Chapter I

Introduction

1.1 Background

IDD is the world's single most significant cause of preventable brain damage and mental retardation. Twenty nine percent of the population (1570 million people) is at risk of iodine deficiency today in the world. The immense danger to health due to IDD arises from the fact that these disorders can began even before the child is born. Although iodine is needed in small amount on an average of 150mcg (100 to 300) per person per day, [1, 2] lack of iodine is associated with wide range of clinical and sub-clinical conditions. The most obvious sign of IDD is goiter, which is a gross enlargement of the thyroid gland in the neck, with a global prevalence of 12%. In addition to goiter, IDD leads to infant mortality, stillbirths, birth complications, mental retardation and depressed psychomotor functions. Moderate IDD in early childhood has been estimated to lower the intelligence quotient by about 10-15 points, while in adults it causes lethargy. [3]

IDD is an important major micronutrient deficiency problem in Nepal. In some isolated mountainous area of Nepal, most of the adult woman had goiter and up to 10% of population were cretins, the severest form of IDD. [4]

First nation wide clinical prevalence survey for goiter conducted in 1956 -1967 showed high prevalence of endemic goiter and cretinism. IDD prevalence survey conducted in high Trisuli and upper Langtang area during 1976-1977 revealed that the total goiter rate was 55.3%, while cretinism was 5.1%. [4] Similar survey conducted in 1979-1982 in 14 districts, the total goiter rate noted was 57.6% and cretinism prevalence was 2.8%. National level survey conducted in 15 districts of Nepal from 1985 to 86 revealed the rate of goiter and cretinism, 39.7 %, 0.4% respectively. [5] A national level survey, Nepal Micro Nutrient Status Survey conducted in 1998 established the low median urinary iodine excretion of 43.65 in women and 35.1 in children, which is less than WHO value

of 100 mcg / L. Similarly NMSS showed a total goiter rate (TGR) of 50% and 40% in women and school age children respectively. [6]

Nepal IDD status survey 2005 provides the national estimates on the status in the country, which are directly comparable to the NMSS 1998. This national level study done in different eco-geographical region revealed that national median UIE increased from 143.8 mcg /l to 188.0 mcg /L among school age children (SAC). The proportion of SAC with low urinary iodine excretion (UIE) values between WHO cut off value of 100 mcg /L decreased from 35.15 to 27.4 percent in 2005.The survey showed an increase in the proportion of house hold using iodized salt with 2 children logo, which is 37.7 percent compared to 9 percent in 1998. Iodine content in salt at household level measured using rapid test kit (RTK) found that 94.9 percent of house hold consumed salt with some iodine content which was an improvement over NMSS 1998 value of 83 percent. In addition 57.7 percent of all household in the country used adequately iodized salt, which was slightly better than 1998 situation of 55.2 percent. [5]

1.2 Statement of the problem

Iodine deficiency is the world's single most significant cause of preventable brain damage and mental retardation. Globally prevalence of goiter is 12 percent and 29 percent of the population is at risk of developing iodine deficiency. Nationwide prevalence survey conducted in Nepal in 1985-1986 showed an overall total goiter rate of 44 percent in school children and adults. More recently, an assessment of IDD problem by estimation of urinary iodine among Nepalese school children conducted in 2005 in 190 urine samples showed 3.2 percent of children had urine iodine less than 20 micro grams per liter. In addition, 27.9 percent children had urine iodine level 100 mcg/L, the normal WHO recommended levels. Current IDD status assessment conducted in 2004 in Nepal noted that 16.3 percent household salt samples were found to have less than 15 ppm iodine, 35. 33 percent samples found to have 15 to 30 ppm, 40 percent samples were found to have 30-50ppm and 12.64 percent salt samples had iodine greater than 50 ppm. The disease burden study (SLTHP, 1997-2017) has shown that great 1st category that includes pre-transition disorders such as infectious diseases, maternal and perinatal disorders and nutrition deficiency in Nepal are responsible for

more than two third of the disease burden i.e. 68%. Therefore, nutrition intervention has been recommended as a priority element of EHCS. [7]

Similarly, NHS strategy (2004) and NHS implementation plan have recognized the nutritional problem of mother and children and have recommended adopting a specific implementation strategy with regards to nutrition. [7]

1.3 Rationale

IDD will remain to be health problems unless human behavior is changed, which is a process requiring multi-sectoral approach. There is hardly any study of this type done in this country regarding iodine supplementation and pregnancy outcomes (mother and newborn health).

