internal infiltration and external contraband of uniodised salt.
- Iodised salt sold at a higher price than uniodised salt. This price difference compels the poor and needy to choose the more inexpensive salt.
- Non-compliance with iodisation laws; the legal provisions on iodisation often do not include salt for animal consumption.
- Inadequate program coordination, monitoring and attention to the salt industry and to aspects of production, transportation, iodisation, packing, distribution and marketing.

These considerations are a good starting point to develop a program, but it is necessary to bear in mind that each country has its own unique salt production and distribution system as well as constraints. To this extent, programs have to be country-specific and need to incorporate tailor-made solutions. While these issues have to be addressed by the individual governments and local industry, external technical and/or financial inputs are occasionally needed.

2.5.2.6 Controversial issues surrounding compulsory salt iodisation

In order to have effective salt iodisation program, all salt required for human and animal consumption should be iodised (Mannar and Dunn, 1995, p.86). This global thrust to eliminate iodine deficiency in humans through the universal iodisation is based on the fact that if only the salt for human consumption is iodised, the non iodised salt, which is cheaper than iodised salt, is also available in the market for animal consumption. This leads to many people to purchase the cheaper non-iodised salt for their use as well. The availability of the two types of salt also poses a major problem of the law enforcing agencies, for they can not take legal action against those selling non iodised salt since it is being used for animal consumption. Universal salt iodisation has the double benefit of ensuring that both humans and animals receive iodine supplementation and also ensuring that only one variety of salt "iodised salt" exists in the market.

Public acceptance and demand for iodised salt is however considered a necessary prerequisite of a successful universal salt iodisation program. In Germany and other European countries, consumer groups often oppose iodine fortification programs advocating the consumer's right to choose between iodised salt and non-iodised products (Peterson, 2000). The controversy also lies on the issue of salt iodisation in view of the increasing prevalence of hypertension especially in developing countries. Depending on the stage of hypertension some individuals take very limited amount of table salt or non at all. With salt iodisation, hypertensive people are faced with a choice of taking salt and not controlling hypertension or not taking salt but do not get iodine. Advocacy and publicity campaigns should therefore stress the need for iodine in humans and animals and highlight alternative interventions.

2.6 MONITORING AND EVALUATION OF IDD CONTROL PROGRAMS

Monitoring and evaluation are essential for iodisation programs, particularly because there is a need to ensure that the iodine deficiency is quantitatively corrected in order to reduce foetal damage and impaired mental function in children (Hetzel, 2000, p.635). Although usually used together, monitoring and evaluation are different activities (Peterson, 2000).

2.6.1 MONITORING

Monitoring is a continuous, methodical process of data collection, and information gathering throughout the life of a project (Rubin, 1995, p.15). The information collected can be used for regular evaluation of progress so that adjustments can be made while work is going on. Questions for later evaluation can also be identified during monitoring, which focuses on inputs, process, and outputs (WHO, 1989, p.34; Peterson, 2000).

Surveys of representative groups with appropriate indicators and quality control of iodised salt production and consumption are the usual monitoring tools (Hess *et al.*, 2001). A system incorporating these or other appropriate measures should be put in place at the beginning of an iodisation program and should include regular follow up, public reporting of its results and sufficient institutional resources to make it realistic (Dunn, 1996). Even after the IDD control has been achieved, it must be constantly monitored or IDD will reappear. Most importantly, the operational program must include clear safeguards for continued monitoring on a permanent basis (Dunn & Van Der Haar, 1990, p.50).

Loss of iodine from salt at any point in the distribution process may limit success of the program. Therefore, for an effective salt iodisation program, monitoring the levels of iodine at various stages and under various circumstances is one of the most important factors. The success of any of the IDD control programs depends on ensuring the specified iodine content at the consumer level (Pandav & Anand, 1997, p.59). To this end the iodine content should be monitored at the iodisation plant, intermediate points, retail outlets and households. The reason for monitoring the salt iodine levels is that it is one of the progress indicators that measure the condition or progress in implementing an IDD control program. There are essentially two techniques for measuring iodine levels in salt: standard titration and the rapid test (spot test) method (WHO, 1994):

Standard titration method: This method is conducted in a laboratory. Iodine is liberated using sulphuric acid. The free iodine is titrated with sodium thiosulphate, using starch as an indicator. Slightly different techniques are employed, depending on whether the iodine is in the form of iodate or iodide. Due to its greater stability, KIO_3 is recommended in developing countries rather than KI (PAMM/MI/ICCIDD, 1995, p.86).

The titration method is used when great accuracy regarding the iodine level is required. It is used mostly to do operational research to determine the concentration of iodine in salt at the production, distribution and consumer levels. It is a more precise quantitative method than a rapid test method but it is too time-consuming and expensive for purposes of routine national monitoring (WHO/UNICEF/ICCIDD, 1994).

Rapid-test (spot-test): These comprise bottles of starch solution (stabilized), one or more drops of which are placed on the salt. If the salt is alkaline a neutralizing solution is first applied. The intensity of the blue colour, which develops, indicates the salt iodine level, up to 50 or 100ppm, depending on the kit used, with an accuracy of +/-10ppm. Most of the rapid (spot) tests available can detect the presence of iodate only (WHO/UNICEF/ICCIDD, 1994).

The rapid test kits are classified into two main categories: Qualitative tests, which indicate only the presence or absence of iodine over a broad range; for example, a positive test result may simply indicate a salt sample with an iodine content some where between 5-100ppm. Semi-quantitative tests, which give an approximate concentration of the iodine content in salt, for example, 0, <15ppm, >15ppm. These tests are not as accurate as the titration method and are not recommended where more precise quantitative measurement of the content of iodine in salt is needed, for example, for the purpose of law enforcement. They are, however, technically simple, rapid and can be performed outside the laboratory. They provide more valuable information for salt iodine quality and estimated quantity (PAMM/MI/ICCIDD, 1995, p.80). However, it must be noted that they should only be used qualitatively. Pandav *et al.* (2000) has indicated that kits are likely to consistently overestimate the availability of iodised salt. The sensitivity of the rapid test kits was not much affected by the increase in the number of observers but specificity decreased sharply. Therefore, it was suggested that titration method should be used for monitoring the iodine content of salt at all levels from production to consumers to ensure effective salt iodisaiton program.

2.6.2 EVALUATION

Evaluation is a learning and management tool (WHO, 1989, p.34; Rubin, 1995, p.15). It is an assessment of what has taken place in order to improve future work. Measuring analysis and interpreting change help people to determine how far objectives have been achieved, whether the initial assumptions about what would happen were right and to make judgments about the effectiveness, efficiency, impact and sustainability of work. Evaluation uses information gathered during regular monitoring but may need other information as well (Rubin, 1995, p.16). It often uses baseline information collected at the very beginning, against which progress can be measured. It happens to set times in the life of a project. It looks at the relevance, effectiveness and impact of a project with the aim of improving an existing project or influencing future policies programs and projects.

Dunn and Van Der Haar (1990, p.50) state that once the IDD control program is in operation, periodic evaluation of its biological effects is mandatory. A reasonable period for a repeat survey is three years after the introduction of the iodisation program. The evaluation measures used are surveys for clinical manifestation of IDD with emphasis on the program and incidence of neonatal hypothyroidism in the areas receiving iodised salt (Stanbury, 1987, p.39).

2.6.3 INDICATORS USED IN MONITORING AND EVALUATING IDD CONTROL PROGRAMS

The various indicators used in monitoring and evaluating IDD control programs are divided into three main groups, namely, process indicators, impact indicators and sustainability indicators.

2.6.3.1 Process indicators

Process indicators are used to assess the iodine content of salt during the process of delivering iodised salt from the producer to the consumer. This process includes the determination of the salt iodine content at the production site, port of entry, point of packaging and at the wholesale, retail and household levels (WHO/UNICEF/ICCIDD, 2001).

(i) Salt iodine content at the production site

Monitoring salt at the point of production is the most important step in a monitoring plan (PAMM/MI/ICCIDD, 1995, p.8) and is the responsibility of the salt producer and health authority (WHO/UNICEF/ICCIDD, 2001). Medium to large salt producers should be urged to hire a person specifically for internal quality assurance (PAMM/MI/ICCIDD, 1995, p.8). If a batch of salt is not adequately iodised at production level, it should be re-iodised prior to distribution.

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 (WHO/UNICEF/ICCIDD, 2001). All brands which have been approved as properly iodised by external inspection could be allowed to use a "seal" or "logo" documenting that the salt is of good quality and meets the approval of the National Bureau of Standards, or some other regulatory commission, which has the authority and is respected by consumers (PAMM/MI/ICCIDD, 1995, p.8). In collaboration with the producers, the government should develop requirements that spell out the steps to be taken in the event that standards are not met. Guidelines should specify exactly what authority has been granted to the inspectors from the government agency responsible for external quality. Reference should be made to regulations and enforcement procedures that may be called into play to ensure timely corrective measures, and this might include fines, loss of tax incentives, loss of license or other penalties.

(ii) Salt iodine content at port of entry and at the point of packaging

Large producers should certify that the salt, which they produce is iodised within a specified range (WHO/UNICEF/ICCIDD, 2001). Such producers should seek certification by the International Organisation for Standardisation as an added guarantee that their salt is satisfactorily iodised. 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 labeled. Each consignment should be tested with a rapid test kit and suspect salt should be held at the border. In countries where salt is repacked into small packets (500g, 1 or 2kg), samples from each consignment should be collected for titration to ensure that the salt is adequately iodised. This can be done by the body responsible for control of IDD in the country, which is usually coordinated by the Ministry of Health (Dunn & Van der Haar, 1990, p.23).

(iii) Salt iodine content at wholesale and retail levels

The major wholesale distributors should be informed of any legislation or regulations concerning iodised salt and should be provided with rapid test kits to check for the presence and concentration of iodine in salt before it is released for retail sale (PAMM/MI/ICCIDD, 1995, p.8). If there are deficiencies noted at the wholesale level, the factories supplying the wholesalers should be notified to take necessary corrective action. At retail level, salt on sale should be tested with rapid test kits and collected for titration (WHO/UNICEF/ICCIDD, 2001). The monitoring of retail shops may be useful for identifying villages with inadequate supplies of iodised salt (PAMM/MI/ICCIDD, 1995, p.8) and should be periodically undertaken by the Health Inspectors.

(iv) Salt iodine content at household level

When production monitoring reveals that adequately iodised salt is being produced in sufficient quantities, it will be essential to ascertain whether the product is reaching households with enough iodine in it (PAMM/MI/ICCIDD, 1995, p.8). There are essentially two methods and purposes for monitoring household salt:

- "Coverage surveys are used to determine the proportion of households with adequately iodised salt; these surveys are most often performed at the provincial or national levels.
- Ongoing process monitoring is used to identify high-risk communities, where too few households have adequately iodised salt; this monitoring is most often done at the district level to obtain information on individual villages."

Salt monitoring, using test kits, should be carried out by environmental health workers, village or community health workers or others (WHO/UNICEF/ICCIDD, 2001). Salt samples should be collected at the household level during periodic surveys to evaluate coverage.

2.6.3.2 Impact indicators

Once a salt iodisation program has been initiated, the principal impact indicator recommended involves urinary iodine levels (WHO/UNICEF/ICCIDD, 2001). Goitre assessment, by palpation or by ultrasound, should remain a component of surveys to establish the baseline severity of IDD. Neonatal TSH levels may also play a role here if a country already has in place a screening program for neonatal hypothyroidism. These indicators are used to assess baseline IDD status and to monitor and evaluate the impact of salt iodisation on the target population.

(i) Urinary iodine concentration

Most of the body's iodine is excreted in the urine, usually over 90 percent, thus the iodine level in urine reflects the subject's intake (WHO/UNICEF/WHO, 1994; May & May, 1998). Urine is easy to obtain in the field, in contrast to serum specimens. Iodine in urine is stable and can withstand collection and transport under field conditions. Finally, measurement of urinary iodine has usually been technically simpler and cheaper than other biochemical markers, such as serum level of thyroid hormones or TSH, or procedures with radioiodine. Therefore, programs of iodine supplementation rely on urinary iodine concentration as the primary indicator of effectiveness (Sullivan *et al.*, 2000, p.2).

Urinary iodine excretion can vary in individuals from day to day and even within a given day (WHO/UNICEF/ICCIDD, 2001). However, this variation tends to even out among populations. Experience has shown that the iodine concentration in early morning urine specimens (casual urine samples) provides an adequate assessment of a population's iodine status, provided a sufficient number of specimens are collected. Although twenty-four hour urine collection accurately determines the amount of iodine excreted, samples are difficult to obtain and are not necessary. Urinary iodine values from populations are not normally distributed, so it is recommended that the median value be used for interpretation of the data and not the mean (WHO/UNICEF/ICCIDD, 1994; May & May, 1998).

Two general approaches have been used to relate the iodine content of a casual urine sample to the 24-hour value (Dunn & Van Der Haar, 1990, p.15). One approach relates urinary iodine to urinary creatinine, a chemical substance, which the body excretes daily in fairly constant amounts. The other approach is simply to measure the concentration of iodine in the urine as μg iodine per litre of urine. Relating urinary iodine to creatinine is cumbersome, expensive and unnecessary (WHO/UNICEF/ICCIDD, 2001). It has also been found to be misleading, especially for individuals who consume very little protein. Therefore it has been found preferable to express results as concentration of iodine in urine (WHO/UNICEF/ICCIDD, 1994).

Many different urinary iodine methods are available, ranging from technically sophisticated/automated techniques, to simple manual techniques with limited instrumentation requirements (May & May, 1998). For public health purposes, especially in developing countries, there is a need for relatively quick, simple and cost-effective methods for determining urinary iodine concentrations in reasonable numbers of samples (May *et al.*, 1997; Rendl *et al.*, 1998; Gnat *et al.*, 2003). Various techniques have been compared and each has its own advantages and limitations (Pino *et al.*, 1996). The main methods used are still based on the reduction of ceric ammonium sulphate using arsenic-containing acids and timed readings in a calorimeter (May *et al.*, 1997). The Sandell-Kolthoff reaction with some prior step involving ashing or digestion is usually the most practical approach for laboratory determination of urinary iodine (Dunn *et al.*, 1993, p.23; May & May, 1998). The recommended methods are able to detect urinary iodine levels as low as 5μg/l to 20μg/l with a coefficient of variation under 10 percent (WHO, 1994; Pardede *et al.*, 1998). However, laboratory techniques require thorough training and standardisation. A median urinary iodine level of between 100μg/l and 200μg/l in a population, indicates adequate iodine intake and optimal iodine nutrition (WHO/UNICEF/ICCIDD, 2001).

(ii) Thyroid size

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 (WHO/UNICEF/ICCIDD, 2001). These include the severity and duration of iodine deficiency, the type and effectiveness of iodine supplementation, age, sex and possible additional goitrogenic factors. The traditional method for determining thyroid size is inspection and palpation. Ultrasonography provides a more precise and objective method for determination of thyroid size.

(a) Inspection and Palpation

Inspection depends on the visual examination of the thyroid (Demaeyer *et al.*, 1979, p.74). It is recommended that a thyroid gland be classified as positive for goitre only when it is 4 to 5 times larger than the normal size when the neck is in the normal position. When the neck is short or the muscles are well developed, inspection alone may fail to reveal a gland that is already 4 to 5 times enlarged. On the other hand, in persons with very thin necks the lobes of the gland can be readily seen and may give the impression of a visible goitre even though the thyroid is not 4 to 5 times its normal size. Nodular glands that would be unnoticed on visual examination of the neck are frequently discovered by palpation.

During palpation, children and adults are examined while standing with the head and neck first in a vertical position and then in an extended position (Demaeyer *et al.*, 1979, p.76). A thyroid gland whose lateral lobes have a volume greater than the terminal phalanx of the thumb of the person being examined, has been considered goitrous (Demaeyer *et al.*, 1979, p.76; Braverman & Utiger, 2000). This definition of goitre is empirical but has been used in most epidemiological studies of endemic goitre and is still recommended (WHO/UNICEF/ICCIDD, 2001). In 1994, the WHO simplified goitre classification by reducing the number of goitre grades from five to three where all palpable thyroids are regarded as grade 1 goitres (Peterson *et al.*, 2000) as shown in Table 5. The new criterion meant that smaller thyroids than before were regarded as goitres. This change resulted in an extra 25 percent of children being classified as goitrous in a study conducted in Tanzania.

Palpation can be easily applied in the field and requires no specialized equipment. In addition, the examiners need not be medical professionals, but they should be trained and initially supervised by other examiners with experience to ensure uniformity of results (Dunn & Van

Der Haar, 1990, p.14). Its major disadvantage is its unreliability. Specificity and sensitivity of palpation are low especially in grades 0 and 1 due to high intra-observer variation (WHO, 1997; WHO/UNICEF/ICCIDD, 2001). However, it gives valuable information on iodine deficiency where ultrasonography is not available (Vitti *et al.*, 1994).

Table 5. WHO thyroid size classification system of 1960 and 1994 (Peterson, 2000).

Thyroid size	Classification grades	
	WHO 1960	WHO 1994
Not palpable	0	0
Palpable lobes smaller than or equal to terminal phalanges of individual's thumbs	0	1
Palpable lobes larger than terminal phalanges of individual's thumbs	1A	1
Visible with neck extended	1B	1
Visible with head in normal position	2	2
Visible at a distance	3	2

It is recommended that a total goitre rate (grade 1 and 2 goitres) of 5 percent or more in school children aged 6 to 12 years of age be used to signal the presence of a public health problem (WHO/UNICEF/ICCIDD, 2001). The cut-off point of 5 percent 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 goitrogen and autoimmune thyroid diseases.

(b) Thyroid size by ultrasonography

Ultrasonographic estimation of thyroid size has been advocated as being more precise than palpation (WHO, 1997; WHO/UNICEF/ICCIDD, 2001). The preliminary trials in urban control areas of Northern and Central Italy indicated an inter-observer error of about 5 percent (Vitti *et al.*, 1994). The procedure is not invasive and can be used to measure more than 100 subjects a day. Its accuracy diminishes when the gland is quite large, but in such instances precise volume is not important for epidemiological purposes. The use of ultrasonography is strongly recommended to define the goitre endemia in areas of mild iodine deficiency and can be learned within a few days (Gutekunst, 1990; Vitti *et al.*, 1994). The disadvantages of ultrasonography are a requirement for training, expensive equipment and the problem of transport from centre to survey site (Stanbury & Pinchera, 1994, p.78). Portable ultrasound equipment is relatively robust but requires electricity and it can be operated from a car battery with the aid of a transformer (WHO, 1994). Ultrasonography should be undertaken by well-trained operators who are able to perform up to 200 examinations a day (WHO, 1997). Since the interpretation of the results is to some extent subjective, it is important that operators participate in a calibration exercise with an experienced team before using this method. Correct interpretation of ultrasonography also relies on the availability of standardized reference criteria from populations whose iodine status is known to be adequate. Adequate intake refers to an average intake of greater than 150μg per person per day and median urinary iodine greater than 100 μg/l.

Results of ultrasonography from a study population should be compared with normative data (WHO/UNICEF/ICCIDD, 2001). No universal normative values for thyroid volume measured by ultrasonography in school children from iodine sufficient populations are presently available. However, the adjusted WHO and ICCIDD thyroid volume references for iodine replete, boys and girls aged 6 to 12 years by age and body surface area (BSA) as shown on Table 6, are currently used (Zimmermann *et al.*, 2001). This criteria is suggested to be considered provisional until data from further validation studies becomes available. The values are slightly lower than the recommended values indicated by WHO and ICCIDD (WHO, 1997), which were found to be inappropriate for the Indonesian school age children (Djokomoeljanto *et al.*, 2001) and in studies performed in other places, such as Malaysia (Foo *et al.*, 1999). For example, the prevalence of goitre was 8 percent in Sumatra Plus Java and 12.5 percent in Bali, when using the Indonesian normative values for age, but when using the WHO and ICCIDD criteria, the prevalence of goitre in these two provinces was 3 percent and 13.3 percent respectively. The WHO, in collaboration with scientists from several countries, is currently in the process of establishing new reference values for thyroid size of 6 to 12 year old children who are iodine sufficient.

(iii) Thyroid stimulating hormone (TSH)

The pituitary secretes TSH in response to circulating levels of T4 (WHO/UNICEF/ICCIDD, 2001). The serum TSH rises when serum T4 concentrations are low and falls when they are high, thus serum or whole blood TSH levels directly reflect the availability and adequacy of thyroid hormones (Hetzel, 1989, p.29). Elevated serum TSH in the neonate indicates insufficient supply of thyroid hormones to the developing brain and therefore constitutes the only indicator that allows prediction of possible impairment of mental development at a population level brought about by iodine deficiency (Delange, 1998). Elevated serum TSH is therefore of considerable concern because it indicates an inadequate thyroid hormone level during the crucial stage of brain development (WHO, 1994).

Table 6. Median and upper limit of normal thyroid volume (ml) measured by ultrasonography in iodine-replete children aged 6-12 years (Zimmermann *et al.*, 2001).

	Boys		Girls	
	P50	P97	P50	P97
Age (yrs)				
6	2.3	3.8	2.1	3.6
7	2.4	4.0	2.4	4.2
8	2.6	4.3	2.8	4.9
9	2.9	4.8	3.1	5.7
10	3.2	5.5	3.6	6.5
11	3.6	6.4	4.0	7.4
12	4.0	7.4	4.5	8.3
BSA* (m^2)				
0.8	2.1	3.3	2.1	3.4
0.9	2.4	3.8	2.5	4.2
1.0	2.7	4.2	2.9	5.0
1.1	3.1	5.0	3.3	5.9
1.2	3.5	5.7	3.8	6.7
1.3	4.0	6.6	4.4	7.6
1.4	4.5	7.6	4.9	8.4
1.5	5.0	8.6	5.5	9.3

*Body surface area

Blood specimens may be obtained from pregnant women or school-age children (WHO/UNICEF/ICCIDD, 1994). Further study of TSH distributions among these older subjects is needed to improve understanding of the specificity of their relationship to iodine deficiency. This is because elevation of TSH values in individuals is associated with all causes of primary hypothyroidism, including goitrogen ingestion, congenital hypothyroidism and autoimmune thyroiditis. Speculation on one of the factors involved has been done on the basis of the comparison of the iodine stores of the thyroid and of the needs of T4 in adults and neonates (Delange, 1998). It is therefore concluded that TSH levels are an excellent indicator of hypothyroidism in neonates but their specificity in older groups is less certain (WHO/UNICEF/ICCIDD, 1994). Thus reference data for TSH are available only among neonates.

TSH screening in neonates has demonstrated its validity and usefulness and is largely implemented in countries with mild degrees of iodine deficiency (Delange, 1998). It is however still insufficiently available in countries with moderate and especially severe degrees of iodine deficiency, essentially because of a lack of resources and infrastructure. There are, however, some disadvantages to this approach. This method requires sophisticated laboratory backup and an organized program of sample collection (Stanbury & Pinchera, 1994, p.81). In addition, any program that involves blood samples carries the risk of unclean needles and the implied risk of hepatitis or HIV and AIDS. TSH screening is inappropriate for developing countries where health budgets are low (WHO/UNICEF/ICCIDD, 2001). In such countries, mortality among children under five is high due to nutritional deficiencies and infectious diseases, and screening programs for congenital hypothyroidism are not cost effective.

2.6.3.3 Sustainability indicators

These indicators are used to assess whether iodine deficiency has been successfully eliminated and to judge whether achievements can be sustained and maintained for the decades to come (WHO/UNICEF/ICCIDD (2001). They involve a combination of median urinary iodine levels in the target population, availability of adequately iodised salt at the household level and a set of programmatic indicators, which are regarded as evidence of sustainability.

In considering whether the sustainable elimination of iodine deficiency as a public health problem has been achieved, the following WHO/UNICEF/ICCIDD (2001) criteria should be met:

"With regard to salt iodisation

- Local production and/or importation of iodised salt in a quantity that is sufficient to satisfy the potential human demand (about 4-5kg/person/year).
- 95% of salt for human consumptions must be iodised 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 15ppm, in a representative sample of households, must be equal to or greater than 90%.
- Iodine estimation at the point of production or importation, and the wholesale and retail levels, must be determined by titration. At the household level, iodine content of salt 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 100μg/l with less than 20 percent of values below 50μg/l.
- The most recent monitoring data (national or regional) should have been collected at least once in the last two years.

At least eight out of the following ten programmatic indicators are necessary:

- An effective, functional national body (council or committee) responsible to the government for the national program 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 of universal salt iodisation and the elimination of IDD.
- Appointment of a responsible executive officer for the IDD elimination program.
- Legislation or regulations on universal salt iodisation. Ideally regulations should cover both human and agricultural salt, but if the latter is not covered this does not necessarily preclude a country from being certified as IDD free.
- Commitment of 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 program of public education and social mobilization to emphasize the importance of IDD and the consumption of iodised salt.
- Regular data on salt iodine at 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.
- 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."

These criteria provide the major indicators for progress towards the goal of elimination of IDD (Hetzel, 2000, p.636). They require adequate laboratory services so that the monitoring and independent evaluation can be carried out which are essential to ensure sustainability. They include both IDD status indicators (urinary iodine) and a control program process indicator (salt iodisation), since it is important to ensure sustained control of iodine deficiency for an entire population rather than to focus on reaching goals based on measuring the IDD status of a single group (WHO/UNICEF/ICCIDD, 1994).

2.7 SUSTAINABILITY OF IDD CONTROL PROGRAMS

Sustainability is critical in all the programs. It is stated that IDD cannot be eradicated in one great global effort like smallpox and poliomyelitis (WHO/UNICEF/ICCIDD (2001). It is a nutritional deficiency that is primarily the result of a deficiency of iodine in soil and water and therefore it will return at any time after its elimination if control programs fail. There are three major components required to consolidate the elimination of IDD and to sustain it permanently, namely political support, administrative arrangements and an assessment and monitoring system.

2.7.1 POLITICAL SUPPORT

Development of a program begins with high-level advocacy to achieve broad commitment to universal salt iodisation as a major national solution to IDD (Van Der Haar, 1997). As the program is progressing, high level advocacy merits continued attention because, at all stages, decisions about resources and priorities by the leaders of government and salt enterprises can have implications for its continued effectiveness. The governmental agency responsible for nutrition or public health should play a major role in planning and executing the program and it is important to include other relevant ministries and interested groups at an early stage in planning the program (Dunn & Van der Haar, 1990, p.23; Maberly, 1994).

Political support for the elimination of IDD depends on community awareness and understanding of the problem (WHO/UNICEF/ICCIDD, 2001). Without this community awareness, politicians are unlikely either to be aware or willing to act. Information, education and communication (IEC) are the most important (and most neglected) components of an IDD control program (Dunn & Van der Haar, 1990, p.48). Many programs in the past have introduced iodine supplementation measures without educating the target group or other involved parties about the grave consequences of IDD and its non-correction. Such unexplained interventions may meet with indifference or resistance and frequently are not sustained. An aggressive campaign to make all interested parties aware of the consequences and prevalence of IDD and the necessity for correction should be a cornerstone of an IDD control program. Education should occur at all levels, including the following: politicians and decision makers, health workers, workers in the salt trade, citizen groups, and the iodine deficient community. All affected parties must understand the grave consequences of iodine deficiency as well as the means for its correction. Education begins with health authorities in the country and extends to other branches of the government, health providers, industry, marketing and the affected communities (Dunn, 1996).

One of the most crucial challenges in the process of eliminating IDD is raising awareness of how widespread and damaging iodine deficiency is. Although 1.6 billion are at risk of IDD, most people know nothing about it and even many health care workers remain unaware of the full impact IDD has, particularly on mental development (PAMM/MI/ICCIDD, 1995). For example, in India the Non- Governmental Organisations (NGOs) reported poor awareness of the causes, consequences and preventative measures associated with IDD, even among district officials (Pandav *et al.*, 1995, p.1). In India, the proportion of respondents who considered goitre as a disease was only 34.3 percent, while 4.4 percent knew correctly the causes of goitre and only 9.8 percent knew that goitre can be prevented by iodisation of salt (Mohapatra *et al.*, 2001). In both countries the prevalence of IDD was reported to be high. The public needs to know that once salt is iodised, a crucial collective step has been taken that changes the course of a nation's development future (PAMM/MI/ICCIDD, 1995, p.1).

2.7.2 ADMINISTRATIVE ARRANGEMENTS

Each country is different regarding the severity and distribution of its iodine deficiency and the factors that govern the choice of treatment strategy (Dunn & Van Der Haar, 1990, p.45). Therefore, the structure and operation of the control program should be tailored to the actual conditions in a particular country. However, Hetzel (1987, p.12) has conceived a model known as the “Hetzel wheel”, which identifies the key factors that are involved in a national IDD program. The national body responsible for the management of the IDD control program should operate within this process model (WHO/UNICEF/ICCIDD, 2001). The success of the "Hetzel wheel" is dependent on full support from political and legislative authority to carry out the program (Hetzel, 1987, p.13). The social process involves the following six components, clockwise on the wheel (WHO/UNICEF/ICCID, 2001):

- "**Assessment of the situation** requires baseline IDD prevalence surveys, including measurement of urinary iodine levels and analysis of the salt situation.
- **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.
- **Development of a plan of action** includes the establishment of an intersectoral task force on IDD and the formulation of a strategy document for achieving the elimination of IDD.
- **Achieving political will** requires intensive education and lobbying of politicians and other opinion leaders.
- **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 needy population. 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.
- **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 functions of the IDD control unit must be kept intact with an appropriate budget to ensure permanent success of the IDD control program (Dunn & Van Der Haar, 1990, p.48). IDD control costs money and United Nations (UN) agencies, such as UNICEF, United Nations Development Project (UNDP), World Bank, Kiwanis international, which are in a position to provide substantial financial support, should be approached. However, the long-range objective must be to make the IDD control unit an integral item in the national or regional governmental budget and not dependent on outside funds. The additional cost of iodine fortification in the process of salt production should eventually be borne by an educated community to assist sustainability (WHO/UNICEF/ICCIDD, 2001).

The administrative structure should be composed of a dedicated IDD control unit (made up of representatives from various government ministries), workers in the salt trade, citizen groups and the iodine deficient community (Dunn & Van Der Haar, 1990, p.45). This multidisciplinary orientation required for a successful program, however, poses special difficulties in implementation (WHO/UNICEF/ICCIDD, 2001). Particular problems often arise between health professionals and the salt industry, with their different professional orientations. Therefore there is a 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 iodised salt. Such teamwork is required for sustainability to be achieved.

2.7.3 ASSESSMENT AND MONITORING SYSTEM

A situation analysis is the first step in planning a program (Dunn & Van Der Haar, 1990, p.25). The available information should be reviewed concentrating on the extent and severity of iodine deficiency, special factors which influence IDD and its severity, health services available for implementation of IDD control program and the possibilities for prevention of iodine deficiency. Measurement of salt and urinary iodine provides the essential elements for monitoring whether IDD is being successfully eliminated (WHO/UNICEF/ICCIDD, 2001). 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 and production quality assurance charts and databases for recording the results of the regular monitoring procedures, particularly for salt iodine, urinary iodine, thyroid size and, when available, neonatal TSH.

According to Maberly (1998), elimination of iodine deficiency requires the following:

- "Developing simple, qualitative tests to verify inexpensively the level of iodine in salt, rather than only to indicate its presence or absence.
- Establishing the best practices of small-scale salt iodisation and simplifying and standardizing the process with appropriate quality assurance.
- Evaluating the impact of using iodised salt in food processing (such as pickling or cheese-making or in various types of cooking) to address the common perceptions of its negative qualities in such processes or inordinately high iodine losses.
- Evaluating factors that have led to successful implementation of IDD programs so that these can be replicated in areas where progress is lagging or be used to model success in other nutrition or public health programs."