The first nation-wide clinical prevalence survey for goiter was conducted in 1965-1967, which showed a high level of endemic goiter and alarmingly high rate of cretinism. [4] Since than more than ten IDD prevalence surveys have been conducted through out the country, most of those are based on children and adult population (non pregnant). Some of the studies have tried to focus the status of IDD among the women of reproductive age group but none have involved the pregnant women.

A nation-wide IDD prevalence survey was conducted in 1985-1986 in 15 districts by Ministry of Health and noted an overall total rate of goiter was 44% in both school children and adults. More recently a situation analysis of children conducted in 1992 by the Ministry of Health and UNICEF showed goiter prevalence rate from 23-46%. [6] In areas with severe iodine deficiency (< 50 mcg intake/day), goitrogenesis as well as hypothyroidism were frequently observed in mother and newborn as a result of the inability of the thyroid gland to adjust to changes in thyroid economy associated with pregnancy. Hence, the pregnant woman and the newborn have been considered primary targets for iodine supplementation in such areas.[8]

The world health report 2002 clearly describes how childhood and maternal under weight are the greatest risk factors among several main factors that affect people's

health and diseases status in the world, particularly in Asia (WHO, 2002). In the Millennium Development Goals under weight has been adopted as a key indicator of poverty and hunger. [8]

In addition, improvement in nutrition can help meeting the MDGs by contributing to the achievement of universal primary education, reducing child mortality, improving maternal health, as well as reducing poverty and hunger. From these points of view, it is recognized that policies, program and process for nutrition improvement have a great role to play in promoting healthy lives and development across the globe.

Since the severe clinical findings of different studies conducted to know the IDD status are only the tip of the iceberg, mild to moderate deficiencies which are difficult to identify with commonly available tests remained to be the most important iodine deficiency disorders in the community. Pregnancy and intrauterine life are the most vulnerable period to be suffered from IDD [9.]

Ministry of Health and Population has prioritized Iodine Deficiency Disorders as a high level activity in its Nutrition Policy and Strategy 2004. MOH has set an objective to virtually eliminate iodine deficiency diseases and sustain the elimination. “By the year 2017 iodine deficiency disorders will be eliminated virtually from Nepal” this is a set goal of MOHP Nepal. [7]

All these finding associated with pregnant women justifies the burning issue for the research on iodine deficiency disorders among pregnant mother and newborn. With these motivations, the present intervention study has been designed to assess the effect of iodine supplementation during second half pregnancy to its outcomes (maternal and neonatal health).

1.4 Hypothesis

Regular supplementation of iodine during second and third trimesters of pregnancy in addition to appropriate MNH care interventions improves overall health status of mother and newborn.

1.5 Research questions

- What was the effect of iodine supplementation during pregnancy in mother and newborn health outcomes?

- What was the prevalence of IDD among the pregnant women & newborn?

- What was the knowledge, attitude and practice about the use and need of iodized salt in their family?
- What was the existing KAP about MNH care among the pregnant mothers?

1.6 Objectives

1.6.1 General Objectives

To find out the maternal and newborn health status in relation to the regular daily iodine supplementation in addition to appropriate maternal and neonatal health care interventions during pregnancy among pregnant women in Chautara hospital.

1.6.2 Specific Objectives

- To identify/assess the status of IDD among pregnant women and their newborns of Sindhupalchowk district.

- To differentiate between the IDD status of pregnant women with and with out regular supplementation of iodine using various indicators of IDD (serum thyroid hormone level and maternal goiter rate).

- To compare the status of newborns of pregnant women with and without iodine supplementation.

- To assess/understand KAP about use and need of iodized salt among the families of pregnant women.

- To assess KAP about care of pregnancy, delivery and newborn among the same pregnant women.