In the planning of a survey, it is important to include other institutions and organizations in the process (Sullivan *et al.*, 2000, p.2). All interested ministries and organizations should be involved to assure they know the survey is to be performed and to allow them to provide input into the survey design and implementation. In many countries non-governmental organizations (NGOs) play and important role in IDD elimination.

2.8 SUMMARY

Iodine deficiency occurs because of its deficiency in the soils and therefore in the food and water originating from that soil. Thus people and animals eating food grown mainly in such soils are all at risk of developing IDD. IDD ranges from endemic goitre to endemic cretinism. Other effects include: mental and physical retardation, impaired school performance and work capacity, increased rates of abortion, stillbirths, congenital anomalies, perinatal, infant and child mortality. Iodine deficiency affects about 740 million people worldwide, about 150 million in Africa and is a clear public health problem in Lesotho.

The available methods for IDD control are mainly through the iodisation of salt and the use of iodised oil. Other available methods include the iodisation of water, bread or sugar. Salt iodisation is the standard medium and long-term strategy for control of IDD because of its availability and high consumption rate. Continuous quality control and verification of the iodine levels in salt is imperative to ensure that the action is sustained and effective. Testing with rapid test kits can be done at retail level in all districts and at all entry points of salt. Where necessary results should be checked by the titration method in a central laboratory. Legislation is required even though salt iodisation may be done voluntary by the salt industry. Ensuring adequate monitoring and evaluation is a necessary condition and one of the best guarantees of successful and sustained implementation of the IDD control program.

CHAPTER 3: METHODOLOGY

3.1 INTRODUCTION

The main objective of this study was to evaluate and monitor the salt iodisation program, which is the only current IDD intervention program in the country. The challenge as indicated by the WHO/UNICEF/ICCIDD (2001) was to apply the IDD indicators using valid and reliable methods while keeping costs to the minimum. The process, impact (outcome) and sustainability indicators were used to monitor and evaluate the salt iodisation process and to assess baseline IDD status. The indicators were also used to assess whether iodine deficiency has been successfully eliminated and to judge whether achievements can be sustained and maintained in the future. The target population in this study was primary school children and women of childbearing age.

In this chapter, the study design, selection of study participants and salt samples, procedures for the collection of information, clinical examination (palpation), biochemical (for urine and salt samples) and statistical analyses will be discussed. The study was designed to include all the districts and ecological zones and the sample size was based on the WHO/UNICEF/ICCIDD (2001) recommendations.

3.2 STUDY DESIGN

The study was designed as a cross-sectional survey, which was household, school, retail and entry point based (Figure 1). The outcome indicators (urinary iodine concentration, thyroid size) and process indicators (salt iodisation) were measured. These indicators were used to estimate the current IDD status, salt iodisation level and the coverage in the household use of adequately iodised salt. Furthermore, the indicators were used to assess the sustainability of the IDD control program.

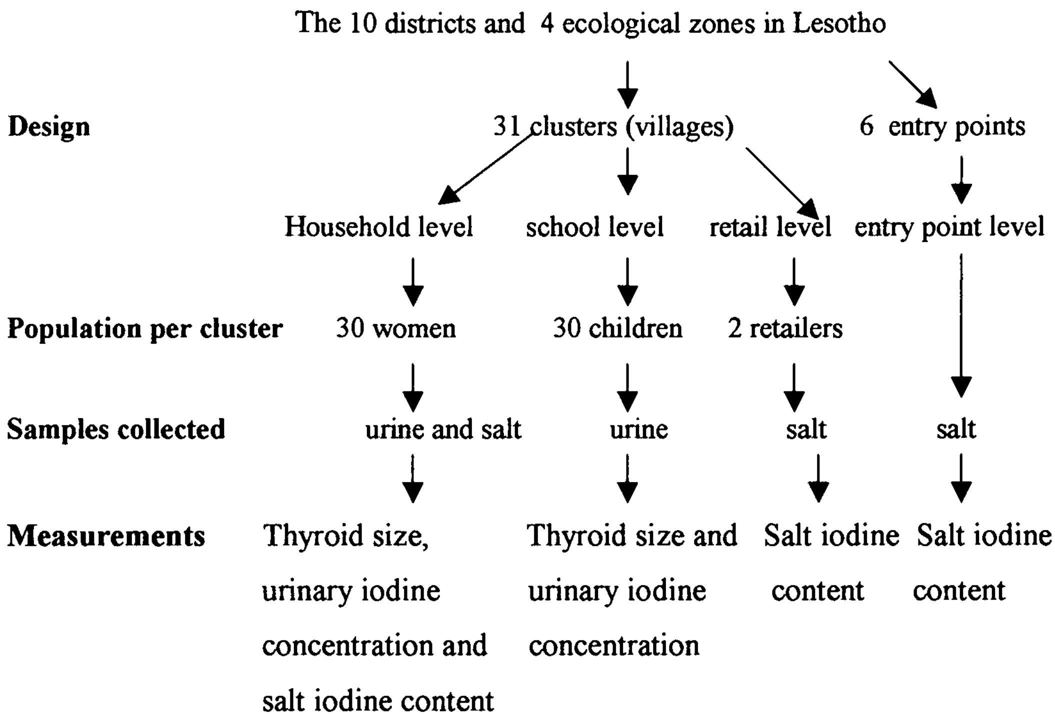

Fig. 1 Schematic outline of the study design and population size

The multistage proportionate to population size (PPS) cluster sampling method was applied based on WHO/UNICEF/ICCIDD (2001) recommendations. Compared to simple random sampling, in cluster sampling there is a design effect, which will widen the 95 percent confidence interval of the overall results. A total of 31 clusters (villages) were proportionally selected from the ecological zones in all ten districts of Lesotho based on the total number of households in each district and ecological zone (Table 7). All the ecological zones in each district were listed and the total number of households in each of the ecological zones in the ten districts was obtained from the 1996 population census data. The cumulative population of households was calculated. The total number of households in the whole country was divided by the number of clusters (31) and the value was used as a sampling interval. and a random number table was used to select the starting point. The clusters were assigned by adding the sampling interval cumulatively (Table 8). To select villages, all the villages in each district and ecological zones were given numbers and labeled pieces of paper put in a box. Pieces of papers were mixed and randomly picked. A list of the names of selected villages is given in Appendix 5. This selection was done with the aid of the Bureau of Statistics in Lesotho.

3.3 REPRESENTATIVENESS OF SAMPLE SELECTION

Lesotho is divided into ten administrative districts and ecologically divided into four distinct zones, namely, Mountains, Foothills, Senqu river valley and Lowlands. The districts include parts of the four ecological zones (Appendix 2). Based on the number of households in each district and ecological zones (Table 7), 31 clusters were proportionally selected from all the districts (Table 8).

Table 7: The total number of households by ecological zones and districts (Bureau of Statistics; Population census, 1996).

	The number of households in each of the ecological zones in each district				Total number of households
DISTRICTS	Ll	Ft	Mt	Srv	
BUTHA-BUTHE	8773	11302	1119	-	21194
LERIBE	49452	8594	4408	-	62454
BEREA	30306	7334	2921	-	40561
MASERU	50727	8812	6869	-	66408
MAFETENG	45216	5112	-	-	50328
MOHALESHOEK	32688	3772	6780	4692	47932
QACHAS'NEK	-	-	13506	3199	16705
MOKHOTLONG	-	-	15045	-	15045
THABA-TSEKA	-	-	11995	2864	14859
QUTHING	-	-	8885	7760	16645
LESOTHO	**215162**	**43936**	**74518**	**18515**	**352131**

Ll = Lowlands
Ft = Foothills
Mt = Mountains
Srv = Senqu river valley

Table 8: Allocation of clusters by ecological zones and districts

	The number of clusters allocated by ecological zones in each district				Total number of clusters
DISTRICT	Ll	Ft	Mtn	Srv	
BUTHA-BUTHE		1	-	-	1
LERIBE	4	1	-	-	5
BEREA	2	1	-	-	3
MASERU	7	1	1	-	9
MAFETENG	4	-	-	-	4
MOHALESHOEK	2	-	1	-	3
QUTHING	-	-	1	1	2
QHACHAS'NEK	-	-	1	-	1
MOKHOTLONG	-	-	1	-	1
THABA-TSEKA	-	-	2	-	2
LESOTHO	**19**	**4**	**7**	**1**	**31**

Ll = Lowlands
Ft = Foothills
Mt = Mountains
Srv = Senqu river valley

3.4 STUDY POPULATION

School going children aged 8 to 12 years and women of child bearing age (15 to 30 years) were included as the target study population. Women and children with severe diarrhoea, fever and severe protein energy malnutrition (PEM) were excluded from the study.

3.4.1 TARGET POPULATION

3.4.1.1 Primary school children

Primary school children aged 8 to12 years were selected as the target population. This group was selected because the proportion of children attending primary school in Lesotho is 89 percent (Ministry of Education 2002), which is above the recommended 50 percent (WHO/UNICEF/ICCIDD, 2001). Children aged 8 to 12 years were selected based on the fact that it is more difficult to perform palpation in smaller children because their small thyroids and stage of puberty might be an additional variable in older children (WHO/UNICEF/ICCIDD, 2001). School-aged children are also a useful target group for IDD surveillance because of their combined high vulnerability, easy access and applicability to a variety of surveillance activities. The children were palpated and asked for urine samples. In each of the selected clusters there is one government primary school, therefore each government school in each cluster was visited.

3.4.1.2 Women of child bearing age

Women of child bearing age (15-30 years) were selected based on WHO/UNICEF/ICCIDD (2001) recommendations. It is stated that screening women of child bearing age provides an opportunity to establish the iodine status of a group that is particularly crucial because of the susceptibility of the developing foetus to iodine deficiency. However, after the age of 30 years, goitre rates are no longer reliable indicators of current iodine status. According to the WHO (1993) preformed nodules or goitres may have occurred in childhood or early adolescence. Furthermore, after long-standing iodine deficiency, serum TSH levels fall or become suppressed due to functional autonomy and, after iodine supplementation, TSH normalizes in only a fraction of the adult population. The women were palpated and asked for urine and salt samples.

3.4.2 EXCLUSION CRITERIA

3.4.2.1 Children and women with severe PEM

Many studies indicate that severe PEM affects thyroid function and the metabolism of thyroid hormones. It also interferes with iodide uptake by the thyroid and with thyroglobulin formation (Beard *et al*, 1990). The suspected children and women were weighed using the calibrated UNICEF digital scale and weights were plotted against ages using the National Centre for Health Statistics (NCHS, 1976) growth charts, and the expected weight for height was determined. The clinical signs of malnutrition were observed by the nurses and then classified using the "Wellcome classification" (Table 9).

Table 9. Wellcome classification (WHO, 1991).

Percentage (%) expected weight for age	**Oedema present**	**Oedema absent**
60-80%	Kwashiorkor	Underweight
Less than 60%	Marasmic-Kwashiorkor	Marasmus

Children and women with severe PEM were therefore excluded from the study using the following cut off point:

Severe PEM: Kwashiorkor, Marasmus or Marasmic- kwashiorkor (WHO, 1991, p.6)

3.2.2.2 Children and women with severe diarrhoea and fever

Variation in urinary volume, through dehydration, increased fluid consumption or dilution has been shown to provide misleading estimates of the actual urinary iodine level (Dunn and Van Der Haar, 1990, p.15; Dunn *et al.*, 1993). As there is variation in urinary volume in severe diarrhoea and fever, suspected women and children were assessed by the nurses and excluded from the study using the following definitions:

Severe diarrhoea: Loose or watery stools more than 3 times a day within 24 hours of the study (WHO, 1992, p.13):

Fever: Abnormal high temperature with sweating within 24 hours of the study (Werner, 1988, p.25).

3.4.3 SAMPLE SELECTION AND SIZE

A total of 1860 women and children were randomly selected and palpated for thyroid size. 1860 urine samples were collected from the women and the children at various time of the day. 1226 salt samples were collected from the randomly selected women and retailers and from the entry points. One officer gave information for the questionnaire on programmatic indicators.

3.4.3.1 Sample selection

In each of the 31 selected clusters, 30 women were randomly selected from the households to be palpated and to give both urine and salt samples. The centre of the village was identified and the direction of the top of the bottle that had been spun was taken. The number of the houses in the line of the direction was counted from the centre to the edge and one house was chosen at random as the starting point. The houses were given numbers, which were picked up from a tin. The household with a picked number was selected. Each household in that direction was visited. When there were no occupants in the selected household, efforts were made to search for them or to return the following day. If the age of the woman was more than 30 or less than 15 the household was not included and the field worker moved to the next household. Where there were two women aged between 15 and 30, one woman was randomly selected. To select one woman randomly in a household, one piece of paper labeled X and one not labeled were put in a tin. The two women were asked to pick a paper without looking in the tin and the woman who chose the piece of paper with an X on it was included in the study. The selected woman was palpated for thyroid size and asked for a sample of salt used in the household. The field worker mixed the salt in its container and three tablespoons were obtained. Where household salt was less than three tablespoons, the available amount was taken. The salt samples were kept in sealed zip plastic bags and labeled stickers were used for identification. The selected woman was also asked to half fill the 40ml capacity bottle with urine. The bottles were tightly closed with plastic screw-caps to prevent leakage and evaporation and were labeled for identification using stickers. Pink coloured stickers were used for pregnant women. The information on the name of the district, ecological zone and woman was collected, including the identification number, age and thyroid size. This information was recorded on the household data sheet (Appendix 6).

In each cluster, there is one government school. Some clusters have both private and government primary schools but only the government schools were included in the study. In each of the 31 selected clusters, 30 children were randomly selected from each school to be palpated and give urine samples. In each school random selection was done with the help of two class teachers, the children aged between 8 and 12 years were separated by gender and given numbered pieces of paper and duplicates put in two tins. The pieces of paper were mixed and 15 picked at random from each tin, and the children with the picked numbers were included in the study. In some cases the number of boys aged between 8 and 12 was less than 15, therefore, the same random sampling was used to select more girls (aged between 8 and 12 years) to arrive at 30 children. The selected children were palpated for thyroid size and asked to half fill the 40ml capacity bottle with urine. The bottles were tightly closed with plastic screw caps to prevent leakage and evaporation and labelled for identification using stickers. The information on the name of the district, ecological zone, school and child was collected, including the identification number, age, gender and thyroid size. This information was recorded on the school data sheet (Appendix 6).

Two retailers in each cluster were also randomly selected and six salt samples purchased. The village chief was asked to name all the retailers in the cluster and the pieces of paper with names on them were put in a tin, mixed and two pieces drawn at random. Three 500g or alternatively 1kg packets of salt samples (preferably different brands available) were purchased by the field workers from the first retailer and three samples from the second retailer, resulting in a total of six salt samples in each cluster. In the case of salt packed in 20kg bags, half a cup of salt was obtained and put into a plastic bag, which was then tightly sealed. Labeled stickers were used to identify the samples. The information regarding the name of the district, ecological zone and retailer, identification number, brand and type of salt was recorded on the retail data sheet (Appendix 6).

There are 13 entry points (or border posts) in the country of which 6 are commercial (goods are allowed to pass) and 7 are non-commercial (goods are not allowed to pass) (Table 10). There are no entry points in the Berea and Thabatseka districts. The people in Quthing district use Qachas'nek, Mafeteng and Maseru entry points while those in Mohaleshoek use Mafeteng and Maseru entry points for their imports. The people in Thabatseka use the Maseru entry point and those in Berea use both the Leribe and Maseru entry points. Salt samples were purchased by the field workers at all the commercial entry points (Table 7 & Appendix 5). At each entry point 10 salt samples were purchased, except for Maseru and Maputsoe where 50 and 20 samples were obtained respectively. This was based on the high rate of goods entering the country from these two entry points. 500g or alternatively 1kg packets of different brands of salt were randomly obtained from each wholesaler or retailer at all the commercial entry points of Lesotho. Two salt samples (preferably different brands) were purchased from the first vehicle at the entry point then two from the next one until enough samples were collected. In the case of salt packed in 20kg bags, the bag was opened and half a cup of salt taken and put in a plastic bag, which was then tightly sealed. Labeled stickers were used for identification. The information on the name of entry point, identification number, brand name and type of salt was recorded on the entry point data sheet (Appendix 6).

Table 10. The entry points of Lesotho

Districts	Border post/entry point	Type	Number of salt samples collected
Maseru	Maseru bridge	Commercial	50
Leribe	Maputsoe	Commercial	20
	Gum tree	Non-commercial	-
Buthabuthe	Caledon	Non-commercial	-
	Monontsa	Commercial	10
Mokhotlong	Sani-top	Commercial	10
Quthing	Tele	Non-commercial	-
	Dilli-Dilli	Non-commercial	-
Qachas'nek	Ramatseliso	Non-commercial	-
	Qachasnek	Commercial	10
Mafeteng	Vanrooyen	Commercial	10
	Sephapho	Non-commercial	-
Mohaleshoek	Makhaleng	Non-commercial	-

3.4.3.2 Sample size

Sample size was based on the WHO/UNICEF/ICCIDD (2001) recommendations, which states that selection of at least 30 samples of both urine and salt per cluster permits the investigation of differences among clusters and gives an indication of localities where iodine deficiency may still be a public health problem. It is recommended that more children or women be palpated for thyroid size. 30 women and 30 children were selected based on the fact that as an evaluation study, the results on palpation would be used to estimate IDD in order to follow trends. These results on palpation would therefore not be used as a reflection of the current iodine intake. The total sample size collected was as follows:

(i) Salt samples

A total of 1226 salt samples were collected in the whole country. 930 (30 households X 31 clusters) were collected at household level, 186 (6 salt samples X 31 clusters) at retail level and 110 at entry points.

(ii) Urine samples

A total of 1860 urine samples were collected from randomly selected women of child bearing age and primary school children. 930 (30 children X 31 clusters) urine samples were obtained from primary school children and 930 (30 women X 31 clusters) from women of childbearing age.

(iii) Thyroid size palpations

1860 women and children were palpated for thyroid size. 930 (30 children X 31 clusters) children aged 8 to 12 years and 930 (30 women X 31 clusters) women aged 15 to 30 were randomly selected and palpated for thyroid size.

(iv) Questionnaire on programmatic indicators

A questionnaire on programmatic indicators (Appendix 7) was administered to one member of the IDD control task force. This member is the chairperson of the IDD control task force and the director of the Food and Nutrition Coordinating Office (FNCO), which coordinates all the nutrition activities in the country. The questionnaire was adapted from the programmatic indicators for sustainable elimination of IDD listed in the WHO/UNICEF/ICCIDD (2001) report.

3.5 MEASUREMENTS AND TECHNIQUES

The variables measured in this study were the iodine content of salt and coverage in the use of adequately iodised salt at household level (process indicators). The urinary iodine concentration, thyroid size and the prevalence of goitre (impact/outcome indicators) and sustainability of the IDD elimination program (sustainability indicator) were also measured. Reliability and validity as defined below were very important in this study and were ensured based on international recommendations.

Reliability is the degree to which a test consistently measures whatever it measures (Gay, 1996, p.32). The more reliable a test is the more confidence it gives that the results obtained from the administration of the test are essentially the same results that would be obtained if the test were re-administered. According to Katzenenellenbogen *et al.* (1999, p.90) variations between measures can be reduced by:

- Standardization and calibration of the instrument. The quality of the instrument or questionnaire must be improved.
- Setting exact ways of measuring (standardization of measurement or interview).
- Intensive training periods for all observers and interviewers.
- Supervision and periodic checks on their work.
- Selection of observers and interviewers along similar criteria with reference to age, sex educational level and other relevant characteristics.
- Repeated measures, which make it possible to assess and adjust for biological variation.

Validity is the degree to which a test measures what it is supposed to measure and consequently permits appropriate interpretation of results (Gay, 1996, p.35). The basic model for validation involves the comparison of a test method against a reference measure of known validity (Margetts & Nelson, 2000, p.16).

3.5.1 THE IODINE CONTENT OF SALT

The iodine content of salt refers to the iodine content of salt at entry points, at retail level and at household level in different districts, ecological zone and at national level, and of different brands and types available in the country, expressed in parts per million (ppm).

3.5.1.1 Cut-off point

A concentration between 40 and 60 ppm is the recommended iodisation level of salt entering the country according to the universal salt iodisation legislation in Lesotho (Appendix 3).

3.5.1.2 Techniques to determine the iodine content of salt

It was important that valid results were obtained in the present study because it will serve as the evaluation and monitoring tool of the country. Therefore, the iodometric titration method was selected for chemical analysis of salt samples at the Medical Research Council (Cape Town). There are a number of methods for testing the iodine content of salt, ranging from qualitative spot tests, which are useful in field settings, to more quantitative methods such as iodometric titrations (PAMM/MI/ICCIDD, 1995, p.86). The iodometric titration method was selected based on the fact that it has been stated that if salt iodine test data is to be used for iodine deficiency program evaluation and monitoring, it is important that the results are reliable, accurate and timely ((PAMM/MI/ICCIDD, 1995, p.86; Sullivan *et al.*, 2000, p.2). Furthermore, PAMM/MI/ICCIDD (1995, p.86) state that the iodometric titrations are performed in Laboratories for validation purposes.

The reaction mechanism of the iodometric titration method includes liberation of free iodine from salt and titration of the free iodine with thiosulfate (WHO/UNICEF/ICCIDD, 2001). Following the method of Mannar and Dunn (1995) and PAMM/MI/ICCIDD (1995), 10g of salt was dissolved in distilled water and made up in 50ml portions (Appendix 8). 1ml of 2N sulphuric acid and 5ml, of 10 percent KI was added. The liberated iodine was titrated with sodium thiosulfate solution using 1ml of 1 percent starch indicator near the end of titration.

The level of thiosulfate in the burette was recorded and converted to parts per million using the conversion table.

3.5.2 COVERAGE OF THE HOUSEHOLD USE OF ADEQUATETLY IODISED SALT

Coverage in the household use of adequately iodised salt refers to the percentage of households using salt that is adequately iodised according to WHO/UNICEF/ICCIDD (2001) criteria.

3.5.2.1 Cut-off point

At household level, salt is adequately iodised when the iodine content of salt is greater than 15ppm according to the WHO/UNICEF/ICCIDD (2001).

3.5.2.2 Techniques to determine the coverage in the household use of adequately iodised salt.

The results obtained from analysing the iodine content of salt (section 3.5.2.2) were used. The percentage of households using adequately iodised salt (salt iodised at greater than 15ppm) was calculated to obtain coverage in household use of adequately iodised salt.

3.5.2.3 Reliability and validity in collection and analysis of salt samples

(a) Reliability

- Data collectors who had been trained collected the samples using the data collection guide (Appendix 9).

- The stability of iodine in salt is influenced by the moisture of salt, ambient temperature, humidity and sunlight exposure (Stewart *et al.*, 1996). Salt samples were therefore collected in the zipped plastic bags and kept away from direct sunlight by trained field workers.

- Samples were collected, labeled correctly and packed after each field visit.

- The nutritionists supervised the work of the other field workers during field visits to ensure that salt samples were collected in accordance with the data collection guide.

- The researcher regularly visited the teams for general supervision of salt sample collection. Each team was visited twice during the fieldwork. During these visits the researcher spent 2 days with the team, and went to the households, retailers and entry point.

- The samples were checked by the supervisor after each field visit and were rechecked by the researcher on arrival from the district. She saw to it that they were correctly, labeled, tightly closed and stored in batches in the boxes ready to be transported to Cape Town for analysis.

- The Coefficient of variation for the analysis of iodine in salt by the iodometric titration method in the laboratory at the Medical Research Council was 2.7 at a concentration of 50ppm. With standard solutions of KIO_3 at concentrations of 25ppm and 70ppm, the coefficient of variation was 1.0. The operation sensitivity, that is, the lowest concentration detectable in standard solutions, was 1ppm and the coefficient of variation was 6.5 at this level.

(b) Validity

- In the absence of external gold standards such as neutron activation analysis, the iodometric titration method for evaluation and monitoring IDD status is recommended internationally (WHO/UNICEF/ICCIDD, 2001).

3.5.3 URINARY IODINE CONCENTRATION

Urinary iodine concentration refers to the iodine content of the urine of primary school children (8-12 years) and women of childbearing age (15-30 years) expressed in micrograms per litre (μg/l).

3.5.3.1 Cut-off point

The WHO/UNICEF/ICCIDD (2001) epidemiological criteria for assessing severity of IDD based on median urinary iodine levels were used (Table 11).

Table 11. The epidemiological criteria for assessing iodine nutrition based on median urinary iodine concentrations in school-aged children (WHO/UNICE/ICCIDD (2001).

Median value (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 IIH within 5-10 years following introduction of iodised salt to susceptible groups
>300	Excessive	Risk of adverse health consequences (IIH, autoimmune thyroid diseases)

3.5.3.2 Techniques in determining the urinary iodine concentration

The method using Ammonium persulfate was used at the Medical Research Council (Cape Town) for measurement of urinary iodine concentration. The procedures followed were as described by Sullivan *et al.* (2000) (Appendix 10). The principle of the method is that urine is digested with Ammonium persulfate to cerous form and is detected by the rate of colour disappearance, which is the Sandell-Kolthoff reaction (WHO/UNICEF/ICCIDD, 2001). This method was selected in the present study based on the fact that it is an internationally recommended method, which offers a number of advantages, especially for laboratories in developing countries where resource limitations often exist (Sullivan *et al.*, 2000, p.36). The advantages include the following:

- Safe digestion process (Ammonium persulfate is the digestion medium).
- Simple manual method.
- Avoids expensive or sophisticated instrumentation.
- Reagents can be made in the laboratory, so the method is not reliant on diagnostic suppliers.
- Good performance characteristics.
- Cost effective and sustainable.

3.5.3.3 Reliability and validity

(a) Reliability

- Data collectors who had been trained collected the samples using the data collection guide (Appendix 9).

- 40ml capacity bottles with screw tops were used to prevent leakage and approximately 20ml urine samples were collected based on May and May's 1998 recommendations for adequate samples.

- Iodine in urine is very stable (May & May 1998). Urine samples were however, kept cool until analysed to prevent smell and mould growth by being transported in cooler bags and stored in refrigerators.

- The nutritionists supervised the work of the other field workers during field visits to ensure that urine samples were collected in accordance with the data collection guide.

- The researcher also regularly visited the teams to supervise urine sample collection. The researcher regularly visited the teams for general supervision. Each team was visited twice during the fieldwork. During this visits the researcher spent 2 days with the team, and went to the households and schools.

- The bottles containing urine samples were labeled with a permanent marker.

- The supervisor checked all samples after each field visit and these were rechecked by the researcher on arrival from the district to ensure that they were correctly labeled, tightly closed and were then stored in batches in the refrigerator at the central laboratory ready to be transported to Cape Town for analysis.

- The coefficient of variation of urinary iodine analysis for the method using Ammonium persulfate in the laboratory at the Medical Research Council is 7.7 percent at a concentration of 10µg/l.

(b) Validity

- The chemical analysis in this study using ammonium persulfate is the recommended method of urinary iodine analysis (WHO/UNICEF/ICCIDD, 2001).

- The Medical Research Council laboratory has successfully participated for a number of years in international quality control exercises for the determination of urinary iodine concentration. The urinary iodine analysis done in this laboratory compared very well with the mass spectrophotometric methodology used in the international quality control program run by the Centres for Disease Control and Prevention (Atlanta, USA).

3.5.4 THYROID SIZE

Thyroid size refers to the thyroid size of children (8-12 years) and women of child bearing age (15-30 years) determined by palpation, where the thyroid gland is considered goitrous when each lateral lobe has a volume greater than the terminal phalanx of the thumbs of the subject being examined.

3.5.4.1 Cut-off point

The WHO/UNICEF/ICCIDD (2001) criteria for classifying the size of the thyroid were used (Table 12).

Table 12. Simplified classification of goitre by palpation (WHO/UNICEF/ICCIDD (2001).

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.

3.5.4.2 Techniques in the determination of thyroid size

Inspection and palpation, which are the traditional methods used to determine thyroid volume were used to assess the thyroid size of the children and women. In areas of moderate to severe iodine deficiency, inter-observer variations in performing this assessment are usually low. However in areas of mild endemicity, and generally when goitres are very small, inter-observer variations can be as high as 40 percent (WHO/UNICEF/ICCIDD, 1994). For this reason the use of ultrasonography has been recommended. Ultrasonography is a safe, noninvasive technique that provides a more precise and objective method of determining thyroid volume than inspection and palpation. However, such examinations are cumbersome and costly to carry out in remote parts of low-income countries (Peterson, 2000). Ultrasonography has never been used and is not available in Lesotho. Therefore, in the absence of ultrasonography, inspection and palpation were used because this gives valuable information on iodine deficiency where ultrasonography is not available (Vitti *et al.*, 1994).

The thyroid size of the randomly selected primary school children and women of childbearing age was determined using the standardised procedure for palpation (Appendix 11). A woman or child to be examined was asked to stand in front of the nutritionist who looked carefully at the neck for signs of visible thyroid enlargement. The nutritionist then stood behind the subject whose neck was in the neutral position and the thyroid was palpated by gently sliding the fingers along the side of the trachea (wind pipe) between the cricoid cartilage and the top of the sternum. The subject was asked to swallow when being examined since the thyroid moves up when swallowing. The size of each lobe of the thyroid was compared to the size of the tip (terminal phalanx) of the thumb of the subject being examined and graded according to WHO/UNICEF/ICCIDD (2001) criteria. Two nutritionists performed inspection and palpation independently. Each nutritionist wrote a goitre grade on a piece of paper and gave it to the subject without looking at the piece of paper written by another nutritionist. The subject took the two pieces of paper to a field worker who recorded the goitre grades on the information sheet of each woman and child. During statistical analysis where the goitre grades of the two nutritionists did not coincide, the highest grade was used.

3.5.4.3 Reliability and validity

(a) Reliability

- Only trained nutritionists who had performed palpation during the previous studies palpated during the study.
- The nutritionists who palpated were retrained thoroughly by a trained nutritionist (Director of FNCO) and were checked for consistency and accuracy during training and pilot study.

- The researcher regularly visited the teams for supervision during palpation by the nutritionists. Each team was visited twice during the fieldwork. During these visits the researcher spent 2 days with the team and went to the households and schools.
- No nutritionist performed more than 60 palpations a day.
- Field workers were trained by the researcher on how to fill in information on the stickers and on the information sheets.
- Based on WHO/UNICEF/ICCIDD (2001) recommendations, women aged between 15 to 30 years and children aged between 8 to 12 years were palpated and the thyroid size graded.
- Two observers performed palpations on each subject independently and both were recorded to assess performance during statistical analysis.

(c) Validity

- As stated earlier, ultrasonography, which is a more objective measure of thyroid size in children, was not available during the study. In the absence of ultrasonography, the standard procedure for inspection and palpation adapted from WHO/UNICEF/ICCIDD (2001) was used.
- During training each observer repeated palpation and the grades obtained were compared with other observers' and the trainers' grades until they coincided. The grades obtained by the trainer were used as the accepted standard (gold standard).

3.5.5 THE PREVALENCE OF GOITRE

The prevalence of goitre refers to the percentage of children (8-12 years) and women of childbearing age (15-30 years) with goitre. Goitre is defined as thyroid size graded 1 or 2 according to WHO/UNICEF/ICCIDD (2001) criteria. The prevalence of goitre was used to assess the severity of IDD.

3.5.5.1 Cut-off point

The WHO/UNICEF/ICCIDD (2001) epidemiological criteria for establishing IDD severity based on goitre prevalence in school-aged children were used (Table 13).

Table 13. The epidemiological criteria for assessing the severity of IDD based on the prevalence of goitre in school-aged children (WHO/UNICEF/ICCIDD, 2001).

	Degrees of IDD, expressed as a percentage of the total of number of children surveyed			
	None	Mild	Moderate	Severe
Prevalence of goitre (TGR)	0-4.9%	5.0-19.9%	20.0-29.9%	>/= 30.0%

3.5.5.2 Techniques to determine the prevalence of goitre

The prevalence of goitre, which is the total number of primary school children and women with goitre over the total number of primary school children and women included in the study, was calculated using the goitre grades obtained during palpation (section 3.5.4.2).

3.5.6 SUSTAINABILITY

Sustainability refers to whether iodine deficiency has been successfully eliminated and whether achievements can be sustained and maintained for the decades to come.

3.5.6.1 Cut-off point

The program was regarded as sustainable when all of the WHO/UNICEF/ICCIDD 2001 sustainability goals had been met (Table 14).

3.5.6.2 Techniques to determine sustainability of the iodisation program

A questionnaire (Appendix 7), bearing the information on programmatic indicators of sustainability adapted from WHO/UNICEF/ICCIDD (2001), was administered to the director at FNCO who is also the chairperson of the IDD control task force and the Micronutrient task force. The researcher also reviewed the available reports to confirm the information obtained from the director of FNCO.

Using the information on salt iodisation (section 3.5.1 & 3.5.2) and urinary iodine concentration results (section 3.5.3) in the present study and the information obtained from the questionnaire (Appendix 7), the sustainability of IDD elimination was determined based on the WHO/UNICEF/ICCIDD (2001) sustainability goals.

3.7.6.3 Reliability and validity

(a) Reliability

The questionnaire was administered to one officer who has all the information on IDD, as she is the chairperson of the IDD control task force, the director of FNCO and the chairperson of the Micronutrient task force. This officer was also asked to show documentation on the responses for confirmation of the given information.

(b) Validity

All information included in the questionnaire was adapted from the WHO/UNICEF/ICCIDD (2001) programmatic indicators of sustainability.

Table 14. Summary of criteria for monitoring progress towards sustainable elimination of IDD as a public health problem (WHO/UNICEF/ICCIDD, 2001).

INDICATORS	GOALS
Salt iodisation Proportion of households using adequately iodised salt	>90%
Urinary iodine Proportion below 100μg/l Proportion below 50μg/l	<50% <20%
Programmatic indicators Attainment of the following indicators: An effective, functional national body responsible to the government for the national program for the elimination of IDD. Evidence of political commitment of universal salt iodisation and the elimination of IDD. Appointment of a responsible executive officer for the IDD elimination Program. Legislation or regulations on universal salt iodisation 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 program of public education and social mobilization on the importance of IDD and the consumption of iodised salt Regular data on salt iodine at the factory, retail and household level 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 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.	At least 8 of 10

3.6 FIELD WORKERS

Field workers were the nutritionists, nurses and other trained people who had been involved in data collection during the previous studies. These field workers were trained and standardized against one another and the trainers (the director of FNCO and the researcher).

3.6.1 SELECTION AND TRAINING

24 field workers were recruited to form 4 teams of 6 people. Detailed letters were sent to the heads of FNCO, Ministry of Agriculture and Ministry of Health asking them to appoint nutritionists and nurses. A total of 8 nutritionists and 8 nurses were included for data collection. Unemployed people who have obtained Cambridge Overseas School Certificate (C.O.S.C, which is equivalent to grade 12 in South Africa) and have previously been involved in data collection were also recruited. A list of these people is available at FNCO and they were sent forms for application. A total of 8 of these unemployed people were selected according to their data collection experience. Each team was therefore composed of two nutritionists, two nurses and two unemployed people.

All the field workers were trained intensively for two days by the trained and experienced nutritionist (Director of FNCO) on palpation using the standardized procedure (Appendix 11). The researcher also taught them on how to fill in the data sheets and how to collect urine and salt samples using the data collection guide (Appendix 9).

3.6.2 TASKS OF FIELD WORKERS AND RESEARCHER

3.6.2.1 Tasks of field workers

In each team different tasks were given to field workers by the researcher as follows:

- Nutritionists palpated the selected women and children and supervised the other data collectors during field work

- Nurses assessed the children and women for exclusion and collected urine and salt samples.

- Unemployed people recorded information on the data sheets and stickers (Appendix 6).

3.6.2.2 Tasks of the researcher

The task of the researcher was to plan and organize for the study, train and supervise the field workers and compile a report. A signed statement of the compiled tasks of the researcher is given in Appendix 9.

A brief description of the task of the researcher is as follows:

(i) Planning and organising

The planning and organising for the study was done within one month (2nd to 27th February 2002)

- Using the population census data obtained from Bureau of Statistics, the researcher selected the number of clusters in each district and ecological zones. The researcher explained the selection methodology to the Statistian who selected the villages.
- Plan the evaluation and monitoring of the salt iodisation program
- Collect and review relevant information.
- Write the proposal for funding to UNICEF and send it through FNCO.
- Organize a meeting with the IDD control and micronutrient task forces for briefing on the activities of the study and support in supervision.
- Write letters to Ministry of Education, Local government and Customs for approval of the study.
- Collect all materials to be used in the study and arrange with laboratories in all the districts for storage of urine samples until collected for forwarding to central laboratory.
- Develop data sheets, stickers for labelling (Appendix 6), a questionnaire (Appendix 7), data collection guidelines and supervisors' checklist (Appendix 9)
- Recruit the 24 field workers.
- Arrange for a pilot study and compile information and recommendations obtained.

- Develop and send consent forms to selected schools.
- Arrange for transport of urine and salt samples from Maseru to Cape Town for chemical analysis.
- Develop a questionnaire on programmatic indicators and ask the Director of FNCO to complete the questionnaire. Interview format used.

(ii) Training and supervising

- Train field workers using the data collection guide (Appendix 9) on random sampling, urine and salt sample collection, labelling and recording of information on the data sheets and stickers.
- Teach supervisors (nutritionists) how to supervise during fieldwork, follow the data collection guidelines and fill in the supervisors' checklist.
- Supervise each team alternatively to ensure that both fieldworkers and supervisors are doing the work efficiently. During this supervisory visits, the researcher also collected data
- Check all the samples and data sheets during field visits (alternative supervisory visits) and, on arrival from the field, take to the central point for completion.
- Pack urine and salt samples in batches for transport to Cape Town. Spend a week in Cape Town involved in chemical analysis of the samples

3.7 PILOT STUDY

After training a pilot study was conducted for a day in 1 village and 1 school not included in the selected sample for the study. This pilot study was conducted to standardize thyroid size measurement, data collection and recording procedures. It was also undertaken to expose the field workers to problems that may be encountered in the field and to show them how to solve them. The trainers evaluated and standardized the measurements and data collection method during the pilot study.

All 4 teams were involved in data collection. Each team was given 30 children and 30 women. Field workers worked together in a team and according to their different tasks. The field workers were evaluated for efficient work during data collection. The amount of time that would be taken to complete the survey in each cluster was also estimated.

A total of 120 children and 120 women were included in the pilot study. There were no problems encountered in both the village and school and nothing was changed regarding the study procedure after the pilot study. It was estimated that one team would need take one day in one cluster, to collect data at household, retail and school level.

3.8 ETHICAL CONSIDERATIONS

The Ethics Committee of the Faculty of Health Sciences at the University of Free State gave its approval for conducting this study (Ethics document number ETOVS NR 32/02). A written approval was also obtained from the Ministry of Education, Ministry of Local government and Customs in Lesotho and from the chiefs and the headmasters of the selected villages and schools respectively. An informed consent form written in Sesotho and English (Appendix 12) had to be signed by the selected women and parents or guardians of children participating (first signature) and the children who participated in the study (second signature). Before signing the participants were assured of anonymity and confidentiality. Those who were not able to write signed with a cross.

3.9 STUDY PROCEDURES

The researcher followed the procedures for the field workers followed logistics while the field procedures.

3.9.1 LOGISTICS

Before data collection could start, the researcher followed the following procedures:

- Letters were sent to the Ministry of Education, Local government, and Customs for approval (Appendix 13). After the approval was obtained, official letters were sent to the school principals and chiefs of the selected schools and villages respectively. Consent forms were sent together with the letters to the schools for the children aged 8 to 12 years to take to their parents for signatures. Letters were also sent to customs officers at all the commercial entry points in the country. These letters indicated the purpose of the study, dates of the visit and what was expected.

- Messages were also broadcast through local radios indicating the villages, schools and entry points to be visited and the purpose of the study.
- Clusters and entry points were allocated for each team. Three teams were allocated 8 clusters each and 5 entry points and 1 team was allocated 7 clusters and 1 entry point.

3.9.2 FIELD PROCEDURES

Each team (6 people) went to the village and then to the school in each cluster and the procedures followed during data collection were as follows:

- The field workers stayed at a chosen centre and travelled daily to the villages (clusters) and entry points.
- In a village, households and retailers were randomly selected after the team had been introduced to the chief. The purpose of the study was explained to each selected woman. She was asked to sign the consent form. Information on district, ecological zone, name, age and whether pregnant or not was collected and noted on the stickers (for urine and for salt samples) and on the data sheet. The woman was palpated using the standardized procedure for palpation (two observers palpated independently and recorded the thyroid size). Salt and urine samples were collected according data collection guide.
- After collection of data at household level the team went to the government school in the same village.
- At the school, the team was introduced to the principal, and, with the help of class teachers, children were randomly selected. The purpose and procedure of the study were explained to the teachers and the selected children. Children were asked to sign the consent forms, which had previously been signed by their parents. The children were palpated according to standardized procedure and urine samples collected as per

data collection guide. The information on the district, ecological zone, age and gender was collected for each child and noted on the stickers and data sheet.

- The supervisor checked the data sheets, stickers and collected samples after each field visit and recorded this in the supervisors' checklist.
- After collection of data in the selected villages and schools in each district the team visited the entry points and salt samples were collected according to the data collection guide.
- The collected salt and urine samples were stored in the refrigerators at the districts' laboratories. When data collection was finished in the districts the samples were transported to the central laboratory in Maseru district where they were rechecked and relabelled with a permanent marker by the researcher. The researcher stored the samples in batches in the boxes (salt samples) and in the refrigerator (urine samples) for a maximum of two weeks and transported them to Cape Town for analysis.

3.10 STATISTICAL ANALYSIS

Statistical analysis was performed by the Department of Biostatistics at the University of the Free State using the SAS software (SAS Institute Inc., 1989). The results were summarized by frequencies and percentages (categorical variables) and by means and standard deviations and ranges or medians in the case of skew distributions (numerical variables). Subgroup comparisons were done using the Kruskall-Wallis test for numerical variables and chi-squared tests for categorical variables. Agreement between observers was analysed using Kappa statistics with 95 percent confidence intervals (CI). 95 percent confidence intervals taking the design effect of the cluster design into account were calculated for the main categorical outcomes. The statistical significance of associations between variables was assessed using Mantel-Haenszel chi-squared tests, adjusting for district.

Associations were assessed between the following variables:

- Salt iodine content and thyroid size.
- Salt iodine content and urinary iodine concentration.

3.11 PROBLEMS ECOUNTERED DURING THE STUDY

The following problems were encountered during the study. These problems were, however, solved and except for the Maseru Border post all samples were collected as required.

- Some selected women and children were not able to give urine therefore the data collectors had to return later for those urine samples.
- At some entry points, salt did not pass through on the sampling day or less than the required samples were obtained, therefore data collectors had to return the next day. Because of this problem, several days were spent at Maseru border gate and, to stay within time schedule, 47 instead of 50 salt samples were collected.
- Some salt samples collected at household level were less than 10grams. However, the available amounts were standardized and chemical analysis continued.
- During statistical analysis some (3 out of 930) data sheets for children were discarded due to ages, which did not fall within the recommended range of the study sample. 18 (out of 930) data sheets for children and 6 (out of 930) for women were also discarded due to duplication of identification numbers on urine samples. However, 99.7 percent of data sheets for children were included for palpation, while 98.1 percent of data sheets for children and 99.4 percent for women were included for urinary iodine analysis. This gives a more than 95 percent response rate, which is sufficient for interpretation of the results.

3.12 SUMMARY

The study was undertaken in all ten districts and four ecological zones. 31 clusters were selected based on the number of households in each district and ecological zone. In each cluster 30 primary school children aged 8 to 12 years, 30 women of childbearing age and 2 retailers were randomly selected. All commercial entry points were also visited. Urine samples were collected from children and women and salt samples from women, retailers and entry points. The women and children were also palpated for thyroid size and a questionnaire was administered to a member of the IDD control program to elicit information on the sustainability of the program.

Accurate methods and techniques had to be selected to analyse the samples. Methods were selected based on WHO/UNICEF/ICCIDD (2001) criteria and were standardized to ensure validity and reliability. The laboratory used for chemical analysis of the results has successfully participated in international quality control exercises. Urine and salt samples were analysed for iodine content and the thyroid palpated to estimate the prevalence of IDD. The criteria for selection of field workers were followed, and they were trained intensively using a field guide and the standardized procedure for palpation. A pilot study was undertaken to identify possible shortcomings in the chosen methods and changes were brought about where necessary. During the pilot study thyroid size measurements results of the field workers were standardized against the results obtained by the trainer. The supervisors were selected based on field work experience in IDD surveys, supervised during field work, recorded and gave daily reports to the researcher. Throughout the procedure of the study the researcher was involved in logistics, training and overall supervision to ensure that techniques were followed as recommended.

Except for the Maseru border post where 47 instead of 50 salt samples were collected, all data was successfully obtained as planned. The results were chemically and statistically analysed. During statistical analysis some information sheets indicated ages above 12 years for children, therefore they were not included for analysis. Similarly some urine sample numbers were duplicated, therefore these samples were not included for analysis. Few samples were, however, discarded resulting in a sufficient sample (>95%) for analysis and interpretation of results. The results are reported in the following chapter.

CHAPTER 4: RESULTS

4.1 INTRODUCTION

The fieldwork started from 4th February and ended on the 24th February 2002. The results obtained from salt and urine analysis and assessment of goitre enlargement are reported in this chapter. Using medians and percentages, salt iodine content is reported by different brands available in the country, by districts and ecological zones and at household level. The iodine content of the two types of salt (coarse and fine) used in the country is also shown in this chapter. Coarse salt packed in 20kg bags or more is meant for animal consumption while coarse salt packed in 500g or 1kg bags, is meant for human consumption. Fine salt is packed in 1kg or 500g bags and is meant for human consumption. The results on urinary iodine concentration for both the children and women are expressed in median and reported by districts and ecological zones. The prevalence of goitre that was determined by assessment of thyroid size of both the children and women is reported as the prevalence by age and gender and by districts and ecological zones. The associations between the salt iodine content and urinary iodine concentration and the prevalence of goitre are also indicated. Finally, the results on sustainability of the iodisation program obtained from the questionnaire (indicating the programmatic indicators of sustainability), salt iodine content and urinary iodine concentration are reported.

4.2 DESCRIPTION OF STUDY GROUP

A total of 930 and 186 salt samples were successfully collected at household and retail level respectively and analysed (Table 15). At entry point level 107 salt samples were collected and analysed instead of the expected 110 samples due to time constraints. The expected sample size at both school and household level was 1 860 (930 children and 930 women). No children and women met the exclusion criteria for the study. During the fieldwork, 930 children were palpated and gave urine samples and 930 women were palpated and gave urine and salt samples. However, 3 information sheets for the children were not included for statistical analysis because the ages did not fall in the range of 8 to 12 years. There was also a duplication of the recorded urine sample numbers and these duplicated samples were not included for statistical analysis. Therefore a total of 927 children (486 females and 441 males) and 930 women (64 pregnant) who were palpated, and 912 children (477 females and 435 males) and 924 women who gave urine samples, were included in the statistical analysis of the results. Only 3 data sheets for children were not included for palpation while 18 data sheets for children and 6 data sheets for women were not included for urinary iodine analysis. In total thyroid size of 1857 women and children were palpated, 1836 urine samples were analysed for iodine concentration and 1223 salt samples were analysed for iodine content. These resulted in a more than 98 percent response rate for children and women, which is sufficient for the determination of IDD status in a population.

Table 15. The National and district level sample size of the study

DISTRICTS	NUMBER PALPATED (n		NUMBER OF URINE SAMPLES (n		NUMBER OF SALT SAMPLES (n)		
	C	W	C	W	HOUSEHOLD	RETAIL	ENTRY POIN'
MOKHOTLONG	30	30	30	30	30	6	10
BUTHABUTHE	30	30	28	30	31	6	10
LERIBE	150	150	148	150	150	30	*
BEREA	90	90	88	90	90	18	20
MASERU	268	270	266	266	270	54	47
MAFETENG	119	120	117	118	119	24	10
MOHALESHOEK	90	90	90	90	90	18	*
QUTHING	60	60	58	60	60	12	*
QACHAS'NEK	30	30	30	30	30	6	10
THABATSEKA	60	60	57	60	60	12	*
TOTAL	**927**	**930**	**912**	**924**	**930**	**186**	**107**

C= Children

W=Women

*No commercial entry point

4.3 SALT IODISATION

The results on the iodine content of salt at entry point level, retail level and household level are presented in this section. These results are also presented by ecological zones and districts as well as by different brands available in the country. The results are reported in medians and not in means because of skew distributions and small sample sizes obtained from some entry points and some districts. The medians are therefore more stable estimates than are the means. Coarse salt, which is salt meant for animal consumption (usually packed in bags of 20kg or more) and fine salt meant for human consumption (usually packed in 500g or 1kg bags) are the only types of salt available in the country. The results on the iodine content of these two different types of salt are also presented. At retail level the brand names of some salt packed in 20kg bags (coarse salt) were not identified on the bags and are referred to as "Unknown coarse salt" in this section. Most of the salt samples at household level were kept in different containers and some households did not know the brand names while some were not sure of the brand names of the salt. Therefore the iodine content at household level is not shown according to brand of salt.

4.3.1 ENTRY POINT LEVEL

The median iodine concentration of salt at entry point level was 36.2 ppm, which ranged from 30.5 ppm (Monontsa) to 55.4 ppm (Sani-top) in the different entry points (Table 16) ($p=0.024$). There was a large variation in the iodine concentration of salt at (0-149ppm in Maseru) and between (12.0-50.6ppm in Monontsa and 0-149ppm in Maseru) the border gates.

According to Table 17, the median iodine content of different brands at entry point level ranged from 12.1ppm (Econo) to 44.4ppm (Orange) ($p=0.050$). A large variation was also observed in the iodine content of salt within the brands (where the largest variation was 4.9ppm to 143.3ppm for Orange salt) and between the brands (1.9-35.9ppm for Dwaga and 4.9-143.3ppm for Orange). Except for some samples of coarse salt, all the salt samples were labeled "iodised salt".

Table 16. The iodine concentration of salt at entry point level

Entry points	Sample size	Iodine concentration (ppm)				
		Mean	Range	Median	25th percentile	75th percentile
QACHA'SNEK	10	28.5	3.9-45.4	34.9	12.9	37.3
SANI-TOP (MOKHOTLONG)	10	57.6	22.2-119.8	55.4	41.5	69.9
MONONTSA (BUTHA-BUTHE)	10	30.1	12.0-50.6	30.5	15.0	44.5
VANROYEN (MAFETENG)	10	41.6	16.1-88.2	38.3	32.6	45.3
MAPUTSOE (BEREA)	20	44.9	8.8-143.3	36.2	31.2	52.1
MASERU	47	31.1	0-149.0	34.9	12.1	41.8
TOTAL	**107**	**36.8**	**0-149.0**	**36.2**	**18.2**	**45.4**

Table 17.The iodine concentration of different salt brands at entry point level

Brands	Sample size	Iodine concentration (ppm)				
		Mean	Range	Median	25th percentile	75th percentile
Marina	23	41.5	2.9-119.8	36.2	30.9	50.6
Cerebos	32	33.0	0-88.2	36.7	17.9	44.6
Sun	7	41.9	16.0-89.5	41.6	16.1	63.0
Crystal	11	33.5	8.8-50.5	34.3	28.9	43.7
Dwaga (Coarse salt)	9	19.7	1.9-35.9	17.2	15.0	31.6
Pak	9	47.4	15.4-149.0	37.9	24.3	49.4
Econo	7	22.2	0-47.1	12.1	5.0	45.8
Orange	9	56.3	4.9-143.3	44.4	37.9	55.8

Table 18 shows that only 25.2 percent of salt at entry point level complied with the legal requirements of 40ppm to 60ppm of iodine in salt when entering the country. Few samples (11.2%) exceeded the legal limit and their iodine content reached up to 149 ppm. More than half of the salt samples (37.4 + 26.2 = 63.6%) were below the legal limit of which 26.2 percent were markedly under-iodised or not iodised at all.

Table 18. The distribution of iodine concentration of salt at entry point level

Iodine concentration range	Number of salt samples	
	n	%
0-19	28	26.2
20-39	40	37.4
40-60	27	25.2
61-80	6	5.6
>80	6	5.6

4.3.2 RETAIL LEVEL

The median iodine concentration at retail level was 37.3 ppm (Table 19), which ranged from 12.4ppm in the Buthabuthe district to 50.2ppm in the Thabatseka district (p=0.010). The iodine content of salt at retail level ranged from 0 to 423.6 ppm. Similar to the results obtained at entry point level, there was a large variation of iodine content of salt within (1.7-423.6ppm in Leribe) and between (5.6-40.8ppm in Buthabuthe and 1.7-423.6ppm in Leribe) the districts. Similar to the entry point level, at retail level all salt samples were labeled "iodised salt" except for some coarse salt samples.

Table 19. The iodine concentration of salt at retail level

District	Sample size	Iodine concentration (ppm)				
		Mean	Range	Median	25th percentile	75th percentile
MOKHOTLONG	6	20.8	5.8-38.5	18.4	10.6	33.2
BUTHABUTHE	6	19.8	5.6-40.8	12.4	7.2	40.6
LERIBE	30	108.6	1.7-423.6	42.6	15.7	128.8
BEREA	18	35.6	0-91.3	34.3	17.7	50.1
MASERU	54	37.4	3.9-83.5	39.8	27.9	49.1
MAFETENG	24	35.4	7.5-58.3	35.1	24.6	48.7
MOHALESHOEK	18	34.9	19.6-51.9	35.2	28.0	41.2
QUTHING	12	72.0	19.7-254.8	49.0	36.7	64.2
QACHAS'NEK	6	31.3	16.5-50.7	30.4	27.3	32.7
THABATSEKA	12	52.3	13.9-106.8	50.2	33.3	58.4
TOTAL	**186**	50.1	0-423.6	37.3	23.0	50.7

According to Table 20, the median iodine concentration was higher in the Senqu river valley (46.1ppm) and lower in the Mountains (28.3ppm) than in the other ecological zones (p=0.045). A large variation in the iodine content of salt was observed in the Lowlands (1.7-423.6ppm) while a small variation was observed in the Senqu river valley (27.5-69.8ppm).

Table 20. The iodine concentration of salt at retail level by ecological zones

Ecological zones	Sample size	Iodine concentration (ppm)				
		Mean	Range	Median	25th percentile	75th percentile
FOOTHILLS	30	49.9	12.7-254.8	41.2	27.4	51.8
LOWLANDS	114	55.4	1.7-423.6	37.3	25.0	50.1
SENQU-RIVER VALLEY	6	47.6	27.5-69.8	46.1	44.4	51.8
MOUNTAINS	36	30.8	0-91.3	28.3	8.4	44.9

The median iodine concentration of different brands of salt ranged from 3.9ppm for Dwaga salt to 88.4ppm for Orange salt ($p<0.001$) (Table 21). The iodine content of brands varied considerably within (where the largest variation was 0-423.6ppm for Orange salt) and between (3.8-13.9ppm for Dwaga salt and 0-423.6 for Orange salt) the brands.

Table 21. The iodine concentration of different brands of salt at retail level

Brand of salt	Sample size	Iodine concentration (ppm)				
		Mean	Range	Median	25th percentile	75th percentile
Econo	31	23.6	5.6-72.7	19.9	16.5	28.9
Cerebos	106	37.9	5.8-59.5	40.1	30.8	48.9
Orange	22	152.8	0-423.6	88.4	53.2	261.6
Dwaga (coarse salt)	3	7.2	3.8-13.9	3.9	3.8	13.9
Unknown-coarse salt	19	51.4	1.7-254.8	28.4	10.6	58.3
Marina	5	41.4	27.4-58.6	42.3	28.0	50.5

According to Table 22, the median iodine concentration was 28.3ppm for coarse salt and 38.3ppm for fine salt ($p=0.213$). The iodine concentration range within these two types of salt differed considerably (1.7-254.8ppm for coarse salt and 0-423.6ppm for fine salt).

Table 22. The iodine concentration per type of salt at retail level

Type of salt	Sample size	Iodine concentration (ppm)				
		Mean	Range	Median	25th percentile	75th percentile
Coarse salt	22	50.1	1.7-254.8	28.3	11.7	58.3
Fine salt	164	50.2	0-423.6	38.3	25.4	50.7

Table 23 indicates that 33.3 percent of retail salt samples were within the legal requirements of 40ppm to 60ppm. Only a few samples (11.9%) exceeded the legal specifications, while most samples (54.8%) were below this. Very few coarse salt samples (9.1%) and most of the fine salt (37%) were within the legal specifications. Most samples of coarse salt (45.5%) and fewer samples of fine salt (18.9%) were below 20ppm.

Table 23. The distribution of iodine concentration of salt at retail level

Type of salt	The percentage of salt samples in each iodine content range									
	0-19ppm		20-39ppm		40-60ppm		61-80ppm		>80ppm	
	n	%	n	%	n	%	n	%	n	%
Fine	31	18.9	56	34.2	60	37.0	4	2.4	13	7.9
Coarse	10	45.5	5	22.7	2	9.1	0	0	5	22.7
Total	41	22.0	61	32.8	62	33.3	4	2.2	18	9.7

According to Table 24, most of the salt samples in the Senqu river valley (66.7%) and very few in the Foothills (23.3%) were within the legal requirement of salt iodisation at 40ppm to 60ppm. No salt samples in the Senqu river valley were below 20ppm, while most samples in the Foothills (40%) were below this.

Table 24. The distribution of iodine concentration of salt in each of the ecological zones at retail level

Ecological zones	The percentage of salt samples in each iodine content range									
	0-19ppm		20-39ppm		40-60ppm		61-80ppm		>80ppm	
	N	%	n	%	n	%	n	%	n	%
FOOTHILLS	12	40.0	8	26.7	7	23.3	2	6.7	1	3.3
LOWLANDS	22	19.3	43	37.7	35	30.7	1	1	13	11.4
SENQU-RIVER VALLEY	0	0	1	16.7	4	66.7	1	16.7	0	0
MOUNTAINS	7	19.4	9	45	16	44.4	0	0	4	11.1

4.3.3 HOUSEHOLD LEVEL

Nationally, the median iodine concentration at household level was 38.5ppm, which ranged from 29.2ppm in the Thabatseka district to 43.2ppm in the Quthing district ($p<0.001$) (Table 25). A large variation was observed in the iodine content of salt within (where the largest variation was 9.6-591.0ppm in Buthabuthe district) and between (0-76.4ppm in Qachas'nek and 9.6-591.0ppm in Buthabuthe district) the districts.

Table 26 shows that the median iodine concentration was higher (40.2ppm) in the Lowlands and Senqu river valley (40.0) and lower (33.1ppm) in the Mountains than in the other ecological zones ($p<0.001$). Similar to the results at retail level, there was a large variation in the iodine content of salt within (0-686.5ppm in the Lowlands) and between (0-257.5ppm in the Mountains and 0-686.5ppm in the Lowlands) the different ecological zones.

Table 25. The iodine concentration of salt at household level in each district

District	Sample Size	Iodine concentration (ppm)				
		Mean	Range	Median	25th percentile	75th percentile
MOKHOTLONG	30	41.5	0-147.9	38.6	27.8	48.7
BUTHABUTHE	30	60.6	9.6-591.0	35.5	23.0	43.8
LERIBE	150	58.6	0-423.2	37.6	24.3	55.4
BEREA	90	38.2	0-135.6	34.4	16.2	54.1
MASERU	270	43.5	0-212.9	41.2	30.0	51.1
MAFETENG	120	40.7	3.4-150.9	39.7	25.9	49.6
MOHALESHOEK	90	46.9	7.5-162.7	42.9	34.3	54.7
QUTHING	60	53.1	0-686.5	43.2	26.1	47.3
QACHAS'NEK	30	30.3	0-76.4	30.5	26.6	33.5
THABATSEKA	60	31.3	0-90.9	29.2	15.3	41.6
TOTAL	**930**	**45.3**	**0-686.5**	**38.5**	**25.8**	**50.4**

Table 26. The iodine concentration of salt at household level by ecological zones

Ecological zones	Sample Size	Iodine concentration (ppm)				
		Mean	Range	Median	25th percentile	75th percentile
FOOTHILLS	150	47.1	0-591.0	39.2	23.0	52.2
LOWLANDS	540	60.3	0-686.5	40.2	27.7	50.9
SENQU-RIVER VALLEY	30	47.2	0-423.2	40.0	29.3	52.2
MOUNTAINS	210	36.8	0-257.5	33.1	18.1	45.5

Table 27 indicates that the mean iodine concentration of coarse salt (33.5ppm) was lower than that of fine salt (48.3ppm) ($p<0.001$). There was a larger variation in the iodine content of coarse salt (0-686.5ppm) than that of fine salt (0-591ppm).

Table 27. The iodine concentration of different types of salt at household level

Type of salt	Sample size	Iodine concentration (ppm)				
		Mean	Range	Median	25th percentile	75th percentile
Coarse	190	33.5	0-686.5	18.5	10.4	38.1
Fine	740	48.3	0-591.0	40.9	30.8	52.1

Nationally, only 1.6 percent of households used non-iodised salt and 98.4 percent of households (86.9+11.5) used iodised salt (Table 28). Of the salt samples that were non-iodised, more (5.8%) were coarse salt than fine salt (0.5%). The majority of households (86.9%) (95% CI 83.1%; 90.7%) used adequately iodised salt (>15ppm). This proportion of households using adequately iodised salt is less than the 90 percent recommended by WHO/UNICEF/ICCIDD (2001). More of the fine salt samples (93.7%) than of the coarse salt samples (60.5%) were adequately iodised.

Table 28. The use of adequately iodised salt at household level

Type of salt	Number of salt samples in each category of Salt iodisation					
	0ppm		</=15ppm		>15ppm	
	n	%	n	%	n	%
Coarse	11	5.8	64	33.7	115	60.5
Fine	4	0.5	43	5.8	693	93.7
Total	15	1.6	107	11.5	808	86.9 (95% CI 83.1%; 90.7%)

4.4 URINARY IODINE CONCENTRATION

The median urinary iodine concentration and the distribution of urinary iodine levels in categories showing the severity of iodine deficiency according to the WHO/UNICEF/ICCIDD (2001) report are presented in this section. These results are presented at national and district level as well as by ecological zones.

4.4.1 PRIMARY SCHOOL CHILDREN

The analysis of the urine samples showed that the median urinary excretion level at national level was 214.7μg/l indicating a more than adequate iodine intake according to the WHO/UNICEF/ICCIDD (2001) report (Table 29). Adequate iodine intake is indicated by the urinary iodine concentration of 100μg/l to 199μg/l. The median urinary iodine concentrations ranged from 62.9μg/l (Qachas'nek) to 302.6μg/l (Mafeteng) in the different districts ($p<0.001$), which indicates mild iodine deficiency to excessive iodine intake. There was no significant difference ($p=0.812$) between the median urinary iodine of boys (219.3μg/l) and girls (212.6μg/l).