Chapter II

Literature Review

Iodine is a chemical element, which is found in trace amount in thyroid hormones. Iodine is necessary for the synthesis of thyroid hormones. [10]

2.1 Iodine deficiency disorders

In areas where there is little iodine in the diet typically remote inland areas where no marine foods are eaten iodine deficiency (ICD 10, E00-E02) gives rise to goiter (so-called endemic goiter), as well as cretinism, which results in developmental delays and other health problems.[1] Population effects of severe iodine deficiency termed IDD include endemic goiter, hypothyroidism, cretinism, decreased fertility rate, increased mortality and mental retardation. [11]

For children aged 0-59 months: 90mcg, for children aged 6-9 years: 120 mcg, for individuals older than 12 years, for adolescents and adults: 150 mcg, for pregnant and lactating women: 200 mcg. [1]

Similarly US, Institute of Medicine recommended daily allowance of iodine is as given. Normal daily iodine intake is 100- 150 mcg per day, 150 mcg for adults and adolescents, and 220 mcg per day for pregnant and 290 mcg per day for lactating mother. For children aged 1 to 11 years recommended daily amount of iodine is 90 to 120 mcg, for infants 110 to 130 mcg is needed. Upper limit of safe daily iodine intake is 1100 mcg per day for adult and it is lower for children. [3]

Thyroid hormones (T3, T4 and TSH) are essential for neuronal development, sexual development, growth and other important functions of thyroid hormones are regulations of metabolic rate, body heat and energy production. [12]

Prevalence of IDD in different group is worth mentioning. Regarding sex prevalence, after 10 years goiter is high among girls in iodine deficiency prone areas. Most devastating complication of IDD occurs when iodine is deficient during fetal and neonatal growth that is pregnant women and lactating mothers. The most common and severe manifestations of IDD are goiter, hypothyroidism and cretinism which is

classified in two different types. One is neurological, manifested with mental retardation (deficiency during pregnancy) and the other is myxomatous type, which is characterized by mental as well as physical growth retardation (deficiency during pregnancy and lactating period). Iodine deficiency is the worldwide leading cause of preventable mental retardation and brain damage. [10]

Internationally, 2.2 billion people are at risk for IDD, of these 30 to 70 % has goiter and 1 to 10 % has cretinism. Regarding morbidity and mortality, mild to moderate IDD are manifested as thyroid functions abnormalities. Severe forms of IDD as endemic goiter and cretinism are related to increased miscarriages and infant mortality. [13] According to the World Health Organization, the number of countries where iodine deficiency was a public health problem was reduced to 54 in 2003, down from 110 in 1993 through its program of salt iodization. The WHO says the drop is due mainly to the use of iodized salt for human and animal consumption to prevent and control iodine deficiency. [14]

In some isolated mountainous area of Nepal, most of the adult woman had goiter and up to 10% of population were cretins, the severest form of IDD. [4]

A national level survey Nepal Micro Nutrient Status Survey conducted in 1998 established the low median urinary iodine excretion of 43.65 in women and 35.1 in children, which is less than WHO value of 100 mcg / L. Similarly NMSS showed a total goiter rate (TGR) of 50% and 40% in women and school age children respectively. [6]

National level survey conducted in 15 districts of Nepal from 1985 to 86 revealed the rate of goiter and cretinism 39.7 % and 0.4 respectively. Nepal IDD status survey 2005 provides the national estimates on the status in the country, which are directly comparable to the NMSS 1998 respectively.

Iodine content in salt at household level measured using rapid test kit (RTK) found that 94.9 percent of house hold consumed salt with some iodine content which was an improvement over NMSS 1998 value of 83 percent. In addition 57.7 percent of all household in the country used adequately iodized salt, which was slightly better than 1998 situation of 55.2 percent. [15]

Pregnancy in an area with a marginally low iodine intake is associated with significant alterations in thyroid function and specifically pregnancy induced goitrogenesis and excessive thyroid stimulation in a significant fraction of the women. Relative hypothyroxinemia, evidenced by a less than adequate rise in total thyroxin levels and the gradual lowering of free thyroxin levels during the first half of gestation with gradual rise, within the limits of normality, of serum TSH after the first trimester; and a marked elevation in serum TBG levels, particularly near term are the effects of mild to moderate iodine deficiency during pregnancy. [16]