A high median urinary iodine concentration (257.7μg/l) was observed in the Foothills (Table 30). The median urinary iodine concentration in the Mountains was 99.30μg/l indicating a mild iodine deficiency and 256.0 μg/l in the Lowlands ($p<0.001$) indicating a more than adequate iodine intake. These results indicate that iodine deficiency is higher in the Mountains than in the Lowlands.

Table 29. The median urinary iodine concentration of children by districts

DISTRICTS	TOTAL NUMBER OF CHILDREN (n)	MEDIAN URINARY IODINE CONCENTRATION (μg/l)
MOKHOTLONG	30	208.0.
BUTHABUTHE	28	203.2
LERIBE	148	282.6
BEREA	88	290.6
MASERU	266	217.7
MAFETENG	117	302.6
MOHALESHOEK	90	178.7
QUTHING	58	158.6
QACHAS'NEK	30	62.9
THABATSEKA	57	103.7
TOTAL	**912**	**214.7**

Table 30. The median urinary iodine concentration of children by ecological zones

ECOLOGICAL ZONES	THE TOTAL NUMBER OF CHILDREN (n)	MEDIAN URINARY IODINE (μg/l)
FOOTHILLS	148	257.7
LOWLANDS	529	256.0
SENQU RIVER VALLEY	30	255.7
MOUNTAINS	205	99.2
TOTAL	**912**	**214.7**

Table 31 shows that the urinary iodine concentrations of the children were in the severe iodine deficiency range (<20μg/l) to excessive iodine intake range (300+ μg/l). The urinary

Table 31. The frequency distribution of urinary iodine in primary school children by districts

DISTRICTS		THE PERCENTAGE OF CHILDREN ACCORDING TO SEVERITY CATEGORIES OF URINARY IODINE CONCENTRATION.					
		<20 μg severe	20-49 μg moderate	50-99 μg mild	100-199 μg adequate	200-300 μg more than adequate	300+ μg excessive intake
MOKHOTLONG	%	3.3	3.3	16.7	20.0	23.3	33.3
N=30	n	1	1	5	6	7	10
BUTHABUTHE	%	0	3.6	7.1	35.7	32.1	21.4
N=28	n	0	1	2	10	9	6
LERIBE	%	6.8	2.0	10.1	16.2	17.6	47.3
N=147	n	10	3	15	24	26	70
BEREA	%	3.4	3.4	4.6	25.0	14.8	48.9
N=88	n	3	3	4	22	13	43
MASERU	%	4.5	3.8	8.7	27.4	20.3	35.3
N=266	n	12	10	23	73	54	94
MAFETENG	%	1.0	0	5.1	20.5	23.1	50.4
N=116	n	1	0	6	24	27	59
MOHALESHOEK	%	7.8	3.3	14.4	32.2	20.0	22.2
N=90	n	7	3	13	29	18	20
QUTHING	%	8.6	15.5	15.5	19.0	10.3	31.0
N=59	n	5	9	9	11	6	18
QACHAS'NEK	%	23.3	23.3	30.0	16.7	3.3	3.3
N=30	n	7	7	9	5	1	1
THABATSEKA	%	10.4	5.3	31.6	31.6	8.8	12.3
N=57	n	6	3	18	18	5	7
TOTAL	**%**	**5.7**	**4.4**	**11.4**	**24.3**	**18.2**	**36.0**
N=912	**n**	**52**	**40**	**104**	**222**	**166**	**328**

concentration of 21.5 percent of the children (5.7+4.4+11.4), were in the severe to mild iodine deficiency range. The urinary iodine concentration of 5.7 percent of the children, were in the severe deficient range (<20μg/l), 4.4 percent in the moderate range (20-49μg/l) and 11.4 percent in the mild range (50-99μg/l) of iodine deficiency. Impressively, the urinary iodine concentration of 24.3 percent of the children, was in the adequate iodine intake range (100-199μg/l) and 18.2 percent in the more than adequate iodine intake range (200-299 μg/l). More than one third of children (36.0%) had urinary iodine concentration in the excessive iodine intake range (300+ μg/l).

A high percentage of children in the Qachas'nek district (23.3%) had urinary iodine concentrations in the severely deficient range. In the Buthabuthe district there were no children with urinary iodine concentrations in the severe deficient range while a higher percentage were in the adequate range (34.5%) of iodine intake than were those in the other districts ($p<0.001$). Similarly the urinary iodine concentrations of very few children were in the severely deficient range (1.0%) while a higher percentage were in the excessive intake range (50.9%) in the Mafeteng district than in the other districts.

It is also shown on Table 31 that 10.1 percent (5.7% + 4.4%) (95% CI 6.0%; 14.2%) and 21.5 percent (10.1% + 11.4%) (95% CI 15.1%; 27.9%) of the children showed a urinary iodine excretion lower than 50μg/l and 100μg/l respectively, which is used as criteria for monitoring progress towards eliminating IDD as a public health problem (WHO/UNICEF/ICCIDD, 2001). These values indicate that iodine has been eliminated as a public health problem because the percentages are less than 20 and 50 respectively.

According to Table 32, iodine deficiency was higher in the Mountains than in the Lowlands. A higher percentage of children in the Mountains (12.7%) and a lower percentage of children in the Lowlands (3.8%) were in the severely iodine deficient range than were those in the other ecological zones ($p<0.001$). 22.4 percent of the children in the Mountains and 25.3 percent of the children in the Lowlands were in the adequate iodine intake range.

Table 32. The frequency distribution of urinary iodine in primary school children by ecological zones

DISTRICTS		THE PERCENTAGE OF CHILDREN ACCORDING TO SEVERITY CATEGORIES OF URINARY IODINE CONCENTRATION.					
		<20 μg severe	20-49 μg moderate	50-99 μg mild	100-199 μg adequate	200-300 μg more than adequate	300+ μg excessive intake
FOOTHILLS (N=148)	%	2.0	2.7	8.8	24.3	21.6	40.5
	n	3	4	13	36	32	60
LOWLANDS (N=529)	%	3.8	1.5	7.2	25.3	19.5	42.7
	n	20	8	38	134	103	226
SENQU-RIVER VALLEY (N=30)	%	10.0	3.3	10.0	20.0	13.3	43.3
	n	3	1	3	6	4	13
MOUNTAINS (N=205)	%	12.7	13.2	24.4	22.4	13.3	14.2
	n	26	27	50	46	27	29
TOTAL (N=912)	**%**	**5.7**	**4.4**	**11.4**	**24.3**	**18.2**	**36.0**
	n	**52**	**40**	**104**	**222**	**166**	**328**

4.4.2 WOMEN OF CHILD BEARING AGE

The median urinary iodine excretion for women at national level was 280.1μg/l (Table 33). Although this median urinary excretion was higher than that of the children, it also indicates a more than adequate iodine intake according to the WHO/UNICEF/ICCIDD (2001) report. The median urinary iodine concentrations ranged from 124.8μg/l (Thabatseka) to 381.6μg/l (Mohaleshoek) in the different districts ($p<0.001$), which indicates adequate to excessive iodine intake (WHO/UNICEF/ICCIDD, 2001). At national level the median urinary iodine concentration of non-pregnant women was higher (283.0μg/l) than that of pregnant women (212.1μg/l) ($p<0.001$).

Table 33. The median urinary iodine concentration of women by districts

DISTRICTS	TOTAL NUMBER OF WOMEN	MEDIAN URINARY IODINE CONCENTRATION (μg/l)
MOKHOTLONG	30	335.5
BUTHABUTHE	30	229.3
LERIBE	150	371.0
BEREA	90	223.6
MASERU	266	350.1
MAFETENG	118	333.7
MOHALESHOEK	90	381.6
QUTHING	60	161.9
QACHAS'NEK	30	195.1
THABATSEKA	60	124.8
TOTAL	**924**	**280.1**

Table 34 shows that the median urinary iodine concentration of the women was 182.6μg/l in the Mountains, indicating adequate intake and 329.9 μg/l in the Lowlands, indicating excessive intake of iodine ($p<0.001$). Similar to the results of the children, these values indicate that iodine deficiency is higher in the Mountains than in the Lowlands.

Table 34. The median urinary iodine concentration of women by ecological zones

ECOLOGICAL ZONES	THE TOTAL NUMBER OF WOMEN (n)	MEDIAN URINARY IODINE (μg/l)
FOOTHILLS	149	292.0
LOWLANDS	535	329.9
SENQU RIVER VALLEY	30	214.5
MOUNTAINS	210	182.6
TOTAL	**924**	**280.1**

According to Table 35, the urinary iodine concentration of the women was in the severe iodine deficiency range (<20μg/l) to excessive iodine intake range (300+ μg/l). The median urinary iodine concentration of 17.9 percent of the women (5.4+4.4+8.1), was in the severe to mild iodine deficiency range. The urinary iodine concentration of 5.4 percent of the women, was in the severe range (<20μg/l), 4.4 percent was in the moderate range (20-49μg/l) and 8.1 percent in the mild range (50-99μg/l) of iodine deficiency. Only 20.1 percent had urinary iodine concentration in the adequate iodine intake range (100-199μg/l), and even fewer, 14.7 percent, were in the more than adequate iodine intake range (200-299μg/l). A high percent of women (47.2%) had urinary iodine concentration in the excessive iodine intake range (300+ μg/l).

In Mokhotlong district no women had urinary iodine concentrations in the severe iodine deficiency range while in the Buthabuthe and Qachas'nek districts no women had urinary iodine concentrations in the moderate iodine deficiency range. Higher percentages of women with urinary iodine concentrations in the severe iodine deficient range were observed in the Quthing district (20.0%) than in the other districts. A lower percentage of women in the Mokhotlong district (13.3%) and a higher percentage of women in the Qachas'nek district (33.3%) had urinary iodine in the adequate intake range than had those in the other districts ($p<0.001$).

Similar to the results of the children, only 9.8 percent (5.4% + 4.4%) (95% CI 6.7%; 13.0%) and 17.9 percent (9.8% + 8.1%) (95% CI 14.0%; 22.0%) of women showed urinary iodine excretion lower than 50μg/l and 100μg/l respectively, which are used as criteria for monitoring progress towards eliminating IDD as a public health problem (WHO/UNICEF/ICCIDD, 2001). These values are less than 20 and 50 percent respectively and therefore indicate that iodine has been eliminated as a public health problem.

Table 35. The frequency distribution of urinary iodine concentration in women by districts

DISTRICTS		THE PERCENTAGE OF WOMEN ACCORDING TO SEVERITY CATEGORIES OF URINARY IODINE CONCENTRATION BY IDD.					
		<20 µg severe	20-49 µg moderate	50-99 µg mild	100-199 µg adequate	200-300 µg more than adequate	300+ µg excessive intake
MOKHOTLONG	%	0	6.7	16.7	13.3	10.0	53.3
N=30	n	0	2	5	4	3	16
BUTHABUTHE	%	3.3	0	20.0	23.3	20.0	33.3
N=30	n	1	0	6	7	6	10
LERIBE	%	2.7	4.7	2.7	16.7	14.0	59.3
N=150	n	4	7	4	25	21	89
BEREA	%	15.6	4.4	4.4	22.2	8.9	44.4
N=90	n	14	4	4	20	8	40
MASERU	%	2.6	2.6	6.8	16.9	16.9	54.1
N=266	n	7	7	18	45	45	144
MAFETENG	%	5.9	2.5	4.2	18.6	11.0	57.6
N=118	n	7	3	5	22	13	68
MOHALESHOEK	%	2.2	3.3	10.0	22.2	21.1	41.1
N=90	n	2	3	9	20	19	37
QUTHING	%	20.0	6.7	10.0	25.0	11.7	26.7
N=60	n	12	4	6	15	7	16
QACHAS'NEK	%	3.3	0	26.7	33.3	23.3	13.3
N=30	n	1	0	8	10	7	4
THABATSEKA	%	3.3	18.3	16.7	30.0	11.7	20.0
N=60	n	2	11	10	18	7	12
TOTAL	**%**	**5.4**	**4.4**	**8.1**	**20.1**	**14.7**	**47.2**
N=924	**n**	**50**	**41**	**75**	**186**	**136**	**436**

Table 36 shows that 8.6 percent of women in the Mountains and only 3.9 percent of women in the Lowlands had urinary iodine concentration in the severe iodine deficient range. The iodine concentrations of few women in the Mountains (15.2%) and very few in the Lowlands (5.4%) were in the mild range of iodine deficiency respectively. These results indicate that iodine deficiency is higher in the Mountains than in the Lowlands ($p<0.001$).

Table 36. The frequency of distribution of urinary iodine in women by ecological zones

DISTRICTS		THE PERCENTAGE OF WOMEN ACCORDING TO SEVERITY CATEGORIES OF URINARY IODINE CONCENTRATION.					
		<20 µg severe	20-49 µg moderate	50-99 µg mild	100-199 µg adequate	200-300 µg more than adequate	300+ µg excessive intake
FOOTHILLS	%	5.4	2.0	7.4	17.5	18.8	49.0
(N=149)	n	8	3	11	26	28	73
LOWLANDS	%	3.9	3.6	5.4	19.3	13.3	54.8
(N=535)	n	21	19	29	103	71	292
SENQU-RIVER	%	10.0	3.3	10.0	23.3	16.7	36.7
VALLEY (N=30)	n	3	1	3	7	5	11
MOUNTAINS	%	10.0	8.6	15.2	23.8	15.2	28.6
(N=210)	n	3	18	32	50	32	60

According to Table 37, a higher percentage of women who had urinary iodine concentrations in the adequate intake range used adequately iodised (20.3%) than did those who used non-iodised salt (13.3%). This relationship between urinary iodine concentration and iodine content of salt was not significant ($p=0.333$, adjusted for the district, $p=0.793$). Also, of the adequately iodised salt samples (>15ppm), most came from the women who had urinary iodine concentration in the excessive iodine intake range (48.0%) and very few came from women who had urinary iodine concentration in the mild iodine deficiency range (4.1%).

Table 37. The association between urinary iodine concentration and salt iodine content

IODINE CONTENT		THE PERCENTAGE OF WOMEN ACCORDING TO SEVERITY CATEGORIES OF URINARY IODINE CONCENTRATION.					
		<20 µg severe	20-49 µg moderate	50-99 µg mild	100-199 µg adequate	200-300 µg more than adequate	300+ µg excessive intake
0	%	0	6.7	20.0	13.3	13.3	46.7
	n	0	1	3	2	2	7
</=15	%	9.4	6.6	7.6	19.8	15.1	41.5
	n	10	7	8	21	16	44
>15	%	15.0	4.1	8.0	20.3	14.7	48.0
	n	40	33	64	163	118	385

4.5 THYROID SIZE AND THE PREVALENCE OF GOITRE

Thyroid size and the prevalence of goitre will be presented in this section at national and district level as well as by ecological zones, age and gender. The size of the thyroid gland of each child and woman was visually inspected and palpated and was graded according to the criteria of the WHO/UNICEF/ICCIDD (2001). The limited usefulness of palpation method during the initial stages of salt iodisation has been documented. Therefore the results on the prevalence of goitre in the study will be used to follow IDD trend in Lesotho not to show the impact of salt iodisation. Each observer graded the subject independently and the goitre grades of both (for each of the four teams) were recorded. During interpretation of data, when the goitre grades of both observers did not the same the highest was used (i.e. if one observer graded 0 and other graded 1, goitre grade 1 was used for interpretation). This was done to ensure that the possibility of the existence of goitre was taken into account. The consensus of observers regarding goitre grades was therefore measured.

The results obtained were in three categories; both observers scored 0 (grade 0), either of the observers scored 1, or both observers scored 1 (grade 1) and both observers scored 2 (grade 2). The category "either of observers" included the cases where both observers got grade 1 and where one of them grade 1. The prevalence of goitre (goitre rate) included the rate of both palpable (grade 1) and visible (grade 2) goitre. For interpretation of the results and discussion, the prevalence of goitre was obtained from both goitre grades 1 and 2 using categories "either of the observers scored 1" and "both observers scored 2" respectively. There was no discrepancy in the observation of goitre grade 2 between the observers.

4.5.1 AGREEMENT BETWEEN OBSERVERS

Unlike the children where only grade 0 and 1 were observed, all three goitre grades (0,1 and 2) were observed in women, therefore, the weighted Kappa was used for women rather than the simple Kappa. The consensus within teams 1, 3 and 4 was good with 95 percent confidence intervals and Kappa values above 0.80 in children (Table 38). Team 2 had a poorer consensus. However, for the women, the consensus of both teams 1 and 3 was not as good as with the children. The values on Table 39 shows that the consensus between the observers was better in children than in women.

Table 38. The Kappa values for the classification of the goitre grades obtained by two observers in each team

TEAMS	SUBJECTS	KAPPA VALUES	95% CONFIDENCE INTERVALS	
			Lower limit	Upper limit
1	Children	0.89	0.79	1.00
	Women	0.54	0.40	0.68
2	Children	0.69	0.52	0.85
	Women	0.68	0.56	0.80
3	Children	0.93	0.86	1.01
	Women	0.82	0.71	0.94
4	Children	0.97	0.92	1.02
	Women	0.93	0.85	1.00

4.5.2 PRIMARY SCHOOL CHILDREN

Table 39 indicates that only grade 0 (no palpable goitre) and grade 1 (palpable but non visible goitre) were prevalent in children in all the children palpated. Grade 2, which is visible goitre, was not observed in any of the districts. A higher percentage (93.4%) and a lower percentage (78.3%) of grade 0 goitre were found in the Quthing and Thabatseka districts respectively than in the other districts. The prevalence of goitre for the whole country was 10.7 percent (either of the observers scored 1), which indicates mild IDD (WHO/UNICEF/ICCIDD, 2001). IDD is eliminated in a population when the prevalence is less than 5 percent. The prevalence of goitre ranged from 6.6 percent in Quthing to 22.6 in the Buthabuthe district ($p=0.039$) indicating mild to moderate IDD. The prevalence of goitre where both observers scored 1 was 8.5 percent, which also indicates mild IDD.

According to Table 40 it is clear that iodine deficiency as represented by the prevalence of goitre (either of the observers scored 1) is higher in the Mountains (18.1%) than in the Lowlands (6.7%) ($p<0.001$). Goitre was not prevalent in the Senqu river valley.

The results on Table 41 show that goitre prevalence increases with age in children ($p=0.024$, adjusted for district $p=0.023$). The prevalence of goitre was lower (4.3% and 8.9%) in children aged 8 and 9 years respectively than in children aged 10 and 11 (12.3%) and children aged 12 years (12.9%).

Table 39. Goitre grade and the prevalence of goitre in children by districts

DISTRICTS		PERCENTAGE OF CHILDREN ACCORDING TO GOITRE GRADE						PREVALENCE OF GOITRE (%)*
	Number of children (n)	0		1 (either of observers)[b]		1 (both observers)		
		n	%	n	%	n	%	
MOKHOTLONG	30	26	86.7	4	13.3	4	13.3	13.3
BUTHABUTHE	30	24	80.0	7	23.3	6	20.0	23.3
LERIBE	150	135	90.0	15	10.0	15	10.0	10.0
BEREA	90	84	93.3	6	6.7	5	5.6	6.7
MASERU	268	240	89.6	28	10.5	17	6.3	10.5
MAFETENG	119	111	93.3	8	6.7	8	6.7	6.7
MOHALESHOEK	90	80	89.0	10	11.1	9	10	11.1
QUTHING	60	58	96.7	4	6.7	2	3.3	6.7
QACHAS'NEK	30	26	86.7	4	13.3	4	13.3	13.3
THABATSEKA	60	47	78.3	13	21.7	9	15	21.7
TOTAL	**927**	**828**	**89.3**	**99**	**10.7**	**79**	**8.5**	**10.7 (95% CI 8.1%; 13.3%)**

* obtained from goitre grade 1 "either of the observers"

[b] where both observers or one of them scored grade 1

Table 40. Goitre grade and the prevalence of goitre in children by ecological zones

Ecological zones		Percentage of children according to goitre grade						The prevalenc of goitre (%)*
	n	0		1 (either of observers)[b]		1 (both of observers)		
		n	%	n	%	n	%	
FOOTHILLS	150	125	83.3	25	16.7	20	14	16.7
LOWLANDS	537	501	93.3	36	6.7	30	5.4	6.7
SENQU RIVER VALLEY	30	30	100	0	0	0	0	0
MOUNTAINS	210	172	81.9	38	18.1	29	13.8	18.1
TOTAL	**927**	**828**	**89.3**	**99**	**10.7**	**79**	**8.5**	**10.7**

*obtained from goitre grade 1 "either of the observers"

[b] where both observers or one of them scored grade 1

Table 41. Goitre grade and the prevalence of goitre in children by age

Age group	n	Percentage of children according to goitre grade						The prevalence of goitre (%)*
		0		1 (either of observers) [b]		1 (both observers)		
		n	%	n	%	n	%	
8	139	138	99.3	6	4.3	1	0.7	4.3
9	157	147	93.6	14	8.9	10	6.4	8.9
10	212	185	87.3	32	15.1	27	12.7	12.3
11	187	168	89.8	23	12.3	19	10.2	12.3
12	232	210	90.5	24	10.3	22	9.5	12.9

*obtained from goitre grade 1 "either of the observers"

[b] where both observers or one of them scored grade 1

Table 42 demonstrates that the goitre prevalence of 14.0 percent in females was higher than that of males (7.0%) ($p<0.001$, adjusted by districts $p<0.001$). This indicates mild IDD, which is found more in females than in males. This goitre prevalence, which is higher in females than in males, was observed in all the age groups.

Table 42. Goitre grade and the prevalence of goitre in children by gender

Age gr	Gender	Sample (n)	Percentage of children according to goitre grade						The prevalence of goitre (%)*
			0		1 (either of observers) [b]		1 (both observers)		
			n	%	n	%	n	%	
8	Females	77	76	98.7	5	6.5	1	1.3	6.5
	Males	62	62	100	1	1.6	0	0	1.6
9	Females	82	74	90.2	11	13.4	8	9.8	13.4
	Males	75	73	97.3	3	4.0	2	2.7	4.0
10	Females	108	91	84.3	22	20.4	17	15.7	20.4
	Males	104	94	90.4	10	9.6	10	9.6	9.6
11	Females	100	86	86.0	16	16.0	14	14.0	16.0
	Males	87	82	94.3	7	8.1	5	5.8	8.1
12	Females	119	106	89.1	14	11.8	13	10.9	11.8
	Males	113	104	92.0	10	8.9	9	8.0	8.9
Total	**Females**	**486**	**433**	**89.1**	**68**	**14.0**	**53**	**10.9**	**14.0**
	Males	**441**	**415**	**94.1**	**31**	**7.0**	**26**	**5.9**	**7.0**

* obtained from goitre grade 1 "either of the observers"

[b] where both observers or one of them scored grade 1

4.5.2 WOMEN OF CHILD BEARING AGE

The results of thyroid assessment of women showed that grade 0 (no palpable goitre), grade 1 (palpable but non visible goitre) and grade 2 (visible goitre) were prevalent in the country (Table 43). All women in the Mokhotlong and Qacha'snek districts had no palpable goitre. Besides Mokhotlong and Qacha'snek districts, a lower percentage (63.3%) and a higher percentage (93.3%) of grade 0 goitre were found in the Berea and Thabatseka districts respectively than in the other districts.

The prevalence of goitre (either observer scored 1 and both scored 2) for the whole country was 19.4 percent, which indicates mild IDD. This prevalence ranged from 6.7 percent (Thabatseka district) to 36.7 percent (Berea district) and indicates mild to severe IDD according to the WHO/UNICEF/ICCIDD (2001) (p<0.001).

Table 43. Goitre grade and the prevalence of goitre in women by districts

DISTRICTS		PERCENTAGE OF WOMEN ACCORDING TO GOITRE GRADE								THE PREVALENCE OF GOITRE (%)
	n	0		1 (either of observers)[b]		1(both observers)		2		
		n	%	n	%	n	%	n	%	
MOKHOTLONG	30	30	100	0	0	0	0	0	0	0
BUTHABUTHE	30	27	90.0	4	13.3	3	10.0	0	0	12.9
LERIBE	150	127	84.7	21	14.0	16	10.7	2	1.3	15.3
BEREA	90	57	63.3	33	36.7	21	23.3	0	0	36.7
MASERU	270	204	75.6	61	22.6	30	11.1	5	1.9	24.5
MAFETENG	120	103	85.8	21	17.5	17	14.3	0	0	17.7
MOHALESHOEK	90	78	86.7	10	11.1	9	10.0	2	2.2	13.3
QUTHING	60	43	71.7	16	26.7	1	1.7	1	1.7	28.4
QACHAS'NEK	30	30	100	0	0	0	0	0	0	0
THABATSEKA	60	56	93.3	4	6.7	0	0	0	0	6.7
TOTAL	**930**	**750**	**80.7**	**170**	**18.3**	**97**	**10.4**	**10**	**1.1**	**19.4 (95% CI 14.8%; 23.9%)**

* from goitre grade " either of observers scored 1" and goitre grade 2

[b] where both observers or one of them scored grade 1

Table 44 indicates that iodine deficiency as represented by the prevalence of goitre was higher in the Mountains (17.7%) than in the Lowlands (14.3%) (p<0.001). There was a higher prevalence of goitre (32%) in the Foothills than in the other ecological zones.

Table 44. Goitre grade and the prevalence of goitre in women by ecological zones

ECOLOGICAL ZONES		PERCENTAGE OF WOMEN ACCORDING TO GOITRE GRADE								PREVALENCE OF GOITRE (%)*
	n	0		1 (either observers) [b]		1(both observers)		2		
		n	%	n	%	n	%	n	%	
FOOTHILLS	150	122	81.3	44	29.3	24	16	4	2.7	32.0
LOWLANDS	540	472	87.4	74	13.7	65	12.0	3	0.6	14.3
SENQU-RIVER VALLEY	30	28	96.7	5	16.7	1	3.3	1	3.3	20.0
MOUNTAINS	210	128	61.0	35	16.7	8	3.8	2	1.0	17.7
TOTAL	**930**	**750**	**80.7**	**170**	**18.3**	**97**	**0.4**	**10**	**1.1**	**19.4**

* from goitre grade " either of observers scored 1" and goitre grade 2

[b] where both observers or one of them scored grade 1

According to Table 45, visible goitre (grade 2) was observed slightly more (1.4%) in women in the age group of 25 to 30 than in the age group of 15 to 19 (1.0%) (p=0.248, adjusted by district p=0.270). However, the prevalence of goitre increased with age from the age group of 15 to 19 (17.3%) to the age group of 20 to 24 (22 %) and decreased in the age group of 25 to 30 (18.4%).

Table 46 shows that a higher percentage of women who used non iodised salt (6.7%) and a lower percentage of women who used adequately iodised salt (1.1%) had grade 2 goitre. This association between goitre grade and salt iodine content was significant (p=0.006, adjusted for the districts p=0.003). Similarly, of the women who used adequately iodised salt, most had grade 0 goitre (81.9%) while very few had grade 2 goitre (1.1%).

Table 45. Goitre grade and the prevalence of goitre in women by age

AGE GROUP (years)	n	PERCENTAGE OF WOMEN BY GOITRE GRADE								THE PREVALENCE GOITRE (%)*
		0		1 (either of observers)[b]		1(both observers)		2		
		n	%	n	%	n	%	n	%	
15-19	282	255	90.4	46	16.3	25	8.9	2	1.0	17.3
20-24	359	317	88.3	75	20.9	38	10.6	4	1.1	22.0
25-30	289	251	86.9	49	17.0	34	11.8	4	1.4	18.4

* from goitre grade " either of observers scored 1" and goitre grade 2

[b] where both observers or one of them scored grade 1

Table 46. The association between goitre grade and the iodine content of salt

IODINE CONTENT OF SALT (ppm)	n	PERCENTAGE OF WOMEN BY GOITRE GRADE							
		0		1 (either of observers)[b]		1 (both observers)		2	
		n	%	n	%	n	%	n	%
0	15	12	80.0	1	6.7	2	13.3	1	6.7
</=15	107	76	71.0	23	21.5	31	29.0	0	0
>15	808	662	81.9	73	19.0	137	17.0	9	1.1

[b] where both observers or one of them scored grade 1

4.6 SUSTAINABILITY OF SALT IODISATION PROGRAM

According to the WHO/UNICEF/ICCIDD (2001) the sustainability indicators involve a combination of median urinary iodine levels in the target population, availability of adequately iodised salt at household level and a set of programmatic indicators, which are regarded as evidence of sustainability.

To assess the programmatic indicators, a questionnaire, bearing information on the programmatic indicators of sustainability, was administered to one officer. This officer, the Director of FNCO has been fully involved in the salt iodisation program since it was initiated. The information obtained was verified by documentation when available. The responses from the Director of FNCO who is the chairperson of the micronutrient and the IDD control task force are shown in Table 47. These responses indicate that only 4 of the 10 programmatic indicators of sustainability have been attained.

Table 48 shows the results on the achievement of the WHO/UNICEF/ICCIDD (2001) sustainability goals by the salt iodisation program. All urinary iodine goals have been achieved. Fewer than half (4 out of 10) of the goals of the programmatic indicators have been attained. At least 8 out of the 10 programmatic indicators have to be attained, indicating that the programmatic indicators do not achieve the goals for sustainable elimination of IDD. 86.9 percent of households (that is, slightly less than 90%) use adequately iodised salt. According to the WHO/UNICEF/ICCIDD (2001) all goals for sustainable elimination as a public health problem should be achieved. Therefore the results on Table 49 show that the salt iodisation program for IDD elimination in Lesotho requires further programmatic inputs before it could be considered a program with a good potential for sustainability.

Table 47. Responses to the questionnaire based on programmatic indicators of sustainability

INDICATORS	ATTAINMENT OFTHE INDICATORS	COMMENTS
Existence of an effective, functional national body responsible to the government for national program for the elimination of IDD.	YES	IDD control task force is multi-disciplinary and is coordinated by FNCO
Evidence of political commitment of universal salt iodisation and the elimination of IDD	NO	There is no evidence of political commitment to the elimination of IDD*
Appointment of a responsible executive officer for the IDD elimination program	YES	The director of FNCO (the Coordinating body) is responsible
Legislation or regulations on universal salt iodisation	YES	The legislation which cover iodisation of both human and animal salt was drafted in 1994 and promulgated in 2000
Commitment to assessment and re-assessment of progress in the elimination of IDD with access to laboratories able to provide accurate data on salt and urinary iodine	NO	Only one person was trained in urinary iodine analysis and the only available laboratory (at the National University of Lesotho) is quality assured externally.
A program of public education and social mobilization on the importance of IDD and the consumption of iodised salt	NO	Radio messages are no longer sent. Pamphlets, posters and booklets are being distributed at a very slow rate.*

Regular data on salt iodine at the factory, retail and household level	NO	This is not done regularly because of costs encountered (especially transportation of samples) to perform analysis outside the country (in South Africa). Customs officers and health inspectors no longer do regular checks using the spot tests
Regular laboratory data on urinary iodine in school-aged children with appropriate sampling for higher risk areas	NO	This is also not done regularly due to high costs encountered during analysis outside the country.
Cooperation from the salt industry in maintenance of quality control	YES	The recent assessment in South Africa (from where Lesotho gets its salt) indicated that the South African salt industry is in a strong position to supply the required amount of iodised salt to the market to achieve the goal of at least 90% of households using adequately iodised salt before 2005 (Jooste, 2001).
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.	NO	All studies conducted are in written reports of which some copies have been misplaced and are not readily available to the public.*

*There was no documentation to support the statement.

Table 48. Results based on the criteria for monitoring progress towards sustainable elimination of IDD as a public health problem

INDICATORS	GOALS	RESULTS OBTAINED IN THE PRESENT STUDY
SALT IODISATION Proportion of households using adequately iodised salt	>90%	86.9% (95% CI 83.1%; 90.7%)
URINARY IODINE Proportion below 100µg/l Proportion below 50µg/l	 <50% <20%	 21.5% (95% CI 15.1%; 27.9%) for the children, 17.9% (95% CI 14.0%; 22.0%) for the women 10.1% (95% CI 6.0%; 14.2%) for the children, 9.8% (95% CI 6.7%; 13.0%) for the women
PROGRAMMATIC INDICATORS Attainment of the indicators	At least 8 out of 10	Only 4 indicators are attained

4.7 SUMMARY

At entry point level 107 salt samples were collected and analysed instead of the expected 110 samples. Only 3 data sheets for children were not included for palpation while 18 data sheets for children and 6 data sheets for women were not included for urinary iodine analysis. This resulted in a more than 98 percent response rate. The median iodine concentration of salt was 36.2ppm (ranging from 30.5-55.4ppm at the different entry points) and 37.3ppm (ranging from 12.4-50.2ppm in the different districts) at entry point and retail level respectively. Among the different brands, the median iodine concentration ranged from 12.1ppm to 44.4ppm at entry point level and from 3.9ppm to 88.4ppm at retail level. A large variation was observed between and within the brands. The median iodine content of fine salt (38.3ppm at retail and 48.3ppm at household level) was higher than that of coarse salt (28.3ppm at retail and 33.5ppm at household level). At household level, the median salt iodine content was 38.5ppm, which ranged from 29.2ppm to 43.2ppm in the different districts. 98.4 percent of households used iodised salt (only 1.6 percent used non iodised salt) and 86.9 percent used adequately iodised salt. The median salt iodine content was lower in the Mountains (28.3ppm at retail and 33.1ppm at household level) than in the Lowlands (37.3ppm at retail and 40.2ppm at household level).

The analysis of the urine samples showed that the median urinary excretion for children was 214.7μg/l indicating a more than adequate iodine intake according to the WHO/UNICEF/ICCIDD (2001) report (Adequate intake range is 100-199μg/l). The median urinary iodine concentration ranged from 62.9μg/l in the Qachas'nek district to 302.6μg/l in Mafeteng district, which indicates mild iodine deficiency to excessive iodine intake. There was no significant difference between the median urinary iodine concentration of girls (212.6μg/l) and boys (219.3μg/l). Iodine deficiency was higher in the Mountains (median of 99.30μg/l) than in the Lowlands (median of 256.0 μg/l). Similar results were obtained from the women of childbearing age where the median urinary iodine excretion was 280.1μg/l, which also indicates a more than adequate iodine intake according to the WHO/UNICEF/ICCIDD (2001) report. The median urinary iodine concentrations ranged from 124.8μg/l (Thabatseka) to 381.6μg/l (Mohaleshoek) in the different districts indicating adequate to excessive iodine intake. This median urinary iodine concentration was higher in the Lowlands (329.9μg/l) than in the Mountains (182.6μg/l), and was higher in non-pregnant women (283μg/l) than in pregnant women (212μg/l). The median urinary iodine concentration of 21.5 percent of the children and 17.9 percent of women was in the severe to mild iodine deficiency ranges. The median urinary iodine concentrations of very few children (10.1% and 21%) and women (9.8% and 17.9%), which were lower than the cut off points of 20 percent and 50 percent respectively, were lower than 50μg/l and 100μg/l respectively, indicating that IDD has been eliminated as a public health problem. More than one third of the children (36%) and almost half of the women (47.2%) had urinary iodine concentrations in the excessive iodine intake range. Although not statistically significant, of the women who were in the adequate intake range, more (20.3%) used adequately iodised salt than non-iodised salt (13.3%).

Goitre grade 0 and 1 goitre were prevalent among the children. The prevalence of goitre in children for the whole country was 10.7 percent, which indicates mild IDD (WHO/UNICEF/ICCIDD, 2001). This prevalence ranged from 6.6 percent to 22.6 percent in the different districts indicating mild to moderate IDD (elimination of IDD is indicated by the prevalence less than 5%). IDD was observed more in females (14.0%) than in males (7.0%) and was less (4.3%) in children aged 8 than in children aged 12 years (12.9%). In women, goitre 0, 1 and 2 were prevalent and the prevalence of goitre for the whole country was 19.4 percent, which indicates mild iodine deficiency. This prevalence ranged from 6.7 percent (Thabatseka district) to 36.7 percent (Berea district) and indicates mild to severe iodine deficiency according to the WHO/UNICEF/ICCIDD (2001). Similar to the results of the children, IDD in women was observed more in the Mountains (17.7%) than in the Lowlands (14.3%). The prevalence of goitre also increased with age from the age group of 15 to 19 (17.3%) to the age group of 20 to 25 (22 %) and decreased in the age group of 26 to 30 (18.4%). There was a significant relationship between the goitre grade of the women and salt iodine content, where 6.7 percent of the women with grade 2 goitre used non iodised salt rather than adequately iodised salt (1.1%).

The responses on the programmatic indicators of sustainability indicated that the iodisation program in Lesotho has attained 4 indicators instead of 8 or more. 86.9 percent (which is slightly lower than the recommended 90%) of salt samples were adequately iodised at household level. Therefore salt iodisation and the programmatic indicators do not reach the WHO/UNICEF/ICCIDD (2001) sustainability goals. Only the urinary iodine excretion reached sustainability goals indicating that salt iodisation program in Lesotho requires additional programmatic inputs before it can be considered as sustainable.

CHAPTER 5: DISCUSSION

5.1 INTRODUCTION

In this chapter the important observations from the results on salt iodisation, urinary iodine concentration, thyroid size, and sustainability of the salt iodisation program will be discussed. Where possible the results obtained in this study are compared to the results of other relevant studies of a similar nature, as reported in the literature available. Throughout the discussion, the trends and differences that were observed in the previous studies conducted in Lesotho and the present study will be highlighted in order to interpret the findings and identify possible reasons for changes, or lack thereof.

5.2 LIMITATIONS OF THE STUDY

The limitations of this study were as follows:

1. An inspection and palpation method, which is less reliable especially when goitres are small, was used instead of ultrasonography to assess the thyroid size of both women and children. This was because ultrasonography, which is a more precise and objective measurement, is not available in the country. It has, however, been indicated that in the absence of ultrasonography, inspection and palpation provides information on the prevalence of goitre in a population. Therefore palpation in the present study was used to give an indication of the prevalence of goitre to track progress not as an impact of salt iodisation on the thyroid size.
2. Thyroid stimulating hormone (TSH) in neonates, which has an additional advantage of highlighting the fact that iodine deficiency directly affects the developing brain, was not assessed in the study. TSH assays are not available in the country.
3. The use of goitrogenic foods as well as the nutritional status of the women and children, were not investigated during the study, due to limited funds. The investigation is important because studies have shown that goitrogenic food and water-borne goitrogens can aggravate goitre. General malnutrition and deficiency of iron, selenium and vitamin A also exacerbate IDD. Although iodine intake has not been

investigated in Lesotho, studies have indicated persisting mild to severe IDD while the use of iodised salt was increasing. Therefore it would have been of benefit to investigate the role of goitrogens and micronutrient deficiencies in the prevalence of IDD in Lesotho.

4. Due to limited funds, iodine intake was also not investigated. The use of iodine containing supplements, herbal medicines and iodine rich substances affect the iodine status of a person.

Despite the limitations, the methods used in the present study were the recommended methods to measure the indicators, which are used in monitoring and evaluating IDD control programs. For impact indicators, WHO/UNICEF/ICCIDD (2001) indicates that goitre assessment by palpation or ultrasound remains a component of surveys to establish the baseline severity of IDD. Neonatal TSH may play a role if a country already has in place a screening program for hypothyroidism.

5.3 THE SELECTED SAMPLE

Primary school children were selected as a target group based on international recommendations. They are considered a convenient test group because they are accessible, reflect the current status of iodine nutrition in the community and are a major priority for prompt correction of IDD (Dunn & Van der Haar, 1990, p.24). A potential disadvantage to the use of this group is that children from the most disadvantaged communities may not attend school (Department of Health, South Africa, 2000). For this reason, the WHO/UNICEF/ICCIDD (2001) has indicated that if the proportion of children attending school is less than 50 percent, school children may not be a representative group. The government of Lesotho introduced free primary education in 2000 and this increased school attendance from 67 percent (in 1999) to 89 percent (Ministry of Education, 2002) hence the present study was school based. The preferred group for IDD surveillance is, however, school children aged 6 to 12 years (WHO/UNICEF/ICCIDD, 2001) or optionally 8 to 10 years (Sullivan *et al.*, 2000, p.3). Based on these international recommendations children aged 8 to 12 years were the target group in the present study. Children aged 8 years rather than 6 years were selected in order to eliminate measurement errors as it has been stated that the smaller the child, the smaller the thyroid and the more difficult it is to perform palpation accurately (WHO/UNICEF/ICCIDD, 2001).

Women of childbearing age were also selected in the present study because it has been shown that pregnant and lactating women are of concern during IDD surveillance (WHO/UNICEF/ICCIDD, 2001). In particular, pregnant women are a prime target group for IDD control activities because they are especially sensitive to marginal iodine deficiency and their iodine status is crucial because of the susceptibility of the developing foetus to IDD (Amoa & Rubiang, 2000). Also, goitrogenesis occurring in both the mother and foetus can be directly correlated to the degree of iodine restriction of the mother (Glinoer & Delange, 2000). Therefore, when iodine supplementation is provided early during pregnancy and maintained throughout, it allows for the correction and almost complete prevention of both maternal and foetal goitrogenesis. However, the total number of pregnant women in the present study was small (64). The results obtained are therefore not representative of the situation in Lesotho, but nevertheless provide some indication of the iodine status in pregnant women. A survey of iodine nutrition in pregnant women to prevent the occasional risk of intellectual impairment should be considered in future studies.

Iodine is essential for women of childbearing age because the damage done to the brain in early pregnancy can occur before the woman is even aware that she is pregnant (WHO, 1995). Therefore screening women aged 15 to 44 years provides an opportunity to establish the iodine status of a group that is particularly crucial because of the susceptibility of the developing foetus to iodine deficiency. Women aged between 15 to 30 years were, however, selected in this study based on the fact that, after age 30, goitre rates are no longer reliable indicators of current iodine intake (WHO/UNICEF/ICCIDD, 2001).

The primary school children and the women of child bearing age were both taken as the study target groups because in Lesotho, school children receive lunch at school through various feeding programs (Ministry of Education, 2002). It has been indicated that if school children have diets that are significantly different from those of adults in the household, there is a necessity to survey both school children and women (Sullivan *et al.*, 2000, p.3). This is due to the fact that if school children receive meals through their school, their dietary intake of iodine may differ from women of childbearing age whose primary source of food is from the home.

If only one nationally representative survey is needed, a single 30-cluster survey at the national level can be performed, and within each cluster, it is recommended that 30 urine specimens be collected (Sullivan *et al.*, 2000, p.12). Based on these recommendations 31 clusters were included in the survey, and in each cluster 30 urine samples were collected from the selected school children and women. The same children and women were also palpated and 30 salt samples were collected from the women. At entry point level, 3 salt samples were not collected (107 instead of 110 salt samples were collected). This is because salt samples did not pass through the entry points every day, therefore at the Maseru border post, to avoid spending more than enough time, only 47 salt samples were collected instead of 50. The identification numbers of some of the collected urine samples were duplicated making it impossible to identify the samples. Out of 1860 urine samples collected, 24 (18 for children and 6 for women) were not included for analysis. Also, out of 930 data sheets for the children, 3 were discarded because the recorded ages were not within the recommendation. It is therefore suggested that during the study, field workers should be identified and be given the task of collecting salt at the border gate only from the first day of data collection. It is also suggested that when the sample size is large, at least two people should recheck (after they have been checked by the supervisors) the samples and questionnaires for proper labeling and recording. However, the response rate was high enough (more than 98%) to draw valid conclusions and make recommendations based on the findings.

5.4 SALT IODISATION

The median iodine concentration of salt at the point of entry of 36.2ppm (ranging from 30.5ppm to 55.4ppm in the different entry points) (p=0.024) is lower than the legal limit of 40ppm to 60ppm specified in the universal salt iodisation legislation for Lesotho. Only 25.2 percent complied with the legal requirements. Lesotho does not produce salt and almost all of the salt entering the country comes from South Africa where it is obtained from production sites and wholesalers. A minimal loss of iodine is expected to occur from producers and wholesalers in South Africa to entry points in Lesotho. This is based on the fact that a study in India showed that small iodine losses of 9 to 10 percent occurred within 15 to 20 days after packaging in polythene bags where after the iodine content remained constant for 300 days (Chauhan *et al.*, 1992). This initial loss of iodine is due to partial draining of iodised brine adhering to the crystal surface of salt crystals and then sticking to sides of the polythene bags. Many studies have also shown that KIO_3, which is used to iodise salt in South Africa, is more stable than KI. Therefore the low mean iodine concentration obtained at entry point level shows under-iodisation of salt by the producers. Similar results confirming under- iodisation were obtained in South Africa where the mean iodine concentration of fine and coarse salt at the production site was 30ppm, which ranged from 1 to 55 ppm and only 25.6 percent of producer's salt complied with the legal requirement of 40 to 60ppm of iodine (Jooste, 2001).

At retail level, 33.3 percent of the salt samples complied with the legal requirements of 40 to 60ppm of iodine in salt, which is low but higher than at entry point level. Also, the median iodine concentration of 37.3ppm (ranging from 12.4-50.2ppm in the different districts) ($p=0.010$) was lower than the legal specifications of iodisation at 40 to 60ppm and slightly higher than at entry point level. This is possibly due to the cross-sectional design of the sampling frame at the different levels, and to the very large differences between the minimum and the maximum content of iodine within and between the brands. At entry point level, the iodine content between different brands ranged from only 19.7ppm to 56.3ppm while at retail level the range was 7.2ppm to 152.8ppm, which is very wide. A recent study in Lesotho also indicated a variation of 9 to 76ppm among the brands and 12 to 76ppm within the brands at retail level (Sebotsa *et al.*, 2002). This variation is expected at household level where there are different storage conditions. At retail level, the large variation implies non-uniformity in salt iodisation.

The median iodine concentration in household salt of 38.5ppm (ranging from 29.2-43.2ppm in the different districts) was slightly higher than at retail level. These findings were not expected because some loss of iodine occurs during distribution between the retailer and the household and through different storage conditions at household level. In Tanzania, large iodine losses were found to have occurred during distribution (Sundqvist *et al.*, 1998). Also, a recent study indicated that most households in Lesotho store salt in uncovered containers such as bottles, cups, mugs and tins thus exposing salt to high temperatures, moisture and heat (Sebotsa *et al.*, 2002). The moisture content of salt, impurities in the salt, atmospheric humidity, light and heat affect the stability of iodised salt (Ranganathan & Rao, 1986).

A large variation in the iodine concentration of salt (0-686.5ppm) at household level implies both non-uniformity in salt iodisation at the production site and the different storage conditions of salt by households. Similarly, a quantitative study conducted in the country indicated a variation in iodine levels among brands ranging from 0 to 97ppm and within brands ranging from 7 to 97ppm at household level (Sebotsa *et al.*, 2002). Other similar studies have also shown large variations in iodine levels, for example in Kenya the iodine content for the Kensalt brand ranged from 6.2 to 386.9mg/kg (Muture & Wainaina, 1994). In South Africa there was iodine content range of 7ppm to 40 ppm within brands and 0 to 80ppm between brands (Jooste *et al.*, 1998).

Although the median and individual iodine levels varied in the present study, the high values did not reach potentially toxic levels and therefore did not pose a public health threat. With the daily per capita salt intake of 3 to 10grams per day (Bureau of Statistics, 2001) the mean iodine concentration at household level is equivalent to a mean daily iodine intake of 135.9μg to 453μg. This mean iodine appears to be safe when considering the expected iodine losses of 20 percent during the preparation of food (WHO, 1996). High levels of iodine intake, particularly during the introduction of a salt iodisation program, increase the risk of adverse effects. The most common serious complication observed in areas of endemic goitre during salt iodisation is a transient increase in IIH (Stanbury *et al.*, 1998). For example, the introduction of iodised salt in Zimbabwe doubled the incidence of IIH during the first 1 to 2 years of the program (Todd *et al*, 1995). However, the benefits of correcting iodine deficiency through salt iodisation far outweigh the risk of IIH (Baltisberger *et al.*, 1995; Delange, 1998).

The median iodine concentration in the Lowlands (37.3ppm at retail level and 40.2ppm at household level) ($p=0.045$) was higher than that in the Mountains (28.3ppm at retail level and

33.1ppm at household level) ($p<0.001$). The geographical variation in the iodine concentration has been observed in earlier studies conducted in Lesotho and appears to be a worldwide problem. In Lesotho most households in the Mountains use non-iodised salt (Sebotsa *et al.*, 2003). The higher use of non-iodised salt in the Mountains than in the Lowlands is mainly due to the fact that in Lesotho most households who rear animals are in the Mountains, with few from the Lowlands (Gay & Hall, 2001). Coarse salt is therefore purchased for animal consumption but is apparently used for human consumption as well. This is the main reason why legislation in Lesotho includes iodisation of salt for animal consumption.

The introduction of universal salt iodisation in Lesotho has brought a great achievement in the availability of iodised salt. More than 90 percent (98.4%) of households use iodised salt. In 1998, 15.3 percent of the households used non-iodised salt (Sebotsa *et al.*, 2002). A qualitative study, conducted in 1999 indicated that only 5.2 percent used non-iodised salt (Sebotsa *et al.*, 2003). The impressive results on the increase in the use of iodised salt before the legislation in Lesotho was promulgated, was attributed to IDD awareness as well as to the flow over effect of mandatory iodisation introduced in South Africa in 1995. The present study shows that only 1.6 percent of households use non-iodised salt, which is low compared to previous studies. The proportion of households using non-iodised salt is also very low compared to the 13.6 percent in South Africa (Jooste *et al.*, 2001). However, this proportion of households who use non-iodised salt is at risk of developing IDD and usually these are the people with the low socioeconomic status. A study in Lesotho indicated that a higher percentage of people with a lower socioeconomic status (10.3%) used non-iodised salt. Those with a higher socioeconomic status (5%) used non-iodised salt mainly because it was cheap (Sebotsa *et al.*, 2002).

A major achievement has also been observed in the household use of adequately iodised salt. The coverage in the household use of adequately iodised salt in the present study was 86.9 percent, which is significantly better than the 81.8 percent obtained in the previous study (Sebotsa *et al.*, 2002). However, the coverage of household use of adequately iodised salt in the present study still does not meet the international standard of 90 percent or higher (WHO/UNICEF/ICCIDD, 2001). This is possibly due to non-iodisation and under iodisation of salt at the production site, iodine losses during transportation and the storage conditions of salt at household level. Similarly in South Africa, the coverage of adequately iodised salt was 62.4 percent and this was suggested to be partly due to under- iodisation at the production site (Jooste *et al.*, 2001).

According to legislation in South Africa, iodisation of salt meant for animal consumption, which is coarse salt packed in bags of 20kg or more, is not compulsory. Only coarse salt packed in 500g or 1kg bags meant for human consumption is iodised. Impressively, the present study indicated an iodine content of coarse salt ranging from 1.7 to 254.8ppm and that only 5.8 percent of coarse salt contained no iodine at household level. In addition, the study in South Africa indicated median iodine content of 38ppm in both fine and coarse salt at the production site, indicating that coarse salt could be as effectively iodised as fine salt (Jooste, 2001). The median iodine concentration of coarse salt (28.3ppm at retail and 33.5 at household level) was, however, less than that of fine salt (38.3ppm at retail level and 48.3 at household level). Also, a higher percentage of fine salt (93.7%) and a lower percentage of coarse salt (60.5%) was adequately iodised, and 5.8 percent of coarse salt and only 0.5 percent of fine salt was non iodised at household level. The possible reason for the variations in iodine content of the two types of salt at retail and household level is the difference in the amount of iodine lost during distribution. Fine salt seems to retain iodine longer than coarse salt, probably because of the uniform crystal size of fine salt and its free-running property (Ranganathan & Rao, 1986) and the impermeable bags used for packaging fine salt (Mannar & Dunn, 1995, p.22). Another possible reason may be higher level of impurities in coarse salt than in fine salt. Non iodisation, under-iodisation and loss of iodine by coarse salt are probably the main reasons for adequately iodised salt at household level not reaching the recommended 90 percent.

Some salt samples had an iodine content which was too low to be of benefit to people and which would possibly put people at risk of developing IDD. These very low quantities of iodine obtained in salt were probably due to under-iodisation of salt or the fact that non-iodised salt samples were mixed with iodised salt at household level. Of particular concern is the fact that salt labeled "iodised salt" contained no iodine. This is possibly due to non-iodisation and under- iodisation at the production site, which is a major problem and needs to be solved by effective monitoring of salt iodine levels at production levels.

The present study and other recent studies have shown an increase in salt consumption in Lesotho. For example, in a study conducted in the Lesotho Highlands Water project catchment area, 21 percent of the households did not have salt and these were the households with a low socioeconomic status (Jooste *et al.*, 1997b). In the recent studies (Sebotsa *et al.*, 2002; Sebotsa *et al.*, 2003) as well as in the present study, all the households visited had salt, although in some households, very little salt (less than a teaspoon) was available. Therefore, these latter three studies highlight the usefulness of salt as a carrier of iodine in Lesotho.

The iodine content of salt varied greatly among the different brands and within the same brands of salt available in the country. This is of great concern because the people who continuously use this iodised salt are exposed to either IDD due consumption of salt that contains too little iodine or exposed to the risk of IIH due to consumption of salt that contains too much iodine. The main reason for this variability is due to non-uniformity during salt iodisation at production site. Mannar and Dunn (1995, p.27) have indicated that during salt iodisation, thorough mixing of the salt after the addition of $KI0_3$ is necessary to ensure even penetration of $KI0_3$. If the mixing is insufficient, some batches of salt will contain too much iodine and others too little. After the Legislation in Lesotho was promulgated, members of the IDD control task force visited some salt producers to make them aware of the legislation. However, the results of the present study show that the issue of salt iodisation needs to be addressed. The IDD control task force should visit all the producers of salt that is available in the country. The salt producers should be made aware of the very important role they play in eliminating IDD in South Africa and all the countries where salt is exported to. They should be advised on the iodisation method depending on the type of salt they iodise. For example it has been indicated that the spray system, although expensive, atomizes the iodate solution and disperses it uniformly on the salt crystals, thus ensuring much more uniform mixing when compared to the drip feed system for all kinds of salt. The drip-feed system is the simplest and cheapest method but when the particle size of the salt is very fine, the system does not disperse the iodate solution with sufficient uniformity. The Authorities in the government of Lesotho and South Africa have to work together with the control task forces of the two countries and the salt producers to invest in the method that though expensive will ensure uniform iodisation.

The results of the present study indicate that there is a great improvement in the household use of iodised salt and adequately iodised salt. However, salt iodisation at entry point level does not meet the specified requirement of legislation on universal iodisation in Lesotho. The results also show than non-iodisation and under-iodisation are possible reasons for the low iodine content of salt in the country. A wide variation between and within the different brands, implying non-uniformity in salt iodisation at production sites, was also demonstrated. Coarse salt was less iodised than fine salt. The level of salt iodisation was also lower in the Mountains than in the Lowlands, and this is possibly due to the more intensive use of non-iodised salt in the Mountains than in the Lowlands. This study probably suggests that although the use of non-iodised salt has decreased markedly, there is still a small amount of salt used at household level that is not adequately iodised.

5.5 URINARY IODINE CONCENTRATION

The median urinary excretion for the whole country in the present study was 214.7μg/l for the children and 280.1μg/l for the women, which, according to the WHO/UNICEF/ICCIDD (2001) report, indicates a more than adequate iodine intake (adequate iodine intake range is indicated by 100-199μg/l). This median urinary excretion, which ranged from 62.9μg/l to 308μg/l in children and from 124.8μg/l to 371.1μg/l in women in the different districts, indicated mild iodine deficiency to excessive iodine intake. The urinary iodine concentration of women has not previously been assessed in the country. However, the results show a great improvement in iodine excretion of children when compared to previous studies conducted in Lesotho. For example, the median urinary iodine concentration in children aged 10 to 14 years was 13μg/l, indicating severe iodine deficiency in a baseline cross-sectional study in the Mohale dam catchment area (Jooste *et al.*, 1997b). In a recent study the median urinary iodine concentration was 26.3μg/l in children aged 8 to 12 years, which indicated moderate iodine deficiency (Sebotsa *et al.*, 2003).

Analysis of the distribution of the data showed values below 100μg/l in 10.1 percent of the children and in 9.8 percent of the women. Additionally 17.9 percent of the women and 21 percent of the children had urinary iodine excretion below 50μg/l. These values are much lower than 20 percent and 50 percent respectively which are used as criteria for monitoring progress towards eliminating IDD as a public health problem (WHO/UNICE/ICCIDD, 2001). The results of the present study, therefore, indicate that IDD has been eliminated as a public health problem in Lesotho. This shows a positive result since the effects of iodine deficiency occur as a spectrum of abnormalities ranging from normal through sub-clinical conditions to overt neurological and physical abnormalities and cretinism.

The urinary iodine excretion was 99.3μg/l for children and 256.1μg/l for women in the Mountains and 182.7μg/l for children and 329.9μg/l for women in the Lowlands. In addition, a higher percentage of children (12.7%) and women (8.6%) in the Mountains were in the severe iodine deficient range than those in the Lowlands were (3.8% of the children and 3.9% of the women). Furthermore, the median urinary iodine of children in Qachasnek district, which is mostly covered by the Mountain zone, was lower than that in the other districts. These results indicate that there is a greater iodine deficiency in the Mountains than in the Lowlands. This result is similar to results obtained from previous studies conducted in Lesotho. For example, the study conducted by the Ministry of Health (Todd, 1988) showed a median iodine concentration of 55μg/l in the Lowlands and 35μg/l in the Mountains in children aged 6 to 13 years. In a recent study, the urinary iodine concentration was 25.7 in the Mountains and 27.2 in the Lowlands, in school children aged 8 to 12 years (Sebotsa *et al.*, 2003). More children living in the Mountains (17.7%) had urinary iodine concentrations in the severe range of iodine deficiency than did those living in the Lowlands (1.9%) in this recent study. This observation is possibly due to the fact that in the Mountain areas, iodine has been leached away from soil by snow and rain. Also due to the use of non-iodised salt in the Mountains than in the Lowlands. For example, 1.8 percent of households in the Lowlands and 7.6 percent in the Mountains used non-iodised salt in a study conducted in 1999 (Sebotsa *et al.*, 2003). In the present study the median iodine concentration was 40ppm in the Lowlands and 33.1ppm in the Mountains. Furthermore the difference in the severity of iodine deficiency in the Mountains and Lowlands is probably due to the fact that most of the villages in the mountains are inaccessible by road. There is therefore little access to health and nutrition facilities, including IDD education.

Although the median urinary iodine concentration of pregnant women (212.1µg/l) was lower than that of non-pregnant women (283.0µg/l), it indicated a more than adequate intake of iodine. These impressive results showing iodine sufficiency in the most vulnerable group are a major achievement in controlling IDD in the country. Iodine deficiency during pregnancy is of particular concern because iodine deficiency in the foetus and in infants can lead to irreversible intellectual deficits with great impact on a population (Brahmbhatt *et al.*, 2001). A number of studies have shown a significantly increased risk of impaired neurodevelopment in the infants of apparently healthy pregnant women with decreased serum thyroid hormone levels (Li *et al.*, 2001). It has also been shown than the decreased maternal thyroid hormone levels can cause subtle, but significant, psychomotor defects in the children born of these women (Glinoer & Delange, 2000).

The urinary iodine concentration of 5.7 percent of the children and 5.4 of the women were in the severely deficient range (<20µg/l); 4.4 percent of children and 4.4 of the women were in the moderate range (20-49µg/l), and 11.4 percent of the children and 8.1 of women were in the mild range (50-99µg/l) of iodine deficiency. Few children (24.3%) and women (20.1%) had urinary iodine concentrations in the adequate iodine intake range (100-199µg/l). Also few children (18.2%) and few women (14.7%) had urinary iodine concentrations in the more than adequate iodine intake range (200-299µg/l). A high percentage of children (36.0%) and women (47.2%) were in the excessive iodine intake range (300+ µg/l). The results of the present study demonstrate a dramatic shift towards higher values in the urinary iodine distribution compared to previous studies. For example, in a baseline cross-sectional study conducted by Jooste *et al.* (1997b) in the Mohale dam catchment area, 60.3 percent of the children aged 10 to 14 years showed urinary iodine concentrations in the severe range of iodine deficiency. A further 25.5 percent were in the moderate range and 6 percent were in the mild range of iodine deficiency. Only 8.2 percent were in the adequate iodine intake range. Recently, it was found that the urinary iodine concentration of 11.3 percent of the children was in the severely deficient range while 82.6 percent was in the moderate range and very few (6.1%) in the mild range of iodine deficiency (Sebotsa *et al.*, 2003). No children showed urinary iodine concentration in the adequate intake range. In view of the three studies, there is an improvement in iodine intake as indicated by the present study when compared to previous studies.

According to the present study and other studies it seems that the dramatic increase in the urinary iodine concentration is due to the current implementation of the salt iodisation program. The last iodised oil supplementation (each capsule containing 200mg of iodine) was done in 1997 to 1998, more than three years before the present study, which was conducted in 2002. This long duration between the time of supplementation and the time of the present study, confirms that iodised oil supplementation did not significantly affect the urinary iodine concentration, which reflects the current IDD situation. This is based on the fact that a multicentre study in children (Algeria, India, Peru) revealed that 1ml oral oil, which contains 480mg of iodine, provides coverage for 1 year and half of that dose gave satisfactory coverage for 6 months (Benmiloud *et al.*, 1994). However, the same dose (480mg) of iodine lasted 2 years in Zaire (Tonglet *et al.*, 1992).

The most recent previous study was conducted one year before the legislation on universal salt iodisation was promulgated and it indicated moderate iodine deficiency (Sebotsa *et al.*, 2003), while the present study, which indicated a more than adequate iodine intake was conducted two years after the legislation was promulgated. A very high increase in the median urinary iodine concentration and a dramatic shift towards higher values in urinary iodine distribution observed in the present study in comparison with the most recent previous study, indicate the short-term effectiveness of compulsory salt iodisation in controlling IDD in populations. The increased use of iodised salt (98.4%) and of adequately iodised salt (86.9%) in Lesotho is probably the main reason for the sufficient urinary iodine concentrations. Although not statistically significant, the results also indicated a positive relationship between urinary iodine and salt iodisation where more women who had urinary iodine concentration in the adequate iodine intake range used adequately iodised salt (20.3%) and few used non iodised salt (13.3%). Similar results were obtained in South Africa in four schools in the Langkloof area. The median urinary iodine concentrations increased markedly from concentrations indicating mild to severe iodine deficiency at baseline to concentrations well into the replete range after one year (Jooste *et al.*, 2000). Similarly salt iodised at a concentration of 40ppm to 60ppm was found to be effective in eradicating mild iodine deficiency within a period of 4 months in primary school children in the Windsorton district of South Africa (I'Ons *et al.*, 2000).

Some of the values on urinary iodine concentrations reached a potentially damaging value of higher than 1000μg/l. This particular situation cannot be fully explained. Similar results were found in one district (Sukoharjo) in Indonesia, where 0.7 percent of the values were higher than 1000μg/l (Djokomoelijanto *et al.*, 2001). A second survey was conducted in this district after 18 months and the median urinary iodine remained elevated at 346μg/l but none reached 1000μg/l. It was suggested that this resulted from transient superimposition of two programs of iodine supplementation by iodised oil and iodised salt. However, in Lesotho, iodised oil capsules, which were given to the people more than 3 years before the present study, did not affect urinary iodine concentration. The daily intake of iodine containing supplements, the intake of herbal medicine and other iodine rich substances were not investigated in the present study and they might have contributed to the observed high urinary iodine concentrations in a few individuals.