The rise in serum TG was highly correlated with changes in TV (thyroid volume), thereby providing an interesting marker for goitrogenesis occurring during pregnancy. Excessive thyroid stimulation was observed in both mothers and newborns. Pregnancy constitutes a challenge for both the maternal and fetal thyroid glands, enhanced by the reduced availability of iodine, and to recommend systematic addition of iodine during pregnancy and lactation in the country. [8]

There is potential risk of goitrogenic stimulation in both mother and newborn in the presence of mild iodine deficiency. Iodine supplementation benefits pregnant women with excessive thyroid stimulation. In conditions of mild iodine deficiency, pregnancy fully justifies the monitoring of thyroid function and volume and therapeutic intervention to avoid hypothyroxinemia and ontogenesis. [17]

2.2 Prevalence of the IDD

The data required to estimate burden of IDD in community includes the following:

- The total population including the number of children under 15 years of age (in which the effects of iodine deficiency are so important);
- The goiter rate, including the prevalence of palpable or visible goiter classified according to accepted criteria;
- The rates of cretinism and 'cretinoidism' in the population;
- Urinary iodine excretion (UIE);
- The level of iodine in the drinking water;

- The level of serum thyroxin (T4) in various age groups. Particular attention is now focused on the levels in the neonate because of the importance of the T4 level for early brain development.

2.3 Indicators of IDD

There are certain characteristics, which delineate the whole range of IDD in community. [10]

- Laboratory indicators: Urinary iodine excretion (UIE), newborn with IDD show raised TSH, measurement of a dried whole blood spot level of thyroglobulin (TG) in children.
- Imaging studies: Radioactive iodine uptake value and thyroid size scanning with ultrasonography.
- Other tests: TFT (Thyroid function test), mild iodine deficiency will fall with in normal reference but moderate to severe deficiency leads to raised TSH and decreased T3, T4
- Histological findings: Diffuse hyperplasia of thyroid gland

2.4 Thyroid function during pregnancy

Iodide deficiency is probably the number one problem when it comes to thyroid disease worldwide, in many of the countries both in Europe and in the developing world, said Dr. Stagnaro-Green. And it is probably the number one reason why children are born with decreased I.Q. What really is needed in those countries is some form of intervention that all mothers who are pregnant get iodide before pregnancy and during pregnancy. [18]

Dr. Alex Stagnaro-Green, a professor of Obstetrics and Gynecology at New Jersey Medical School, says thyroid disease is, after diabetes, the most common endocrine disease worldwide during pregnancy, due in large part to iodide deficiency. Iodide deficiency usually happens when soil contains low levels of iodine, causing a low concentration of iodine in food products and insufficient iodine intake in the population. Dr. Stagnaro-Green says during pregnancy, a baby's development is dependent on the

mother's thyroid function. If thyroid abnormalities are not detected, he says it can lead to several complications for mother and baby. [19]

One of the most exciting studies that have come out in the last 30 years was published this year, about six month ago, from a group in Italy, he said. Half the women they gave thyroid hormone, the other half they didn't give thyroid hormone. They found that the half they gave thyroid hormone to, their miscarriage rate and their preterm delivery rate was at the normal level. The half that had thyroid antibodies and not given the thyroid hormone, their miscarriage rate was four to eight times higher. That was the first study to demonstrate that an intervention makes a difference. If another study confirms that and expands upon it, then there will probably be a very strong call for universal screening for all women for thyroid disease in pregnancy. Assessment of TF during pregnancy should be done with careful clinical evaluation of the patient's symptoms as well as measurement of TSH and free, not total thyroid hormones. [12]

Regarding pregnancy and IDD more than a dozen national and more than three times of national, international publications were reviewed most of them are concerned with clinical endocrinology only few are relevant in public health. A couple of findings are mentioned below.