Although there is a great improvement in both the median urinary iodine excretion and iodine distribution in the present study in comparison with the previous study, there is a possibility that a proportion of the population is at risk of developing IIH. According to the WHO/UNICEF/ICCIDD (2001), in populations characterized by longstanding iodine deficiency and rapid increment in iodine intake, median values for urinary iodine above 200μg/l are not recommended because of the risk of IIH. It has also been reported that IIH following iodine supplementation cannot be entirely avoided even when supplementation is of only physiological amounts of iodine and has been reported in almost all iodine supplementation programs (Kahaly *et al.*, 1997). For example in a well controlled longitudinal study in Switzerland, the incidence of hyperthyroidism increased by 27 percent during the year after the iodine supply was increased from 90μg per day to the recommended value of 150μg per day (Baltisberger *et al.*, 1995). Subsequently there was a steady decrease in the incidence of the disorder. Similarly the daily administration of a physiological dose of 200μg iodine to 32 young adults with simple goitre and iodine deficiency resulted in mild and transient hyperthyroidism in one of them (Kahaly *et al.*, 1997). IIH was observed in Zimbabwe where salt was iodised at 30ppm to 90ppm and this resulted in the recommendation that iodisation at the production level be reduced to 20ppm to 40 ppm (Todd *et al.*, 1995). The side effects of iodine excess have not been investigated in Lesotho but some of these effects, especially hyperthyroidism, need to be assessed in future studies for corrective action. Generalized mild and progressive iodine prophylaxis is therefore necessary in Lesotho to counteract the effects of iodine deficiency and IIH.

The occurrence of IIH is probably related to the relative increase, and rapidity of increase, of iodine intake, which occurs when iodised salt is introduced in populations that are severely iodine deficient. According to Delange (1998), the reason is that iodine deficiency increases thyrocyte proliferation and mutation rates. Possible consequences are the development of hyper-functioning autonomous nodules in the thyroid, and hyperthyroidism after iodine supplementation (Dremier *et al.*, 1996). According to the WHO/UNICEF/ICCIDD (2001), IIH can occur in susceptible groups during the 5 to 10 years following the introduction of iodised salt. Beyond this period of time, median values up to 300μg/l have not demonstrated side effects, at least not in populations with adequately iodised salt. It has also been clearly shown that on a population basis, the benefits of correcting iodine deficiency through universal salt iodisation vastly outweigh the risks of IIH (Baltisberger *et al.*, 1995; WHO/UNICEF/ICCIDD, 1996). In consideration of the above, the only challenge left to the IDD control task force in Lesotho is to implement a good monitoring system. This is based on the fact that it has been reported that IIH and other harmful side effects can be almost entirely avoided by adequate and sustained quality assurance and monitoring (Delange, 1998). For example, after the introduction of salt iodisation in 7 formerly severely iodine deficient countries in Africa, IIH occurred in only 2 of them and was not a systematic complication of correction of iodine deficiency (Delange *et al.*, 1999). This complication was found to occur principally because of poor monitoring of the iodine content of iodised salt and of the iodine intake at the population level resulting in a sudden and large increment in iodine intake.

The results on urinary iodine excretion in the present study indicate that iodine deficiency has been eliminated as a public health problem in the country. In comparison with previous studies in Lesotho, there has been a dramatic increase in the urinary iodine excretion, which can probably be attributed to the current salt iodisation program. A proportion of the population, especially those living in the Mountains is, however, still iodine deficient and this situation needs to be addressed. High urinary iodine levels were observed in some women and children indicating a risk of IIH in susceptible individuals. This study therefore confirms that iodine deficiency and the risk of IIH can be addressed by salt iodisation and that regular monitoring of the iodine content of salt should be emphasized to contribute to the sustainability of the program.

5.6 THYROID SIZE AND THE PREVALENCE OF GOITRE

In addition to urinary iodine excretion, which is widely recognized as a valid means for ascertaining the iodine intake in a population, estimation of the prevalence of goitre in an area gives important indications about the severity of iodine deficiency and the necessity of prophylactic measures (Vitti *et al.*, 1994). For this reason, the goitre rate has been frequently used as an indicator of the degree of iodine deficiency in a population (Peterson, 2000). Goitre is usually the most obvious clinical sign of iodine deficiency and is almost invariably the result of inadequate dietary intake (Lamberg, 1993; Delange, 1994). The results from palpation in the present study showed only grade 0 and grade 1 goitres in children and grade 0, grade 1, and 2 in women. The goitre prevalence of 10.7 percent in school children and 19.4 percent in women indicates mild IDD according to the WHO/UNICEF/ICCIDD (2001) (IDD is eliminated when the prevalence of goitre is <5%). This goitre prevalence ranged from 6.6 percent to 22.6 percent in the different districts in children, indicating mild to moderate IDD, and from 6.7 percent to 36 percent in women, indicating mild to severe IDD.

A downward trend has been observed in the prevalence of goitre of children in Lesotho since 1960 where it was found to be 41 percent in school children aged 6 to 13 years, indicating severe IDD (Munoz & Anderson, 1962). Moderate IDD was observed when the goitre prevalence of 27.8 percent in school children aged 6 to 14 years (Salhus, 1962) and 21 percent in school children aged 6 to 13 years (Todd, 1988) was obtained. The national micronutrient study indicated an increase in the prevalence of goitre, where it was 42.5 percent in children aged 6 to 16 years, indicating severe IDD (Wolde-Gebriel, 1993). Recently, goitre prevalence indicating mild IDD (17.5%) and the absence of IDD (4.9%) were observed in children aged 10 to 14 years (Jooste *et al.*, 1997b) and in children aged 8 to 12 years (Sebotsa *et al.*, 2003) respectively. A similar downward trend was also observed in the results of women aged 15 to 49 years where goitre prevalence decreased from 45 percent (Todd, 1988) to 39.4 percent (Worlde-Gebriel, 1993), indicating severe IDD. The prevalence of goitre in the present study (10.7% in children and 19.7% in women) is lower than the prevalence of goitre in the previous studies, indicating a decrease in the prevalence of IDD in the country.

The impressive results regarding the reduction of goitre prevalence are attributed to both the previous iodised oil supplementation (1995 to 1998) and the use of iodised salt, which has possibly increased due to awareness campaigns. This conclusion is based on the fact that oral iodised oil is considered an effective alternative method for reducing thyroid size, particularly in school children and pregnant mothers in endemic goitre areas (Isa *et al.*, 2000). Furthermore, the effectiveness of iodised salt prophylaxis to correct iodine deficiency and reduce goitre prevalence is reported in several studies. For example in Car Nicobar where IDD poses a mild to moderate public health problem, the supply of iodised salt and its iodine content was found to be adequate, that is 82.5 percent had iodine of 15ppm (Mallik *et al.*, 1998). The prevalence of goitre was also shown to have drastically decreased and the median urinary iodine levels were equal or above the cut-off point of 10µg/dl in all countries in a seven-country study in Africa (Botswana, Cameroon, Democratic Republic of Congo, Kenya, Nigeria, Tanzania, Zambia and Zimbabwe) after the introduction of iodised salt (WHO/UNICEF/ICCIDD, 1996). Also in Kenya, the prevalence of goitre in three districts declined rapidly and there was an increase in urinary iodine excretion after the introduction of legislation for salt iodisation (Gitau, 1988). The present study showed that of the women who had grade 2 goitre, more used non iodised salt (6.7%) than adequately iodised salt (1.1%) indicating that salt iodisation is inversely related to the prevalence of goitre. However, considering the slow regression of goitre after the introduction of mandatory salt iodisation (I'Ons *et al.*, 2000; Jooste *et al.*, 2000), the decrease in goitre grade is possibly mainly due to the use of iodised oil capsules and the previous use of iodised salt (Sebotsa *et al.*, 2002; Sebotsa *et al.*, 2003).

The persisting high prevalence of goitre observed in Lesotho is possibly due to the geographical location of the country. About 75 percent of the country is mountainous, where the climate varies from snow to heavy rainfalls and has been indicated that soil and water in Lesotho contain very small amount of iodine (Wolde-Gebriel, 1993). It has been documented that most severe iodine deficiency occurs in mountainous areas where the soil has been washed away by snow, rain and glaciers (Dunn & Van der Haar, 1990) and in lowlands far from the oceans, such as the central part of Africa (Delange, 1994). Secondly, the selenium and iron status of the children and women were not assessed during the present study; however, a recent study conducted in Lesotho indicated early iron deficiency anemia in 22 percent and latent iron deficiency (at risk) in 23 percent of children under the age of five (Mabeleng, 2002). The possibility of these micronutrients affecting the iodine status in Lesotho is based on the fact that several international studies have shown that selenium (Zimmermann *et al.*, 2000b) and iron (Zimmermann, 2002; Hess *et al.*, 2002) deficient children have shown less response to interventions. Selenium deficiency can lower deiodinase activity and adversely affect thyroid metabolism (Beckett *et al.*, 1993) and iron deficiency may alter central nervous system control of thyroid metabolism (Beard *et al.*, 1990).

Where iodine deficiency is endemic, it may affect the entire population with different age groups manifesting different physiological and pathological consequences (WHO, 1993). Studies have shown that the prevalence of goitre increases with age, reaching a maximum after the first decade (WHO, 1993; Delange, 1994). This was observed in the present study where the overall prevalence of goitre was 10.7 for children and 19.4 for women. Several local studies have also confirmed that iodine deficiency in children is characteristically associated with goitre, of which the prevalence increases with age. For example, in school children aged 5 to 15 years, the prevalence of goitre was found to increase with age in both sexes up to the age of 12 to 14 years (Jooste *et al.*, 1997b). Recently, the prevalence of goitre was 3.0 percent for children aged 8 years and 6.3 percent for children aged 12 years (Sebotsa *et al.*, 2003).

The possible reason for the differing goitre prevalence with age is that during adolescence, particularly in girls, a significant increase in the number of hyperplastic glands becomes apparent (Demaeyer *et al.*, 1979, p.73). This is due to an increased demand in the body for iodine. Goitres frequently appear in pregnant and lactating women for the same reason. Furthermore, exposure to iodine deficiency of a mild to moderate degree in childhood causes subtle enlargement of the thyroid gland in the juvenile population that may persist after correction of iodine deficiency (Aghini-Lombardi *et al.*, 1997). The age related decrease in iodine intake, although to a moderate degree, might also be the result of food pattern changes paralleling the observed physiological reduction in energy intake (Valeix *et al.*, 1999). It could also be due to the public awareness of the need for a voluntary reduction in added salt to control hypertension. It would have been very beneficial to assess daily salt intake by the women and children in the present study. However this can be considered in future studies.

The prevalence of goitre was higher in girls (14%) than in boys (7.0%). Other international and local studies have shown that girls have a higher prevalence of goitre than have boys. For example in the Netherlands, the prevalence of goitre among adolescents in 1985 to 1986 varied between 19 and 39 percent among girls and between 7 and 31 percent among boys (Brussard *et al.*, 1997). In India the goitre prevalence was 23.6 percent in females and 9.7 percent in males amongst school children aged 7 to 18 years (Mallik *et al.*, 1998). In Lesotho, similar observations were indicated in most studies conducted since 1960. For example, the total goitre rate was 41.8 percent in females and 40.0 percent in males in school children aged between 6 and 13 years (Munoz & Anderson, 1960), and 46.5 percent in females and 22.5 percent in males in clinic attendants aged 12 years and over (Slobodian, 1987). In 1993 the prevalence of goitre was 34.4 percent in males and 41.6 percent in females in school children aged 6 to 16 years (Wolde-Gebriel, 1993). A study conducted in the Mohale Dam catchment area indicated the prevalence of goitre in school children between 5 and 15 years as 12.4 percent in boys and 20.0 percent in girls (Jooste *et al.*, 1997b). The recent study also indicated a goitre prevalence of 5.4 percent in girls and 4.5 percent in boys (Sebotsa *et al.*, 2003). The observed higher prevalence of goitre in girls than in boys is suggested to be due to the differences in their metabolism of iodine during growth (WHO, 1993).

Similar to urinary iodine excretion, the prevalence of endemic goitre varies from region to region in Lesotho. For example, the prevalence of goitre was found to be higher in the Mountains than in the Lowlands in the present study. Similar results have also been shown in the previous studies on iodine deficiency conducted in Lesotho since 1960 (Munoz & Anderson, 1962; Todd, 1988; Wolde-Gebriel, 1993; Sebotsa *et al.*, 2003). The results were also similar to those of a study conducted in the Asir region in Saudi Arabia where it was found that children of high altitude areas were 2.5 times more likely to develop goitre than their counterparts in low altitudes (Ebu-Eshy *et al.*, 2001). A possible reason for the differences in the prevalence of goitre and iodine deficiency within Lesotho is that some of the villages in the Mountains are difficult to reach by road. There is possibly little access to iodised salt, limited campaigns on IDD awareness and limited supplementation with iodised oil to these areas, as it was observed in the most recent previous study. A higher percentage of children who reported to have never received capsules and those who received iodised oil capsules only once were from the Mountains rather than the Lowlands (Sebotsa *et al.*, 2003). Also, non-iodised salt samples were more obtainable in the Mountains than in the Lowlands

It is alarming to find that a fair proportion of children (10.7%) are goitrous in the present study. Several studies have shown that goitrous children are nutritionally deprived (Pardede *et al.*, 1998) and perform more poorly in exams (Benade *et al.*, 1997) than the non-goitrous children. There is therefore a need to do further study on the mental performance of school children and their nutritional status to investigate the possibility of this group being influenced by iodine deficiency.

The obtained goitre prevalence (19.4%) from the women indicating mild IDD is also of great concern. It has been reported that goitres, unless so large that they interfere with the airways, are generally harmless in themselves but they indicate a risk of more severe IDD (Filteau *et al.*, 1994). For example, iodine deficient women of childbearing age may have poor reproductive performance or may give birth to cretins. Even in the absence of such devastating consequences of iodine deficiency, there is evidence of more modest intellectual and neuromotor impairment. Although not clinically obvious such modest mental slowness or apathy could have serious consequences for development in poor countries by affecting literacy or other programs as well as motivation for improving living conditions. Grade 2 goitres observed in women are of particular concern due to the high hospital costs of surgical removal of visible goitres.

Despite the high urinary iodine levels indicating more than adequate iodine intake, there is still a considerable goitre prevalence indicating mild IDD in the present study. Two factors may be responsible. Firstly, it has been stated that dietary iodine deficiency is usually the primary cause of endemic goitre, but other factors such as goitrogens, drug side effects, Vitamin A deficiency and PEM may also induce the development of goitre (Authur *et al.*, 1993). However, in view of poor iodine status reflected by low urinary iodine excretion of mild to moderate deficiency (21.5% of the children and 17.9% of the women), it is evident that an inadequate iodine intake was the major cause of the goitres in the present study. Secondly, in high IDD areas where iodine intake is improving, it may well be that the iodine status reflected by urinary iodine content is changing faster than is indicated by the goitre (Muslimatun *et al.*, 1998). For example, in China the prevalence of goitre declined gradually, while the urinary iodine increased sharply within one year in a group purchasing iodised salt at different iodine content (Zhao *et al.*, 1999). It could thus be accepted that the regression of goitres occurs gradually over a number of years after the introduction of a national salt iodisation program.

Other possible reasons for the causes of goitre rate indicating mild iodine deficiency in the face of generally high urinary iodine concentrations may include a lesser effectiveness of iodised salt prophylaxis in reducing the size of goitres of children exposed to iodine deficiency in the first years of life (Aghini-Lombardi *et al.*, 1997; Delange *et al.*, 1999). Also, goitres in adult women appear to change slowly, if at all (Jooste *et al.*, 1997a; Zimmerman *et al.*, 2003). In adults, after a long-standing iodine deficiency, serum TSH levels fall or become suppressed due to functional automy, that is, latent or overt thyrotoxicosis (WHO, 1994). Following iodine supplementation, TSH normalizes in only a fraction of the adult population. Lastly, the large majority of goitres reported in women and all goitres in children, were of grade 1 for which the accuracy of the determination is relatively low especially when the palpation is performed by different observers. It has been documented that palpation is reliable when thyroids are grossly enlarged and it is inaccurate in distinguishing mild thyroid enlargement from normal thyroid size (Dunn, 1996; Vitti *et al.*, 1994).

Ultrasonographic estimation of thyroid size has been advocated as being more precise than palpation (Peterson, 2000). Discrepant data between palpation and ultrasound has been found in many international studies. For example, in Italy 11.2 percent of subjects from the iodine deficient areas who were judged as goitrous by palpation, had normal thyroid volume by ultrasound, and 12.7 percent of subjects with an abnormal thyroid volume by ultrasound were judged non goitrous by palpation (Vitti *et al.*, 1994). Therefore, due to high misclassification between and within examiners, some investigators have dismissed palpation as a method of diagnosing goitre.

Examinations with ultrasonography are, however, cumbersome and costly to carry out in remote parts of low-income countries where goitre surveys are mostly needed. Also, ultrasonography of thyroids in women or adults in general is not recommended because there are no international references for these groups (Sullivan *et al.*, 2000). Therefore, in the absence of ultrasonography, clinical examination of thyroid size by palpation and classification into goitre grade 0, 1, and 2 provides an acceptable and simple alternative (Hetzel, 2000, p.164). Thyroid palpation in school children is a cost-effective way to assess the iodine status of a population if the palpation system is precise and easy to apply (Peterson *et al.*, 2000). It is also most useful as an initial signal that IDD may be present and as an indicator that more refined assessment is needed (Hetzel, 2000, p.164). Therefore, because ultrasonography is not available, palpation is taken as a useful indicator to establish the baseline severity of IDD.

Taking the invalidity of palpation into consideration, the experienced field workers were recruited for the present study, retrained before the study and during the study the inter-observer variation in performing palpation was assessed. A high correlation was observed in most of the teams (3 out of 4 teams) where the Kappa values were above 0.80. These results support the idea that training and experience are important for the validity and reliability of the palpation method. The concurrence of goitre grades obtained by two observers in some teams (1 and 2) in the present study, was, however, not good as regards women (0.54 for team 1 and 0.68 for team 2) as it was with the children (0.89 for team 1 and 0.69 for team 2). Vitti *et al.* (1994) also found that a higher frequency of overestimations and underestimations of goitre by palpation occurred in older age groups. It was suggested in this study that conditions that may cause underestimation include prominent neck muscles or abundant neck adipose tissue, while a slim neck may cause overestimation. This suggestion is regarded as the possible cause of the little concurrence obtained between some observers in the present study.

Goitre prevalence assessed by palpation has been used in Lesotho to assess IDD situation. Taking the invalidity of the palpation method and the fact that thyroid size decreases slowly with salt iodisation, the results of the present study will be used to follow the trend in the prevalence of IDD in the country. Although severe to mild IDD has been indicated in the previous studies a decrease in the prevalence of goitre has been observed.

The results of the present study indicate that the prevalence of goitre in both the children and women in the country demonstrates mild IDD. Goitre grade 0 and 1 were observed in children while goiter grade 0, 1 and 2 were observed in women. Compared to previous studies, the prevalence of goitre in the country has decreased possibly due to the use of iodised oil capsules and the previous use of iodised salt, which was attributed to awareness campaigns. The salt iodisation program has had a minimal impact due to the fact that studies have shown that the regression of goitre takes longer time after the introduction of iodised salt. Relative to previous studies conducted in the country the prevalence of goitre has decreased dramatically. Consistent with other international and local studies, the prevalence of goitre was higher in the Mountains than in the Lowlands, higher in girls than boys and increased with age. According to the present and other studies, the reduction in the prevalence of goitre in both the children and women in the country was most likely attributable to salt iodisation.

5.7 SUSTAINABILITY OF IDD CONTROL PROGRAM

Although urinary iodine excretion achieves the goals of sustainable elimination, salt iodisation and the programmatic indicators of sustainability do not. Some salt samples were not adequately iodised at household level. The 86.9 percent, which is coverage in the household use of adequately iodised salt, is slightly below the recommended 90 percent. Only 4 instead of at least 8 of the programmatic indicators are attained. The attainment of the indicators was based on the information given by one person and very few documents were available to support the information. Also the answers were not rated or scored and therefore each the answer for each question was elaborative. The information obtained from the assessment of the indicators was therefore used in the present study to give a general overview of the operational activities of IDD elimination. It is therefore suggested that more specific questions be used and more people be involved in contributing to giving answers during future studies. The results in the present study indicate that salt iodisation, which is the current IDD control program should be strengthened to ensure sustainability.

A considerable amount of salt samples at household level are not adequately iodised at household level. The coverage in the adequately iodised salt was more than 90 percent (93.7%) for fine salt while it was lower than 90 percent (60.5%) for coarse. Therefore coarse salt is responsible for the average coverage percent not reaching the recommended 90 percent. This is due to the fact that some coarse salt is not iodised during production because legislation in South Africa does not include compulsory iodisation of salt packed in bags of 20kg or more, which is coarse salt meant for animal consumption. In Lesotho, this coarse salt meant for animal consumption is used also for human consumption. The present study and the study conducted in South Africa (Jooste, 2001) have shown than coarse salt can also be as effectively iodised as fine salt. However, under iodisation at production site is a major problem because some salt samples labeled "iodised salt" contained very little iodine (1-14ppm).

The loss of iodine during distribution also affects the availability of adequately iodised salt at household level and consequently causes low iodine intake. Storage conditions of salt, which differ considerably in the country (Sebotsa *et al.*, 2002), might have contributed to loss of iodine in salt through exposure to sunlight, heat and humidity (Ranganathan & Narasinga, 1986; Stewart *et al*, 1996). Effective monitoring of salt iodisation at all levels with special attention being given to coarse salt is therefore very important for sustainable elimination of IDD in Lesotho.

With regard to programmatic indicators of sustainability, there is no commitment to assessment and reassessment of progress in the elimination of IDD. At present, there are two laboratories which can be used for both salt and urine analysis; one is at the central hospital and the other at the National University of Lesotho (NUL). The central laboratory is very busy because it is in the only referral hospital in the country and analysis of blood and urine specimens for all the referred patients from all the districts are performed. The laboratory at NUL is only available when the university is closed for lectures, which is in December and in May to July.

A major draw back is that the laboratory at NUL, which is the only available laboratory for both salt and urinary iodine analysis, is not quality assured at every level. Quality assurance in the urinary iodine analysis is of great importance (Sullivan *et al.*, 2000, p.44) because urinary iodine analysis results are used when assessing the overall biological impact of IDD elimination and salt iodisation programs. It is also important for salt analysis, especially when salt iodine test data is to be used for iodine deficiency program evaluation and monitoring (Mannar & Dunn, 1995, p.11). Although quality control within the laboratory is done efficiently, external quality control has never been done. This is of concern because participation in an external control exchange program is an important independent means of assessing laboratory performance. In addition to this problem there is lack of personnel for analysis of urinary iodine in Lesotho since only one person was trained at the Medical Research Council in South Africa (Cape Town) for urinary iodine analysis. Therefore the micronutrient task force has to rely on the availability of this officer who is also employed full time at NUL and has a very busy work schedule. Due to these problems, salt and urine samples have been sent to South Africa for analysis and as it is very costly to transport samples from Lesotho to South Africa, regular analysis of salt and urine sample is not done in Lesotho.

In addition to problems of chemical analysis, there is no database for recording the results. The written reports from studies funded by both government and UNICEF (which is the only bilateral agency interested in IDD in Lesotho) are kept at the FNCO resource centre and this is below standard. Some of these reports are missing and for some only one copy is available, making it very difficult to obtain information. Copies of the reports available at UNICEF resource centre are only those of studies funded by UNICEF. The lack of a database for recording of the results makes it difficult to track change in IDD issues in the country.

The government in Lesotho is elected every five years and within the five years the Prime Minister is mandated to change the Ministers and the Principal Secretaries of the Ministries if necessary. Because of the lack of an effective awareness program, the policy makers have not been made aware of IDD issues. This has lead to lack of commitment to elimination of IDD by political leaders. Similarly, at entry point level and retail level, the customs officials and health inspectors are no longer doing random and regular spot checks. The main reason is that new officers who are probably not aware of the legislation and IDD have been employed. These officers needed training and the IDD control task force was not able to do this because of lack of funds for this activity. Additionally salt iodine test kits have expired and due to administrative issues, it has taken a long time to procure the new test kits and these test kits were still not available during the present study.

This study showed that of all sustainable indicators, only the urinary iodine concentration achieved the sustainability goals. Some salt samples, which were mostly coarse salt, were not adequately iodised at household level. This is possibly due to non-iodisation and under-iodisation at production sites. The programmatic indicators of sustainability indicate that there is not sufficient commitment to salt iodisation in the country. The results therefore suggest that the salt iodisation program has improved considerably over the last decade, but it requires additional programmatic inputs and monitoring of salt iodine content to ensure sustainability.

CHAPTER 6: CONCLUSIONS AND RECOMMENDATIONS

This chapter gives a brief general conclusion from the findings of the present study, followed by recommendations based on the findings. The estimates in the findings should be considered as representative of the situation in Lesotho because of the high response rates of both the school children and the women achieved in this study and high school attendance rates reported by Head Teachers. The sample was selected based on international recommendations and the sample size obtained was adequate to make conclusions. The methods used were also valid and reliable. The current IDD status and salt iodisation are evaluated to make the best possible recommendations to the benefit of the country.

6.1 CONCLUSIONS

6.1.1 SALT IODISATION AND CURRENT IDD STATUS IN LESOTHO

The results of the present study indicate a major achievement in the household use of iodised salt (98.4%) and use of adequately iodised salt (86.9%). However, most of the salt samples were not within the Lesotho legal requirements of salt iodisation, namely 40ppm to 60ppm of iodine. Only 25.2 percent of salt samples at entry point level (median of 36.2ppm) and 33.3 percent (median of 37.3ppm) at retail level were within the Lesotho legal requirements. This is possibly due to non-iodisation, non-uniformity and under-iodisation of salt at production side. The non iodisation, under-iodisation and lack of uniformity in salt iodisation observed in the present study illustrate the importance of monitoring salt iodine levels at production sites and entry point level. Although the present study indicates a decrease in the availability of non-iodised salt in comparison with previous studies, its availability (1.6%) is still of, particular concern because legislation in Lesotho does not allow non iodised salt to enter the country. The results showing the use of salt that is not adequately iodised at household level and the availability of non-iodised salt suggests that the presence of the legislation does not guarantee success of the program. A successful program necessitates enforcement of the legislation. The findings of the present study, therefore, reinforce the basic principle of a salt iodisation program. This principle clearly stipulates that the program must be well monitored and carefully controlled to minimize the risk of IIH and to prevent iodine deficiency (Djokomoeljanto *et al.*, 2001). Salt iodine levels should be set at the lowest level that will prevent IDD while minimizing the risk of IIH, and adjusted to ensure the median urinary of 100 to 199 μg/l in the population (Hess *et al.*, 1999).

The median urinary excretion for the whole country in the present study was 214.7μg/l (ranging from 62.9μg/l to 308μg/l in the different districts) for the children and 280.1μg/l (ranging from 124.8μg/l to 371.1μg/l in the different districts) for the women. These median urinary values indicate a more than adequate iodine intake according to the WHO/UNICEF/ICCIDD (2001) report. On the contrary the goitre prevalence of 10.7 percent (ranging from 6.6% to 22.6% in the different districts) in school children and 19.4 percent (ranging from 6.7% to 36%) in women indicates mild iodine deficiency (WHO/UNICEF/ICCIDD, 2001). The prevalence of goitre is lower compared to previous studies. These results showing the similarity between the results obtained from the children and the women prove the fact that primary school children are a good reflection of their community.

However, there is a lack of association between goitre and urinary iodine concentration. The lack of association between the two variables can be explained by the fact that urinary iodine excretion reflects recent iodine ingestion and can change within days with a variation in dietary iodine, while goitre reflects a longer past exposure to iodine deficiency (Muslimatun *et al.*, 1998). In particular, in countries in which the iodine status is improving due to an effective IDD control program, a discrepancy between both indicators must be expected. The large variation between the two variables in the present study can also be due the invalidity of the palpation method used to assess thyroid size, especially when thyroids are not too enlarged as observed in the present study. These findings confirm the results of other studies, which suggest that in areas with a long lasting history of iodine deficiency, the prevalence of goitre does not necessarily revert to normal despite over-correction of iodine deficiency (Delange *et al.*, 1999). In addition, that much more time is required for correcting the prevalence of goitre than correcting urinary iodine after the implementation of universal salt iodisation.

Urinary iodine excretion was taken as an important variable in this study to indicate the current IDD situation in Lesotho. This decision was based on the fact that urinary iodine analysis is the most common biochemical method used for assessing the iodine status of populations and therefore plays an important role in public health surveillance in many countries (May *et al.*, 1997). Also, success or failure of the IDD elimination program is based primarily on the urinary iodine results (Sullivan *et al.*, 2000, p.35). Furthermore, the regression of goitres occurs gradually over a number of years after the introduction of a national salt iodisation program (Jooste *et al.*, 1997a; Zimmermann *et al.*, 2003) and cannot be relied upon to reflect accurately current iodine intake although they may be useful in following trends (WHO/UNICEF/ICCIDD, 2001). The median urinary iodine concentration, which was 214.7μg/l for the children and 280.1μg/l for the women, for the whole country, indicates a more than adequate iodine intake (WHO/UNICEF/ICCIDD, 2001). The results of the present study results show a great improvement in urinary iodine excretion when compared to previous studies, which indicated mild to severe iodine deficiency.

According to the WHO/UNICEF/ICCIDD (2001), an indication of iodine deficiency posing no public health problem consists of a median value for urinary iodine concentration being greater than or equal to 100 μg/l in more than 50 percent of the population samples, and in addition, no more than 20 percent of the population samples should be below 50 μg/l. In the present study, the median urinary iodine concentration of 21 percent of the children and 17.9 percent of the women was greater than 100 μg/l while the median urinary iodine concentration of 10.1 percent of the children and 9.8 percent of the women was greater than 50 μg/l. Based on these results and the WHO/UNICEF/ICCIDD (2001) criteria, iodine deficiency is no longer a public health problem in Lesotho.

Although the present study is not fully comparable with the past studies due to differences in sampling, it indicates a remarkable increase in the urinary iodine concentration after the introduction of universal salt iodisation legislation. 78.5 percent of the children and 82.1 percent of women were found to be iodine replete. Data from the present study clearly indicates that IDD has been eliminated as a public health problem in Lesotho and indicates the high rate of success of the salt iodisation program. More importantly, the results prove the short-term effectiveness of universal salt iodisation in increasing urinary iodine excretion. The findings also suggest that in developing countries like Lesotho, salt iodisation appears to be the most effective means of addressing IDD. The districts and the ecological zones where severe iodine deficiency was observed need further follow up to determine whether the results represent a steady state in urinary iodine concentration or whether further improvement can be achieved over a longer period of exposure to adequately iodised salt.

The large proportion of women (51.9%) and children (44.2%) who had urinary iodine concentrations above 200μg/l indicate that the susceptible population in Lesotho is at risk of developing IIH. It has been stated that IIH associated with iodine prophylaxis programs in developing countries is probably an important, underestimated, and neglected problem (Bourdoux *et al.*, 1996). This is probably because recognition of the disease is difficult clinically and requires biochemical tests that are not available in most developing countries. However, a multicentre African study implicated inadequate monitoring of iodine intake and the salt industry in the increased incidence of IIH following salt iodisation (WHO, 1998). Therefore, to reduce the risk of IIH in Lesotho, the immediate implementation of an effective monitoring program in the country is necessary.

6.1.2 SUSTAINABILITY OF IDD CONTROL PROGRAM

The results of the present study indicate that, although the urinary iodine concentration reaches the WHO/UNICEF/ICCIDD sustainability goals, IDD elimination in Lesotho requires additional programmatic inputs to ensure sustainability. Some of the households used salt that is not adequately iodised and most of this salt was coarse salt. 86.9 percent of households instead of the recommended 90 percent or more used adequately iodised salt. Non-iodisation, under-iodisation at production sites and loss of iodine in salt during distribution are probably the main reasons for some salt samples not being adequately iodised at household level. Of the 10 programmatic indicators of sustainability, only 4 are attained, which is below the recommendation of attainment of at least 8 indicators. The 4 indicators attained are:

1. Existence of an effective, functional national body responsible to the government for the national program of IDD.
2. Appointment of a responsible executive officer for the IDD elimination program.
3. Legislation on or regulation of universal salt iodisation.
4. Cooperation from the salt industry in maintenance of quality control.

The findings on the sustainability of the program suggest that after IDD control has been implemented, there is still a lot of work to be done to ensure that the program is sustainable.

A major threat when an iodisation program is not sustainable is that IDD will reappear. In several developed and developing countries, in which iodine deficiency was eliminated, it recurred because of a lack of vigilance and a breakdown in the continuation of the intervention (Li *et al.*, 2001). Therefore the present study calls for an immediate need for permanent and sustainable elimination of iodine deficiency in Lesotho, which requires collaboration among private salt producers and the IDD control task force to promote and monitor the use of iodised salt. To ensure continued success of an established salt iodisation program in the country, regular monitoring of urinary iodine and other biological measures of iodine nutrition should be critically considered.

6.2 RECOMMENDATIONS

6.2.1 ENSURING SUSTAINABILITY OF AN IDD CONTROL PROGRAM

Political support, administrative arrangements and assessment as well as a monitoring system are the three major components required to consolidate the elimination of IDD and to sustain it permanently (WHO/UNICEF/ICCIDD, 2001). Based on these components it is recommended that a concept of "re advocacy", which underlines the need for continuous political commitment (Ling, 2003), be introduced as the first step to sustainable elimination of IDD in Lesotho. Although governments are in power for a period of five years in the country, past experience has shown that changes in Ministers' and Principal Secretaries' posts happen within the five-year periods. It is therefore important to for the IDD control and Micronutrient task forces to initiate a continuous awareness program to ensure that the newly appointed policy makers are aware of IDD and to solicit their support. The policy makers should be made aware that IDD cannot be eradicated in one great global effort as it is a result of a deficiency of iodine in soil and water and can therefore return at any time after their elimination if control programs fail. Emphasis should be given to the economic aspects of IDD work against brain damage and impaired learning.

It has been stated that political support for the elimination of IDD depends on community awareness and understanding of the problem (WHO/UNICEF/ICCIDD, 2001). To overcome this challenge, a strong will, wider awareness and cooperation should be taken as the key solutions to sustainable elimination of IDD in Lesotho. Although the knowledge, attitude and practices of the people with regard to salt was not evaluated in the present study, it is believed that the awareness campaigns, which started in 1994, were effective because studies indicated an increase in the use of iodised salt even before the legislation was promulgated (Sebotsa *et al*, 2002; Sebotsa *et al.*, 2003). The media coverage for elimination of IDD is at present inadequate since only pamphlets, posters and booklets are being distributed and this distribution occurs at a very slow rate. Therefore media coverage should be accelerated and broadened by the IDD control and Micronutrient task force to reach each and every person. Radio slots should be arranged with the four current existing local radio stations, where "phone in" programs should be done at least once a week so that people are allowed to ask questions and be answered directly. The local newspapers should also be approached. There, should be a quarterly national campaign to inform the policy makers and the public about IDD and the use of iodised salt, emphasizing its benefit to the children's development and learning ability. Proper methods of salt storage at household level should be included in the messages. Furthermore the IDD messages should be included in the curriculum of primary schools, secondary schools, high schools, the National Teachers Training College and the National University of Lesotho. School competitions conducted once a year will create more interest under students and the community regarding IDD prevention and control in the country.

Administratively, the IDD control task force, which is multi-sectoral and coordinated by the FNCO, needs to be strengthened. The terms of reference for the IDD control task force should be reviewed to emphasize the role of monitoring the IDD status, education of the public, salt iodisation and law enforcement. An officer from Ministry of Communication should join the task force team to ensure that proper channels exist for the awareness program and that awareness does not decrease as has happened. The presence of this officer will ensure proper communication channels between the policy makers, IDD control task force and the salt industry. Members of the task force should be assigned to different areas of responsibilities such as assessment of progress, enforcement of the legislation and education and communication. Assignment of the responsibilities will create a feeling of ownership of the program and motivate the members to ensure that the program does not fail. More important is the training of new members of the task force team on IDD issues.

Customs officers and health inspectors need to be trained since new officers have been employed. This training should emphasise regular monitoring of salt samples using the spot test kits where suspect salt should be taken for more qualitative analysis and non iodised salt be confiscated. Salt is used by Roads department in the Ministry of Works to melt snow on the tarred roads in the Mountain areas during winter. Therefore the confiscated salt can be taken to this department. Salt that does not meet the legal recommendations for Lesotho should be noted and the salt producers be approached and be shown the importance of salt iodisation which will benefit the consumers for IDD elimination and the increase the market for the producers. There has not been any communication between the Lesotho and South Africa authorities. After the awareness to the policy makers the authorities and the IDD control bodies in both countries should communicate and work with the salt industry to ensure effective salt iodisation. The IDD control task force must make sure that spot test kits are always available and not expired. The responsibility for procurement of these test kits and training activities must be put to the FNCO so that it will make sure that this are included in the government budget to avoid relying solely on donors for funds. In this way, work will go smoothly because the FNCO is placed directly under the Prime Minister's office where there are open channels for administrative issues.

Assessment and monitoring of the program needs laboratories and the production of assurance charts and databases (WHO/UNICEF/ICCIDD, 2001). The Laboratory at the NUL should be expanded, quality assured and more personnel be trained on both salt and urine analysis. The government funds allocated for prevention of micronutrient deficiencies, together with funds from UNICEF and other bilateral agencies such as WHO, should be used to invest in ensuring quality analysis of the samples. Salt is not produced in the country and this highlights the importance of the IDD control task force liasing with the salt industry in South Africa to ensure both internal and external quality control. Iodine content should be monitored at entry point, retail level and household level. Special attention should be paid to the iodine content of coarse salt.

Periodic evaluation of the impact of salt iodisation, which includes assessment of urinary iodine levels, is also crucial. Evaluating factors that have led to successful implementation of IDD programs, so that these can be replicated in areas where progress is lagging or be used to model success in other nutrition or public health programs is necessary. The Ministry of Agriculture is planning to have a national database and the Research subcommittee, which is coordinated by the FNCO, is planning to introduce a surveillance system in the country this year. The IDD control task force should liase with the committees to ensure that IDD is included in the national database and national surveillance system. In addition the FNCO resource centre should be upgraded to ensure availability of information regarding the cause, prevalence and prevention of IDD to the public.

The principal challenge to sustainable elimination is the permanent intervention of adequate dietary iodine intake (Li *et al.*, 2001). Because dietary iodine supply is influenced by a number of commercial, agricultural and cultural factors (Hess *et al.*, 2001), regular monitoring of iodine nutrition through iodised salt and other food sources of iodine, as well as herbal medicines and drugs containing iodine, is necessary. Periodic surveillance and prudent adjustments to the iodine level in salt has maintained adequate iodine nutrition in Switzerland. Also, in a multicentre African study, inadequate monitoring of iodine intake and the salt industry was implicated in the increased incidence of IIH following salt iodisation (WHO, 1998). Therefore, with the FNCO as the coordinator, the Micronutrient task force, the IDD control task force and the Research subcommittee should ensure periodic monitoring of adequate intake of iodised salt. This should include assessment of the iodine content of regularly used processed food. Clusters or villages representing the country should be selected and taken as sentinel sites for regular assessment of iodine status.

The clinical assessment of goitres in the present study and recent previous studies in Lesotho has indicated that grade 1 goitres are more prevalent. However, the invalidity of the palpation method when goitres are small has been documented (WHO/UNICEF/ICCIDD, 2001). Therefore the use of ultrasonography and other biological measure of iodine nutrition should be considered and the necessary equipment be purchased. For example, blood should be analysed for thyroid function (FT4, FT3, TSH and Tg) and cord blood TSH levels for neonatal hypothyroidism. This analysis should be done because if infants with congenital hypothyroidism are not identified and treated very soon after birth, when they become dependent on their own thyroid secretion, they will become permanently mentally retarded (Mohapatra *et al.*, 2001). However, before, routine screening for hypothyroidism in pregnant women is introduced, efforts should be made to increase dietary iodine intake, where the beneficiaries would be not only pregnant women and their offspring, but everyone. The cost of these proposed monitoring methods is very high and can only be achieved by prioritizing IDD interventions in the country and not implementing all the methods at once. The equipment and can be purchased at least each year using funds from both the government and donor agencies.

A nationwide effort to promote iodised salt and to provide women of childbearing age with advice on dietary sources of iodine should be implemented by community health workers, nutritionists and other extension workers. A sustained awareness campaign throughout the country is necessary. Customs officials, in collaboration with the Micronutrient taskforce, the IDD control task force and Health inspectors, must also ensure that only adequately iodised and properly packaged salt is available. In view of the general susceptibility of low socio-economic groups to iodine deficiency, it is of great importance that coarse salt, which is used by most households in this segment of the population, is optimally iodised at production sites to ensure adequately iodised coarse salt at household level.

This study should be taken as the first of a series of national surveys, which will monitor and evaluate the iodine status of the Lesotho population. The salt iodisation program should be monitored and iodine levels in salt adjusted periodically to ensure a median urinary iodine excretion of 100 to 199μg/l (Delange *et al.*, 2001), which indicates adequate iodine intake. Iodine levels in salt should be set at the lowest level that will prevent all manifestations of IDD while minimizing the risks of IIH; however there is no level of iodine in salt that offers complete protection against some increase in the incidence of hyperthyroidism in a previously iodine deficient population (WHO/UNICEF/ICCIDD, 1996). Therefore, optimal iodine intake should be brought to a level at which it can prevent cretinism and endemic goitre, but not much higher (Corvilain *et al.*, 1998). This level is, however, difficult to assess because of two opposite constraints: the need to provide a sufficient iodine supply during foetal life and childhood and the need to reduce iodine incorporation in autonomous thyroid glands, in view of their inability to compensate for an excessive iodine uptake. The best approach may, therefore, be generalized mild and progressive iodine prophylaxis. In order to determine the appropriate level of iodine to be added to salt in a salt iodisation program, an estimation of the habitual salt consumption in the population is essential (Hess *et al.*, 2001). Therefore the amount of salt taken daily should be assessed in Lesotho.

The current legislation is flexible in that it specifies a range of 40 to 60 ppm for salt iodisation, therefore the Micronutrient task force and the IDD control task force can adjust the levels based on new scientific evidence without the need for a lengthy parliamentary process. The information collected during the quality control assessment suggests that the South African salt industry is in a strong position to supply the required amount of iodised salt to the market to achieve the goal of at least 90 percent of households using adequately iodised salt countrywide before the year 2005 (Jooste, 2001). Hopefully Lesotho is going to benefit from this optimal iodisation because the present study indicates that some households use salt that is not adequately iodised. However, monitoring salt iodine concentration at entry point level should never be stopped.

6.2.2 FURTHER STUDIES

In Tanzania, the urinary iodine concentration of women indicated moderate and mild iodine deficiency while that of children was normal (Sundqvist *et al.*, 1998). Therefore assessment of iodine status in vulnerable groups other than school children such as pregnant women and neonates is critical to reduce the risk of brain damage and subsequent intellectual impairment. Affected babies should be followed up and treated if necessary.

Although iodine deficiency can be regarded as the major cause of endemic goitre, its degree does not always account for the severity of the endemia. Additional factors that can contribute to goitre, in particular when the iodine supply is close to the borderline of the requirement, include goitrogenic substances in food and bacterial pollution of water supply, some micronutrient deficiency (e.g. selenium, ion and vitamin A) and PEM. Therefore, in some regions where the goitre prevalence is still significantly high, the role of goitrogens such as the possible goitrogenic effects of some members of the Brassica group such as cabbage, and other micronutrient deficiencies in the etiology of goitre, need to be examined. If endemic goitre persists and goitrogens have been found not to play a significant role, thyroid dysfunction should be checked. The nutritional status of the population, especially that of the children, should be included during the studies.

Studies have shown that iodine deficiency occurs as a spectrum of abnormalities ranging from normal through sub-clinical conditions to overt neurological and physical abnormalities and cretinism (Hetzel, 1993). Mental performance of the school-age children should be assessed. Measurements and evaluation of exam marks are important, easy and non-expensive variables, which show the effects of iodine deficiency and they should, therefore, be included in future studies.

It has been stated that some people in some countries now have iodine intakes that are unnecessarily high and that this may occasionally be associated with IIH (WHO, 1996). The prevalence of IIH should also be investigated in Lesotho especially after the enforcement of the universal salt iodisation legislation. Primary health care personnel should be trained and equipped to recognize and manage the anticipated increase in patients with IIH. This recommendation is based on the fact that IIH is possible during iodine supplementation, therefore if there are enough funds the health care workers can be trained.

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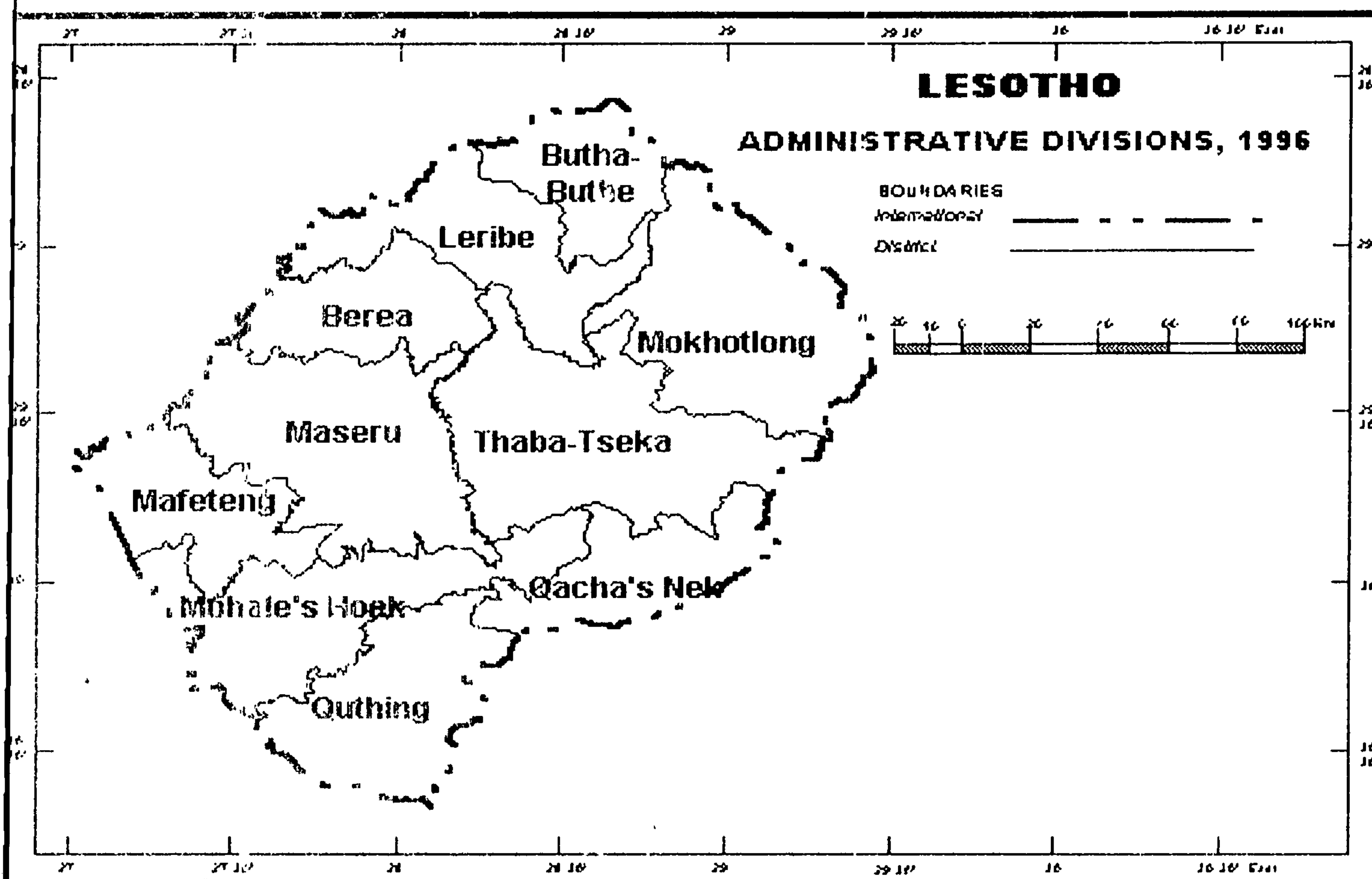
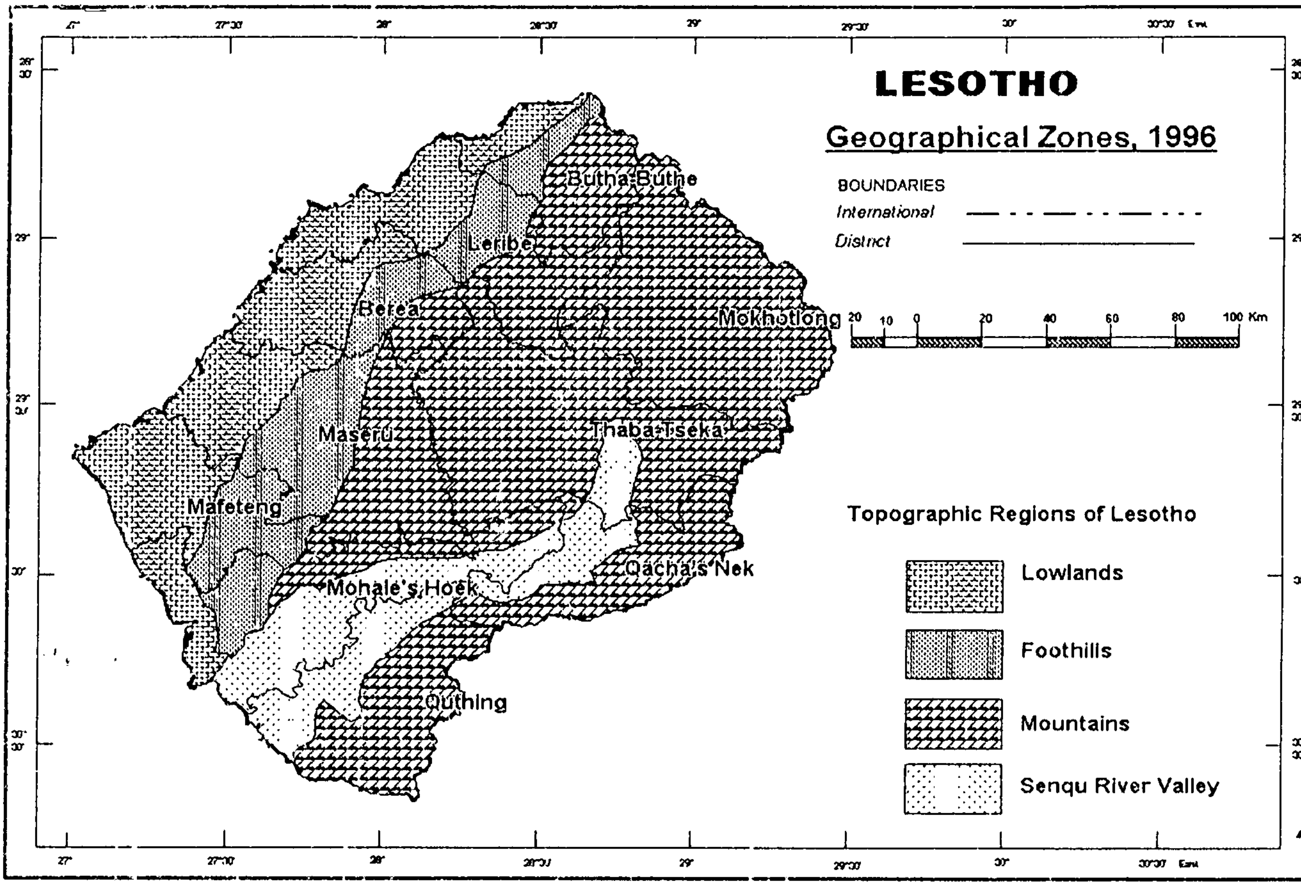
APPENDICES

APPENDIX 1: The administrative districts of Lesotho



APPENDIX 2: The ecological zones of Lesotho



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CONTENTS

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LEGAL NOTICE NO. 13 of 1999
Lesotho Iodization Regulations, 1999

Pursuant to section 71 of the Public Health Order 1970[1], I,

VOVA BULANE

Minister of Health, make the following Regulations:-

Citation and commencement

1. These Regulations may be cited as Lesotho Salt Iodization Regulations, 1999, and shall come into operation on the date of publication in the Gazette.

Interpretation

2. In these Regulations, unless the context requires otherwise,
"food grade salt" means salt containing not less than 97% crystalline sodium chloride on a dry matter basis, including table salt and coarse salt;
"impermeable packaging material" means material which may consist of one or more of the following substances: low density polyethylene, high polyethylene, woven polypropylene or similar materials, and includes polycoated cardboard;
"iodated salt" means food grade salt or other salt intended for human and animal consumption to which between 40 and 60 ppm (mg/kg) iodine in the form of potassium iodate has been added;
"low sodium salt" means salt containing less than 67% sodium chloride;
"the Order" means the Public Health Order, 1970, Order No. 12 of 1970, and any expression to which a meaning has been assigned in the Order shall bear that meaning;
"table salt" means salt that contains no more than 4% moisture and 40-60 ppm (mg/kg) fluoride and not less than 98.4% sodium chloride in its water free state.

Requirements

3. A manufacturer shall ensure that:-

(a) food grade salt or other salt intended for human or animal consumption which is imported into Lesotho shall contain between 40 and 60 ppm (mg/kg) iodine and labeled "iodated salt";
(b) iodated salt is to be packed in sealed impermeable packaging material with a lining of high density polypropylene;
(c) the date of iodation is to be indicated on the label of the product together with other information such as lot or batch number, manufacture date, expiration date of the salt and net weight thereto.

Random check tests

4. 1) Health Inspectors shall conduct and administer random check tests at retail

level to monitor salt iodine quality and levels.

2) Customs and Excise officials shall conduct random check tests at all ports of entry into Lesotho to monitor salt iodine levels on all imported salt.

Offences

5. (1) No person shall –

(a) import into Lesotho; or
(b) sell,

food grade or other salt intended for human or animal consumption unless iodine has been added thereto.

(2) A person who contravenes the provisions of sub-regulation (1) commits an offence and is liable on conviction to a fine not exceeding one thousand maloti or imprisonment for a period not exceeding one year, or both fine and imprisonment.

(3) In addition to a fine or imprisonment imposed under sub-regulation (2), the Health Inspectors shall confiscate such salt.

Exemptions

6. These Regulations shall not apply to food grade salt or other salt intended for-

(a) use in the manufacture of compound food stuffs which is packed in bags of 20 kg or more and labeled "non-iodated salt"; or

(b) experimenting purposes

DATED:

V. Bulane
Minister of Health

NOTE

1. Order No. 12 of 1970

APPENDIX 4: The legislation on salt iodisation in South Africa

Act 54 of 1972 G.N.R. 996/1995

FOODSTUFFS, COMESTICS AND DISINFECTANTS REQULATIONS

No. R.996: 7 July 1995

REGULATIONS RELATING TO SALT

The Minister of Health has, in terms of section 15 (1) of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act No. 54 of 1972), made the regulations in the schedule.

SCHEDULE

Definitions

1. In these regulations "the Act" means the Foodstuffs, Cosmetics and Disinfectants Act 1972 (Act No. 54 of 1972), and any expression to which a meaning has been assigned in the Act shall bear that meaning and, unless the context indicates otherwise __

"food grade salt' means salt containing not less than 97% crystalline sodium chloride on a dry matter basis, including table salt;

"impermeable packaging material' means material which may consist of one or more of the following substances; Low density polyethylene, high density polyethylene, woven polypropylene or similar materials, and includes polycoated cardboard;

" iodated salt' means food grade salt or other salt intended for use in or on foodstuffs to which between 40 and 60ppm (mg/kg) iodine in the form of potassium iodate has been added;

" low sodium salt' means salt containing less than 67% sodiumchloride; and

" table salt" means salt that contains no more than 4% moisture and 50 ppm (mg/kg) fluoride and not less than 98,4% crystalline sodium chloride in its water-free state.

Requirements

2. (1) No person shall sell food grade salt or other salt intended for use in or on foodstuffs unless iodine has been added thereto.

(2) Food grade salt or other salt intended for use in or on foodstuffs which is imported shall contain between 40 and 60 ppm (mg/kg) iodine on entering the Republic of South Africa.

(3) Food grade salt or other salt intended for use in or on foodstuffs which is exported from the Republic of South Africa may contain more than 60ppm (mg/kg) iodine.

(4) Iodated salt shall be packed in sealed impermeable packaging material

(5) The label of iodated salt shall contain the word "iodated salt" as part of the name of the product.

(6) Wherever possible the date of iodation shall be indicated on the label of the product.

Exemptions

3. These regulations shall not apply to____
   (a) food grade salt or other salt intended for use in the manufacture of compound foodstuffs which is packed in bags of 20 kg or more and which is labeled "non – iodated salt";
   (b) salt available at pharmacies in packages of 1 kg or less which are labeled "non – iodated salt "; and
   © low sodium salt as defined in regulation 1.

Repeal

4. Regulation 41 (1) to (10) of the regulations promulgated under the repealed Foods Drugs and Disinfectants Act. 1929 (Act No. 13 of 1929), and published under Government Notice Nol R.2519 of 10 December 1954, as amended by Government Notices Nos. 1618 of 5 October 1962 and R295 of 4 March 1966, is hereby repealed.

Commencement

5. These regulations shall come into operation on 1 December 1995.

APPENDIX 5: List of villages/clusters and border posts included in the study

RURAL VILLAGES

DISTRICT	ZONE	CLUSTER	VILLAGE
BUTHABUTHE	FOOTHILL	01.31	BOIKETSISO

DISTRICT	ZONE	CLUSTER	VILLAGE
LERIBE	LOWLAND	08.34	HA MPSHE
		11.27	HA RAMOLOI
		14.36	HA LECHESA
	FOOTHILL	06.21	HA MALEFANE

DISTRICT	ZONE	CLUSTER	VILLAGE
BEREA	LOWLAND	18.31	HA MALEFETSANE
		21.25	HA FUSI
	FOOTHILL	16.37	SETORONG(SEKUTUNG)

DISTRICT	ZONE	CLUSTER	VILLAGE
MASERU	LOWLAND	29.27	LERALLENG
		32.16	HA NQOSA
	FOOTHILL	34.23	KOLBERE+ LEHLAKENG
		37.40	HA NCHAKE
	MOUNTAIN	34.15	LIKOTOPONG (PSHATLELLA)

DISTRICT	ZONE	CLUSTER	VILLAGE
MAFETENG	LOWLAND	38.4	HA MASOETSA
		40.06	HA RAMOKHELE
		42.28	HA KONOTE

DISTRICT	ZONE	CLUSTER	VILLAGE
MOHALE'S HOEK	LOWLAND	45.05	HA MOLETSANE
	MOUNTAIN	50.13	HA SEBILI

DISTRICT	ZONE	CLUSTER	VILLAGE
QUTHING	MOUNTAIN	55.34	SEKHELE
	S.R.VALLEY	52.16	HA LEKETE

DISTRICT	ZONE	CLUSTER	VILLAGE
QACHA'S NEK	MOUNTAIN	59.46	LIKONYELENG

DISTRICT	ZONE	CLUSTER	VILLGAGE
MOKHOTLONG	MOUNTAIN	65.24	MALINGOANENG
THABA-TSEKA	MOUNTAIN	600.30	MATOMANENG
		62.13	BOKHOASA

URBAN VILLAGES

DISTRICT	CLUSTER	VILLAGE
LERIBE : MAPUTSOE	12.59	HA NYENYE

DISTRICT	CLUSTER	VILLAGES
MASERU	23.20	BOCHABELA
	25.30	HA TSOLO
	27.03	UPPER THAMAE
	28.06	PHOMOLONG
MAFETENG	44.29	MATHENENG
MOHALE'S HOEK	47.44	STADIUM AREA

List of boarder post/entry points

Districts	Boarder post/entry point	Number of salt samples to be collected
Maseru	Maseru bridge	50
Leribe	Maputsoe	20
Buthabuthe	Monontsa	10
Mokhotlong	Sani-top	10
Qachasnek	Qachasnek	10
Mafeteng	Vanrooyen	10

APPENDIX 6: Data sheets and stickers

EVALUATION OF IDD CONTROL PROGRAM IN LESOTHO 2002
HOUSEHOLD DATA SHEET

1. Interviewer's code number------------	☐☐ 1-2
2. Identification number-----------------	☐☐☐☐ 3-6
3. District------------------------------------	☐☐ 7-8
4. Ecological zone------------------------	☐ 9
5. Cluster number-------------------------	☐☐ 10-11
6. Village-----------------------------	☐ 12
7. Name---------------------	
8. Age	☐☐ 13-14
9. Pregnant? Yes = 1 No = 2	☐ 15
10. Goitre grade (observer 1)	☐ 16
11. Goitre grade (observer 2)	☐ 17
12. Salt sample number--------------------	☐☐☐☐☐☐☐ 18-24
13. Brand of salt-----------------------------	
14. Type of salt 1. coarse 2. fine	☐ 25
15. Urine sample number------------------	☐☐☐☐☐☐☐ 26-32
16. Urine iodine content--------------------	☐☐☐☐ 33-36
17. Salt iodine content----------------------	☐☐☐☐ 37-40

EVALUATION OF IDD CONTROL PROGRAM IN LESOTHO 2002

SCHOOL DATA SHEET

1. Interviewer's code number--------------	☐☐ 1-2
2. Identification number--------------------	☐☐☐☐ 3-6
3. District-----------------------------------	☐☐ 7-8
4. Ecological zone--------------------------	☐ 9
5. Cluster number----------------------------	☐☐ 10-11
6. School------------------------------------	☐ 12
7 Name--------------------------------------	
8. Age	☐☐ 13-14
9. Gender F = 1 M = 2	☐ 15
10. Goitre grade (observer 1)	☐ 16
11. Goitre grade (observer 2)	☐ 17
12. Urine sample number-	☐☐☐☐☐☐☐ 18-24
13. Urine iodine content--------	☐☐☐☐ 25-28

EVALUATION OF IDD CONTROL PROGRAM IN LESOTHO 2002

RETAIL DATA SHEET

1. Sample number------------------------- ☐☐☐☐☐☐ 1-6
2. District---------------------------------- ☐☐ 7-8
3. Ecological zone-------------------------- ☐ 9
4. Cluster number--------------------------- ☐☐ 10-11
5. Retailer number--------------------- ☐ 12
6. Brand of salt------------------------------
7. Type of salt 1. coarse
   2. fine ☐ 13
8. Salt iodine content------------------------ ☐☐☐☐ 14-17

EVALUATION OF IDD CONTROL PROGRAM IN LESOTHO 2002

ENTRY POINT DATA SHEET

9. Sample number------------------------ ☐☐☐ 1-3

10 Border post----------------------------- ☐☐ 4-5

11 Entry point number-------------------- ☐ 6

12. Brand of salt----------------------------

13. Type of salt 1. coarse

14 2. fine ☐ 7

15. Salt iodine content---------------------- ☐☐☐☐ 8-11

Stickers for labeling of samples at household level

Stickers for salt samples (white coloured)

Name of village--------------
Cluster no--------------------
Id no--------------------------
Age----------------------------
Sample no-------------------

Stickers for urine samples (pink coloured)

Name of village--------------
Cluster no--------------------
Id no--------------------------
Age----------------------------
Sample no-------------------

Stickers for labeling of samples at school level

Stickers for urine samples (yellow coloured)

Name of school-------------
Cluster no-------------------
Id no-------------------------
Age---------------------------
Gender------------------------
Sample no------------------

Stickers for labeling of samples at retail level

Stickers for salt samples (white coloured)

Retailer no--------------------
Cluster no----------------------
Brand -------------------------
Type--------------------------
Sample no--------------------

Stickers for labeling of samples at entry point level

Stickers for salt samples (white coloured)

Entry point no----------------
Brand ------------------------
Type--------------------------
Sample no-------------------

APPENDIX 7: Questionnaire on programmatic indicators of sustainability

A QUESTIONNAIRE INDICATING THE PROGRAMATIC INDICATORS 2002

Do any of the following programmatic indicators exist in the country?