There was no statistically significant difference in the frequency of PPTD in the three groups (P = 0.56): +/+ group, 59% (95% confidence interval, 36–79%), +/- group, 60% (36–81%); and -/- group, 46% (26–67%), although a small trend was observed. One of the six women leaving the study had evidence of PPTD (abnormal TSH 3 months postpartum), and one had normal TSH 3 months postpartum (no further test available). Neither these data nor intention to treat analysis including all six censored women altered the outcome. PPTD developed in 55% of the participants. In 67% of the cases, abnormal TSH was accompanied by abnormalities in thyroid hormones (clinical PPTD), whereas 33% had abnormal serum TSH only (sub clinical PPTD). [21, 22]

2.5 Iodine supplementation and thyroid function in late pregnancy

Measurements of TSH, thyroid hormones, and thyroid antibodies in week 35 of pregnancy in women receiving iodine (+/+ and +/- groups) and women not receiving iodine (-/- group) are described. There were no statistically significant differences when

comparing absolute values at 35 weeks gestation. Iodine supplementation modified changes in TSH and TG during pregnancy. In the group without iodine there was a small, but systematic, increase in TSH during pregnancy, whereas the TSH alterations during pregnancy in the group with iodine showed a more diverse pattern, with no significant difference between early and late pregnancy. The small increase in TG during pregnancy reverted to a considerable fall after iodine supplementation. Free T_4 declined during pregnancy, and iodine supplementation made no significant difference. Antibody levels were lower in late pregnancy, with no differences between groups. [22]

Iodine requirements are increased during pregnancy and the postpartum period, and consequently, the recommended iodine intake is higher. [23] A possible unintended effect of increasing the iodine intake in pregnant and lactating women with mild to moderate iodine deficiency is an increase in postpartum autoimmune thyroid dysfunction.

However, in the current study we found no significant increase in the prevalence, severity, or duration of PPTD when 150 µg iodine were given to TPO-Ab-positive women during pregnancy only or during pregnancy and the postpartum period. Iodine supplementation induced minor late pregnancy differences in thyroid function similar to those found in previous studies of pregnant women in areas of mild to moderate iodine deficiency. [22] These variations probably had little clinical significance.

Two randomized studies have previously focused on iodine supplementation and its impact on the prevalence and severity of PPTD [16]. Janssen *et al.* hypothesized, based on their observation of low iodine excretion during the hypothyroid phase of PPTD [22] that iodine deficiency might worsen this phase of PPTD. In a subsequent study performed in Sweden, an iodine-sufficient area, they randomized 58 TPO-positive women to receive no supplement, 0.1 mg L-T_4, or 150µg iodine/day during the postpartum period. [23] Contrary to their hypothesis, they found an aggravation of the hypothyroid phase of PPTD in the iodine group. The frequency of PPTD was not different from those in the control and L-T_4 groups. They recommended that iodine should not be given during the postpartum period.

Reinhardt and colleagues addressed the efficacy and safety of iodine given during the postpartum period in an area of mild iodine deficiency (Germany). [21] They randomized 70 women with no previous thyroid disease and no iodine supplementation during

pregnancy to receive either 50 or 250µg iodine/day in the postpartum period (8 months). The study did not include a control group. Thyroid dysfunction developed in 6 women in the group receiving 50µg iodine and in 5 women in the group receiving 250 µg. Seven had sub clinical and 4 had manifest thyroid dysfunction, and 8 of these were either TPO-Ab or Tg-Ab positive. They concluded, on the basis of a prevalence of manifest thyroid dysfunction of 5.7% (4 of 70), that iodine supplementation, up to 250 µg/day, in the postpartum period was safe. [21]

The present study supports that iodine supplementation during pregnancy and postpartum is safe, even in women with circulating TPO-Ab. We did not confirm that women given iodine supplementation during the postpartum period had a more severe hypothyroid phase of PPTD, as found by Kämpe et al. [17] On the contrary, we found that the hypothyroid phase tended to be less severe in women receiving iodine postpartum [significantly higher T_4 ($P = 0.03$) and lower TSH ($P = 0.04$) in the +/+ group compared to the -/- group, with no significant difference in free T_4]. As our study environment is more iodine deficient, the difference in findings could be a matter of substrate availability for hormone synthesis during the period of thyroid regeneration. Several studies have demonstrated high urinary losses of iodine during the previous phase of thyroiditis. [24]