1. An effective, functional national body responsible to the government for the national program for the elimination of IDD. **Y/N**

Comments--

----

2. Evidence of political commitment of universal salt iodisation and the elimination of IDD **Y/N**

Comments--

----

3. Appointment of a responsible executive officer for the IDD elimination program **Y/N**

Comments--

----

4. Legislation or regulations on universal salt iodisation **Y/N**

Comments--

----

5. 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 **Y/N**

Comments--

----

6. A program of public education and social mobilization on the importance of IDD and the consumption of iodised salt **Y/N**

Comments---

----

7. Regular data on salt iodine at the factory, retail and household level **Y/N**

Comments---

----

8. Regular laboratory data on urinary iodine in school aged with appropriate sampling for higher risk areas **Y/N**

Comments---

----

9. Cooperation from the salt industry in maintenance of quality control **Y/N**

Comments---

----

10. 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. **Y/N**

Comments---

Adapted from WHO/UNICEF/ICCIDD (2001)

ENDIX 8: Method used to determine the iodine content of salt

(Extract from: The Use of Iodized Salt in the Prevention of Iodine Deficiency Disorders - A handbook of monitoring and quality control. New Delhi, UNICEF/ROSCA, 1989)

A2.1 Principle

The iodine content in iodized salt containing potassium iodate is estimated by a process called iodometric titration. Free iodine reacts with sodium thiosulphate solution as follows:

$2\ Na_2S_2O_3$	+	I_2	-->	$2\ NaI$	+	$Na_2S_4O_6$
Sodium thiosulphate		Iodine		Sodium iodide		Sodium tetrathionate

Sulphuric acid is added to a solution of iodized salt liberating iodine, which is titrated with sodium thiosulphate. Starch is used as an external indicator. The potassium iodide solution is added to keep the iodine in the dissolved state.

A2.2 Preparation of reagents

1. 0.005 Normal Sodium thiosulphate ($Na_2S_2O_3$)

Dissolve 1.24 g sodium thiosulphate crystals ($Na_2S_2O_3.5H_2O$) in 1 L boiled, double-distilled water. This volume is sufficient for testing 200 salt samples. Store in a cool, dark place. Properly stored, the solution can be kept for a few months. Standardize the sodium thiosulphate solution every three months using standard potassium iodate solution.

2. 2 N Sulphuric acid (H_2SO_4)

To 90 ml double-distilled water add 6.0 ml concentrated sulphuric acid (H_2SO_4) slowly. Add boiled, double-distilled water to make 100 ml. This volume is sufficient for 100 salt samples. Store in a cool dark place. The solution may be kept indefinitely.
Caution: To avoid violent and dangerous reaction always add the acid to water, never water to acid! Stir the solution while adding.

3. Potassium iodide (KI, AR)

Dissolve 100 g KI in 1 Litre of double-distilled water. This volume is sufficient for testing 200 salt samples. Store in a cool, dark place. Properly stored, the solution may be kept for 6 months.

4. Soluble chemical starch

Dissolve reagent-grade sodium chloride (NaCl) crystals in 100 ml boiled, double-distilled water. While stirring, add NaCl until no more dissolves. Heat the contents of the beaker till 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 can be stored for 3 to 4 weeks.

Dissolve 1 g of chemical starch in 10 ml boiling double-distilled water. Continue to boil till it completely dissolves. Add the saturated NaCl solution to make 100 ml starch solution. This volume is sufficient for testing 20 salt samples. Prepare fresh starch solution every day since starch solution cannot be stored.

A2.3 Laboratory procedure

The procedure is as follows:

1. Carefully weigh 10 g of the salt to be tested;

2. Pour the salt into a 50 ml measuring cylinder;

3. Slowly add boiled, double-distilled water;

4. Shake to dissolve the salt completely;

5. Add more water to make 50 ml;

6. Pour the salt solution (50ml) into a conical flask with stopper;

7. Pipette out 1 ml of 2 N sulphuric acid and add this to the salt solution;

8. Pipette out 5 ml of 10% potassium iodide and add this to the salt solution; **(Do not pipette acid or KI by mouth!)**

9. The solution turns yellow. Close the flask with the stopper and put it in the dark for 10 minutes. A closed box, cupboard or drawer may be used;

10. Pour 0.005N sodium thiosulphate solution into a burette;

11. Adjust the level in the burette to "0";

12. After 10 minutes, take the flask out of the dark box;

13. Shaking the flask, titrate the solution in the flask with sodium thiosulphate from the burette;

14. Stop titration as soon as the solution turns pale (becomes very light yellow);

15. Add a few drops (1 to 5 ml) of 1% starch solution to the flask;

16. The solution turns deep purple;

17. Continue titration until the purple coloration disappears and the solution becomes colourless;

18. Note the burette reading;

19. From the attached table, read the iodine content of the sample in parts per million

A2.4 Reporting

Iodine testing is easy and takes only about twenty minutes per sample. Maintaining accurate records is as important as the testing itself. The results are to be recorded in a register indicating:

* date of testing,
* sample number,
* batch number of the salt,
* date of iodization,
* source of sample,
* date of sampling, and finally,
* level of iodine in the sample.

Daily reports of the findings are made and the supervisor is to be alerted if the iodine content is less than the prescribed level. Your report will lead to action to protect the consumer. Delay on your part will delay these actions and harm the consumer.

A list of laboratory equipment and reagents required for analysis of iodized salt and available as a standard kit through UNICEF Copenhagen is attached.

IODINE CONTENT (IN PARTS PER MILLION)

Burette Reading	Parts per million	Burette Reading	Parts per million	Burette Reading	Parts per million
0	0.0	4.0	42.3	8.0	84.6
0.1	1.1	4.1	43.4	8.1	85.7
0.2	2.1	4.2	44.4	8.2	86.8
0.3	3.2	4.3	45.5	8.3	87.8
0.4	4.3	4.4	46.6	8.4	88.9
0.5	5.3	4.5	47.6	8.5	89.9
0.6	6.3	4.6	48.7	8.6	91.0
0.7	7.4	4.7	49.7	8.7	92.0
0.8	8.5	4.8	50.8	8.8	93.1
0.9	9.5	4.9	51.9	8.9	94.2
1.0	10.6	5.0	52.9	9.0	95.2
1.1	11.6	5.1	54.0	9.1	96.3
1.2	12.7	5.2	55.0	9.2	97.3
1.3	13.8	5.3	56.1	9.3	98.4
1.4	14.8	5.4	57.1	9.4	99.5
1.5	15.9	5.5	58.2	9.5	100.5
1.6	16.9	5.6	59.2	9.6	101.6
1.7	18.0	5.7	60.3	9.7	102.6
1.8	19.0	5.8	61.4	9.8	103.7
1.9	20.1	5.9	62.4	9.9	104.7
2.0	21.2	6.0	63.5		
2.1	22.2	6.1	64.5		
2.2	23.3	6.2	65.6		
2.3	24.3	6.3	66.7		
2.4	25.4	6.4	67.7		
2.5	26.5	6.5	68.8		
2.6	27.5	6.6	69.8		
2.7	28.6	6.7	70.9		
2.8	29.6	6.8	71.9		
2.9	30.7	6.9	73.0		
3.0	31.7	7.0	74.1		
3.1	32.8	7.1	75.1		
3.2	33.9	7.2	76.2		
3.3	34.9	7.3	77.2		
3.4	36.0	7.4	78.3		
3.5	37.0	7.5	79.4		
3.6	38.1	7.6	80.4		
3.7	39.1	7.7	81.5		
3.8	40.2	7.8	82.5		
3.9	41.3	7.9	83.6		

APPENDIX 9: Data collection guide and supervisors' checklist

DATA COLLECTION GUIDE (For all field workers)

HOUSEHOLD LEVEL (30 salt samples and 30 urine samples per cluster)

1. Report yourself to the chief
2. Identify the center of the village
3. Spin a bottle and take a direction of the top of the bottle
4. Then count the number of houses in that line from the center to the edge and choose one house at random as the starting point
5. Visit each household in that direction. If the age of a woman is older than 30 or younger than 15 go to the next household
6. If there are more than one women between the age 15 and 30 choose one woman at random for urine sample and palpation (Label 1 piece of paper and put it together with unlabelled paper in a tin ask the women to pick up the papers. The woman with a labeled paper is the one to be included in the study)
7. In each household explain briefly the purpose and procedures of the study, hand in the consent form and explain where necessary. Collect the form after it has been signed
8. Assess for exclusion criteria **(This is done only by the nurses)**
9. Palpate the woman according to the standardized procedure **(This is done only by the nutritionists)** and record the information in the household data sheet
10. Hand in the bottle and ask for urine sample **(ask the woman to half fill the bottle)**. Check if the bottle is properly closed, label the bottle and record in the household data sheet
11. Put bottle of urine in the cooler bag **(do not expose urine sample to direct sunlight). Pack the bottles in an upright position**
12. Ask for salt used in the household, mix the salt and put three to four teaspoons in the plastic bag. Ensure that the plastic is tightly closed. Label the sample using the appropriate sticker and record in the household data sheet **(do not expose salt sample to direct sunlight)**
13. Thank the woman for her corporation and participation and inform her about the feed back.

SCHOOL LEVEL (30 urine samples per cluster)

1. Report to the principal
2. Ask for children aged 8 to 12 years and for assistance from class teachers
3. Explain the purpose and procedure of the study and collect the previously given consent forms **(before data collection day)**
4. Assess for exclusion criteria **(This is done only by the nurses)**
5. Separate children by gender

6. Give all the children numbered pieces of paper and put duplicates in the two tins- one for girls and the other for boys
7. Mix and pick up 15 pieces of paper from each tin and call the numbers
8. Palpate the selected children using the standardized procedure (**This is done only by the nutritionists**) and record in the school data sheet. Give the selected children plastic bottles and ask for urine sample (**ask the children to half fill the bottle**). Check if the bottle is properly closed. Label the bottle and record in the school data sheet
9. Put the urine sample in the cooler bag (**do not expose urine sample to direct sunlight). Pack the bottles in an upright position.**
10. Thank the teachers and children for their assistance, corporation and participation and inform them about the feedback

RETAIL LEVEL (6 salt samples / cluster)

1. Ask the chief and write the names of all the retailers on the pieces of paper and put in a tin. Mix and ask the chief to pick two pieces. Then visit the selected retailers
2. Purchase three different brands of salt available in the first shop
3. Go to the second shop and purchase again three brands of salt not available in the first shop or otherwise purchase any brands available
4. Label the samples and record in the consolidated retail cluster data sheet

ENTRY LEVEL (minimum of 10 salt samples. *check entry point list)

1. Report to the head of Customs office and ask for assistance
2. Purchase "if necessary" different brands from the first vehicle
3. Purchase different brands from the second vehicle until you have collected enough. Label the samples and record in the entry point data sheet

Checklist for supervisors (for each cluster)

1. Ensure that you have enough equipment every morning
2. Check that samples are labeled correctly and correspond with the data sheet after each field visit
3. After each field visit ensure that urine samples are refrigerated in the laboratory at the hospital and salt samples are packed in boxes

District-------------------------------

Ecological zone--------------------

Cluster no---------------------------

Village-------------------------------

School-------------------------------

Number of salt samples from household level---------------

Number of salt samples from retail level------------------

Number of salt samples from entry point-----------------

Total number of salt samples -------------------------

Number of urine samples from pregnant women------------

Number of urine samples from other women----------------

Number of urine samples from school children-------------

Total number of urine samples collected--------------------

Are all samples labeled? Yes / No

Is the expected number of samples collected? Yes/No

If no what action has been taken--

Do information on the sticker correspond with data sheet? Yes / No

If no what action has been taken--

Comments---

Name of supervisor-------------------------------

Signature of supervisor--------------------------

Date--

THE TASKS OF THE RESEARCHER

The task of the researcher was to plan and organize for the study, train and supervise the field workers and compile a report.

A brief description of the task of the researcher is as follows:

(i) Planning and organising

- Using the population census data obtained from Bereau of Statistics, the researcher selected the number of clusters in each district and ecological zones. The researcher explained the selection methodology to the Statistitian who selected the villages.
- Plan the evaluation and monitoring of the salt iodisation program
- Collect and review relevant information.
- Write the proposal to UNICEF and send it through FNCO.
- Organize a meeting with the IDD control and micronutrient task forces for briefing and support.
- Write letters to Ministry of Education, Local government and Customs for approval of the study.
- Collect all materials to be used in the study and arrange with laboratories in all the districts for storage of urine samples until collected for forwarding to central laboratory.
- Develop data sheets, stickers for labelling (Appendix 6), a questionnaire (Appendix 7), data collection guidelines and supervisors' checklist (Appendix 9)
- Recruit the 24 field workers.
- Arrange for a pilot study and compile information and recommendations obtained.
- Develop and send consent forms to selected schools.
- Arrange for transport of urine and salt samples from Maseru to Cape Town for chemical analysis.
- Develop a questionnaire on programmatic indicators and ask the Director of FNCO to complete the questionnaire. Interview format used.

(ii) Training and supervising

- Train field workers using the data collection guide (Appendix 9) on random sampling, urine and salt sample collection, labelling and recording of information on the data sheets and stickers.
- Teach supervisors (nutritionists) how to supervise during field work, follow the data collection guidelines and fill in the supervisors' checklist.
- Supervise each team alternatively to ensure that both fieldworkers and supervisors are doing the work efficiently. During this supervisory visits, the researcher also collected data
- Check all the samples and data sheets during field visits (alternative supervisory visits) and, on arrival from the field, take to the central point for completion.
- Pack urine and salt samples in batches for transport to Cape Town. Spend a week in Cape Town involved in chemical analysis of the samples

MSebotsa 20/08/2003
Mahlwonyela Sebotsa (Researcher)

APPENDIX 10: Method used to determine the iodine content of urine samples

ıc method described in this Appendix is to be published in a report based on a joint 'HO/UNICEF/ICCIDD consultation *Assessment of the Iodine Deficiency Disorders and their limination: A Guide for Programme Managers* which was held in Geneva, May, 1999

Method A, using ammonium persulfate – ICCIDD Recommended Method

inciple
rine is digested with ammonium persulfate. Iodide is catalyst in the reduction of ceric ammonium ılfate (yellow) to cerous form (colorless), and is detected by rate of color disappearance (Sandell-olthoff reaction).

quipment
cating block (vented fume hood not necessary), colorimeter, thermometer, test tubes (13 x 100 mm) agent flasks and bottles, pipettes, balance.

cagents
Ammonium persulfate (analytical grade)
As_2O_3
NaCl
H_2SO_4
$Ce(NH_4)_4(SO_4)_4 2H_2O$
Deionized H_2O
KIO_3

olutions
. Ammonium persulfate, 1.0 M. Dissolve 114.1 g $H_2N_2O_8S_2$ in H_2O then 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 N) H_2SO_4 to about 700 ml deionized water *(careful - this generates heat!)* and 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 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, and store in 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 (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 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] (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.

cedure

Mix urine to suspend sediment.
Pipette 250 µl of each urine sample into a 13 x 100 mm test tube. Pipette each iodine standard into a test tube 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.
Add 1 ml 1.0 M ammonium persulfate to each tube.
Heat all tubes for 60 minutes at 100° C.
Cool tubes to room temperature.
Add 2.5 ml arsenious acid solution. Mix by inversion or vortex. Let stand for 15 minutes.
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.
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 and read successive tubes at the same interval used to add the ceric ammonium sulfate.

culation of results

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

es

This is modified from former Method A by substituting ammonium persulfate for chloric acid (more toxic) as digestant.
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.
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.
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.
The volumes and proportions of sample and reagents can be varied to achieve different concentrations or a different curve shape, if conditions warrant it. If different tube sizes are used, corresponding size holes in the heating block are also needed.
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 are uniformly heated and that the temperature be constant within the range described above.
Test tubes can be reused if they are carefully washed to eliminate any iodine contamination.
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.

fferences between the urinary iodine method in this document and the ICCIDD method

following are some of the differences between the UNICEF/PAMM method and the ICCIDD hod. First, the UNICEF/PAMM method does the following: (1) ceric ammonium sulfate is one-half CCIDD concentration, but adds 1.33 times as much; (2) the temperature is 90-95E; (3) the arsenious is one-half the ICCIDD concentration, but 1.4 times as much is added; (4) color read at 420; (5) ples are read at 30 second intervals; (6) the curve is plotted by log; and (7) 60 tubes (equals 48 nown samples) are done each assay.

APPENDIX 11: Standardised procedure for inspection and palpation

INSPECTION

- A PERSON (SUBJECT) TO BE EXAMINED STANDS INFRONT OF THE EXAMINER WHO LOOKS CAREFULLY AT THE NECK FOR ANY SIGN OF VISIBLE THYROID ENLARGEMENT
- THE SUBJECT IS ASKED TO LOOK UP AND THEREBY FULLY EXTEND THE NECK. THIS PUSHES THE THYROID FORWARD AND MAKE ANY ENLARGEMENT MORE OBVIOUS

PALPATION

- THE EXAMINER STANDS BEHIND THE SUBJECT WITH A NECK IN THE NEUTRAL POSITION
- THE EXAMINER PALPATES THE THYROID BY GENTLY SLIDING HER/HIS OWN FINGERS ALONG THE SIDE OF THE TRACHEA (WIND PIPE) BETWEEN THE CRICOID CARTILAGE AND THE TOP OF THE STERNUM. BOTH THE 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 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

- GOITRE IS GRADED ACCORDING TO WHO/UNICEF/ICCIDD (2001) CLASSIFICATION

Adapted from WHO/INICEF/ICCIDD (2001)

APPENDIX 12: Consent form in Sesotho and English

CONSENT FORM IN SESOTHO

FOROMO EA TUMELLO

TSALOMORAO LE TLHATHLOBO EA MOLAO OA LETSOAI LE NTLAFALITSOENG HO FELISA MAFU A BAKOANG KE KHAELLO EA IODINE

BOITLAMO BA MOTSOALI/MME

Na-- ke itlama hore:

1. Na me ea lilemong/ motsoali ke kopiloe/nanoaka o kopiloe ho nka karolo lipatlisisong tsa kantoro ea bohokahanyi ba lijo le phepo e nepahetseng.

2. Ke hlaloselitsoe hore:
   - Sepheo sa lipatlisiso tsena ke ho fumana bomeo ba kolu baneng ba lilemo tse robong ho isa ho tse leshome le metso e meli Lesotho, mme mosese oaka o tla nkuoa ho ea etsa lipatlisiso.
   - Tsebo e tla fumanoa e tsa sebelisoa ke muso oa Lesotho ho felisa mathata a oakoang ke khaello ea iodine meleng, mme e tla thusa baahi bohle ba Lesotho.
   - Nka hana ho nka karolo kapa ka tlohela ho araba lipotso.
   - Sephetho se tla lula ele lekunutu feela se tla sebelisoa ke batho ba etsang lipatlisiso.

Litaba tsena li hlalositsoe ho nna ke --------------------(lebitso la mohlalosi), mme ke utluisisa puo eo ho ngotsoeng ka eona. Ke ile ka fuoa monyetla oa ho botsa moo ke sa utluisiseng.

Na motsoali ke lumela ho tiea hore ngoana oaka o tla nka karolo lipatlisisong tsena.
E saennoe-----------------------------------ka la--------20-------

Na/me ea lilemong ke lumela ka ho tiea ho nka karolo lipatlisong tsena.

E saennoe ----------------------------------- ka la--------20-------

--- ----------------------

lebitso kapa khatiso ea monoana paki

--- ----------------------

lebitso la motsoali kappa khatiso ea monoana paki

CONSENT FORM IN ENGLISH

MONITCRING AND EVALUATION OF IDD CONTROL PROGRAM IN LESOTHO (2002).

DECLARATION BY OR ON BEHALF OF THE PARTICIPANT

I--- confirm that:

1. I/The participant/ mother has been asked to participate/allow my child to participate in the above mentioned research survey of the Food and Nutrition Coordinating Office.
2. It has been explained to me that:

- The purpose of this survey is to collect information of the goitre and urinary status of the children (8-12years) and women of child bearing age in Lesotho and that my/my child's thyroid size will be measured and urine taken for analysis.

- The information obtained from this survey will be used by the Lesotho government to monitor and evaluate iodine deficiency disorders elimination program, which will help all the people of Lesotho.

- I can refuse to participate in this research and I may withdraw from the study at anytime during an interview.

- The results and information I will give will be kept confidential, but it will be used anonymously for making known the findings to other scientists/researchers

The information in this consent form was explained/translated to me by -------------------- (name of interviewer/translator) and I confirm that I have a good command in this language and understood the explanations. I was also given the opportunity to ask questions on things I did not understand clearly.

I/ the parent/guardian hereby agree that my child will take part in this research survey
Signed/confirmed at-------------------------------on---------20--------

I/the participant(child) hereby agree voluntarily to take part in this research survey.
Signed/confirmed at-----------------------------------on -----20-----

--	-----------------------------
signature or hand mark of parent/guardian	Witness
--	-----------------------------
signature or hand mark of participant	witness

APPENDIX 13: Letters sent for approval and approval letters

G. P. 139

SAVINGRAM

FROM: DIRECTOR FNCO **RECEIVED DATE STAMP**

TO: DIRECTOR: EDUCATION
LOCAL GOVERNMENT
CUSTOMS

REF.NO. FNCO/PR/17

SIGNED: f. M. Sebotsa ....
(Full Signature)

NAME: M.M NTSIKE (MRS) **FILE NO.......................**
(Typed) **(Receiving Min./Dept.)**

DATE: 5 JANUARY 2002

RE: Evaluation of Iodine deficiency Disorders control program

The Micronutrient task force and the Iodine Deficiency Disorders (IDD) control task force, plan to undertake a study in the selected villages and schools from the beginning of February. The study will be under the technical leadership of Mrs Sebotsa who is the nutritionist at the Food and Nutrition coordinating office. The aim of the study is to evaluate the salt iodisation program, which is the current intervention to eliminate IDD in the country.

The exercise includes obtaining urine samples from primary school children and women of childbearing age in the selected villages and government schools in the same villages. Salt samples will also be collected from the retailers, households and border posts.

Your office is humbly requested to allow the micronutrient task force and the IDD control task force to undertake this important study.

A list of selected villages and border posts is attached.

We appreciate your usual cooperation in activities related to micronutrients in the country.

G. P. 139

SAVINGRAM

FROM: DIRECTOR LOCAL GOVERNMENT

TO: DIRECTOR: FNCO

REF.NO. LG/MP/213

SIGNED:.......................................
(Full Signature)

NAME: M.KUTLOANO (MR)
(Typed)

DATE: 9 JANUARY 2002

RECEIVED DATE STAMP

FOOD & NUTRITION
DIRECTOR
2002 -01- 10
P/BAG A78, MASERU 100
LESOTHO
TEL:(+266) 323715
COORDINATING OFFICE

FILE NO......................
(Receiving Min./Dept.)

Re: Evaluation of Iodine deficiency Disorders control program

We refer to your letter dated 5th of January 2002. As Local government we ensure the well being of the public and therefore support all activities working towards this goal. We therefore approve that the task forces conduct the mentioned study and guarantee you will get all the support you need from us.

We wish you all the best.

G. P. 139

SAVINGRAM

FROM: DIRECTOR EDUCATION **RECEIVED DATE STAMP**

COORDINATING OFFICE
LESOTHO
2002 -01- 10
DIRECTOR
FOOD & NUTRITION

TO: DIRECTOR: FNCO

REF.NO. EDU/GN/23

SIGNED:.................................
(Full Signature)

NAME: M.THULO (Mrs)
(Typed)

FILE NO.......................
(Receiving Min./Dept.)

DATE: 8 JANUARY 2002

RE: EVALUATION OF IODINE DEFICIENCY DISORDERS CONTROL PROGRAM

With reference to your letter dated 5 January 2002. Education office approves the conduction of such study, which will hopefully benefit the country. Our office will offer you support throughout the whole exercise

G. P. 139

SAVINGRAM

FROM: DIRECTOR CUSTOMS

TO: DIRECTOR: FNCO

REF.NO. CUS/UH/131

SIGNED:......................................
(Full Signature)

NAME: S.TSOEU (MR)
(Typed)

DATE: 10 JANUARY 2002

RECEIVED DATE STAMP

FOOD & NUTRITION
DIRECTOR
2002 -01- 11
P/BAG A78, MASERU 100
LESOTHO
TEL:(+266) 323710
COORDINATING OFFICE

FILE NO......................
(Receiving Min./Dept.)

<u>RE: Evaluation of Iodine deficiency Disorders control program</u>

Please refer to your letter dated 5th January 2002. We are pleased that you have planned to conduct the evaluation of the salt iodisation program. Customs approves such activity and will ensure that you receive the support from the customs officers.

We appreciate all your efforts to plan and implement activities, which are of benefit to the population in Lesotho.

SUMMARY OF THE THESIS

The broad range of disorders in a population caused by an inadequate dietary supply of iodine was denoted as iodine deficiency disorders (IDD), which include endemic goitre, hypothyroidism, cretinism and congenital anomalies. When iodine deficiency is widespread, mental retardation impedes national human resource development. Despite the known effective control measures, 130 WHO member states have a significant IDD problem. Severe to mild IDD have been reported in Lesotho since 1960.

The most cost-effective and sustainable intervention to eliminate IDD is the iodisation of all edible salt. However, several countries with long standing salt iodisation programs have reported declining levels of urinary iodine. In Lesotho, the legislation on universal salt iodisation was promulgated in 2000. Therefore the aim of the study was to evaluate the salt iodisation program in Lesotho in terms of process, impact and sustainability indicators.

A 30 cluster national survey was conducted where the proportion to population size method was administered. In each cluster, 30 women aged 15 to 30 years, and 30 primary school children aged 8 to 12 years, were randomly selected. The selected women and children were palpated and thyroid size graded according to WHO/UNICEF/ICCIDD (2001) criteria and urine samples collected. 30 salt samples were collected from these selected women, 6 samples from 2 randomly selected retailers in each cluster, and 107 samples collected from all the commercial entry points in the country. The salt samples were analysed using the iodometric titration method while urine samples were analysed using the method using ammonium persulfate according to WHO/UNICEF/ICCIDD (2001) recommendations. This analysis was performed at the Medical Research Council in Cape Town (South Africa) where the Coefficient of Variation for urinary iodine analysis was 7.7 at a concentration of 10μg/l, and was 2.7 at a concentration of 70ppm for titration method of salt analysis. The statistical analysis was done using the SAS program at the University of the Free State (South Africa).

A total of 927 children and 930 women who were palpated, and 912 children and 924 women who gave urine samples, were included in the analysis of the results. 930 salt samples from

household level, 186 from retail level and 107 from entry point level were analysed. 3 salt samples from entry point, 18 and 6 data sheets for urinary iodine of women and children respectively were not included during statistical analysis. The median iodine concentration of salt was 36.2ppm (ranging from 30.5-55.4ppm in the different entry points), 37.3ppm (ranging from 12.4-50.2ppm in the different districts) and 38.5ppm (ranging from 29.2-43.2ppm in the different districts) at entry point, retail level and household level respectively. At household level only 1.6 percent used non iodised salt and 86.9 percent used adequately iodised salt.

The analysis of the urine samples showed that the median urinary excretion was 214.7µg/l (ranging from 62.9µg/l to 302.6µg/l in the different districts) for the children and 280.1µg/ (ranging from 124.8µg/l to 381.6µg/l in the different districts) for the women, indicating more than adequate iodine intake according to the WHO/UNICEF/ICCIDD (2001) report. The median iodine concentration was higher in boys (219.3µg/l) than in girls (212.6µg/l), higher in the Lowlands (256.0 µg/l in children and 329.9 µg/l in women) than in the Mountains (99.30µg/l for children and 182.6µg/l in women) and higher in non-pregnant women (283.0 µg/l) than in pregnant women (212.1 µg/l). In the whole country, the prevalence of goitre was 10.7 percent (ranging from 6.6% to 22.6 % in the different district) in children and 19.4 percent (ranging from 6.7% to 36.7% in the different districts) in women, which indicates mild IDD (WHO/UNICEF/ICCIDD, 2001). IDD were observed more in females (14.0%) than in males (7.0%) and was less (4.3%) in children aged 8 than in children aged 12 years (12.9%). In women IDD increased with age from the age group of 15 to 19 (17.3%) to the age group of 20 to 25 (22 %) and decreased in the age group of 26 to 30 (18.4%). Similar to urinary iodine results, IDD was observed more in the Mountains (17.7% for women and 18.1% for children) than in the Lowlands (14.3% for women and 6.7% for children).

Only the urinary iodine excretion reached the WHO/UNICEF/ICCIDD (2001) sustainability goals. At household level, 86.9 percent of the households, which is slightly lower than the recommendation of at least 90 percent, use adequately iodised salt. Out of 10 programmatic indicators of sustainability, only 4 indicators have been attained by the salt iodisation program in Lesotho. According to the WHO/UNICEF/ICCIDD (2001) at least 8 of the programmatic indicators should be attained for sustainable elimination of IDD.

The study demonstrates a major achievement in the household use of iodised salt and adequately iodised salt. However, salt is not iodised according to the legislation on universal salt iodisation in Lesotho due to under iodisation and non- uniformity of salt iodisation at the production site. Iodine deficiency has been eliminated as a public health problem in Lesotho and this is due to the introduction of the legislation on universal salt iodisation. This study highlighted the effectiveness of iodised salt in increasing urinary iodine concentration. Iodine deficiency increased with age and was higher in girls than in boys, and higher in the Mountains than in the Lowlands. IDD elimination in Lesotho will be sustainable if more than 90 percent of the households use adequately iodised salt and the programmatic indicators such as commitment to reassessment, political commitment, implementation of social mobilization program and reqular monitoring are achieved by the IDD control task force.

The administrative structure and activities of the IDD control task force need to be revised and strengthened for the sustainable elimination of IDD. The terms of reference of the committee should be revised, budgets for the activities be drawn, new members added and trained and responsibilities given to each member. Awareness campaigns, which will start at policy makers' level, should be initiated. Law enforcement should be an integral part of the salt iodisation program. Effective regular monitoring of salt iodine content at all levels with special attention to iodisation of coarse salt is recommended together with periodic evaluation of the iodisation program.

Key words: goitre, urinary iodine concentration, iodine deficiency disorders, salt iodisation, sustainability, monitoring and evaluation