2.6 Long-term consequences

Although abnormalities in thyroid function mostly were transient and tended to normalize with in 9 months postpartum.14 women (21%) still had abnormal serum TSH at the end of the randomized study (9 months postpartum). Twelve had hypothyroidism (9 sub clinical and 3 clinical), and 2 had hyperthyroidism (1 sub clinical and 1 clinical). [24]

Follow-up 3 yr postpartum (median) of the initial cohort (n = 72) showed that four women later had a registered diagnosis of thyroid disease. From the +/- group, the woman with symptoms of PPTD during the study period had transient hypothyroidism 1.5 yr later, one woman developed euthyroid goiter, and one developed permanent hyperthyroidism due to Graves' disease (she left the study after pregnancy and therefore was excluded). From the -/- group, one woman had hyperthyroidism due to toxic adenoma. [24]

Of the remaining 68 women, 67 completed a questionnaire and had a test of thyroid function. Four women had either sub clinical (n = 2) or clinical (n = 2) hypothyroidism. These 4 women were all sub clinically hypothyroid at the end of the randomized study. Thus, a total of 8 women (11%) had evidence of thyroid disease at follow-up.

2.7 Hypothyroidism during pregnancy

The incidence of hypothyroidism in pregnant women has been estimated to be 0.3–0.7%. There is a known association between hypothyroidism and decreased fertility [25]. For this reason, the frequency of hypothyroidism in pregnancy is actually lower than the 0.6–1.4% frequency in the general population. Causes of hypothyroidism during pregnancy are listed here. Autoimmune thyroid disease (Hashimoto thyroiditis) and post thyroid ablation therapy are the most common causes of hypothyroidism [25]. Hypothyroidism during pregnancy has been associated with pregnancy-induced hypertension, placenta abruptio, postpartum hemorrhage, and an increase in the frequency of low birth-weight infants. [26]

Recently, Haddow et al. [12] reported that untreated hypothyroidism during pregnancy may cause a significant decrease in the IQ of children. In this study, the authors measured thyroid hormone concentrations in 25 216 pregnant women. Thyroid deficiency was undetected at the time of pregnancy in 48 of 62 women with low thyroid hormone concentrations. The IQ scores of children born to these women were, on average, seven points lower than those of children born to women with thyroid values within the appropriate reference intervals. Approximately 20% of these children had IQ levels of 85 or lower. This study suggests that TSH should be measured before or early in pregnancy to allow adequate treatment of the mother. Further research is required to determine when screening should take place, and treatment guidelines. [20]

2.8 Diagnosis of hypothyroidism

As with the assessment of hyperthyroidism, laboratory evaluation of hypothyroidism should be made using TSH and an assessment of free hormone values, either directly or via a calculated index. Total T_4 and T_3 measurements should be considered unreliable because of the increase in TBG concentrations. In addition, pregnant women who are on thyroid replacement therapy require larger doses compared with non-pregnant

patients because of increases in the TBG concentration and increased type III deiodinases from the placenta. [24]

When thyroid deficiency occurs simultaneously in a pregnant woman and her fetus, the child's neuropsychological development is adversely affected. Whether developmental problems occur when only the mother has hypothyroidism during pregnancy is not known.

In 1996 and 1997, thyrotropin was measured in stored serum samples collected from 25,216 pregnant women between January 1987 and March 1990. We then located 47 women with serum thyrotropin concentrations at or above the 99.7th percentile of the values for all the pregnant women, 15 women with values between the 98th and 99.6th percentiles, inclusive, in combination with low thyroxin levels, and 124 matched women with normal values. Their seven-to-nine-year-old children, none of whom had hypothyroidism as newborns, underwent 15 tests relating to intelligence, attention, language, reading ability, school performance, and visual–motor performance. [27]

The children of the 62 women with high serum thyrotropin concentrations performed slightly less well on all 15 tests. Their full-scale IQ scores on the Wechsler Intelligence Scale for Children, third edition, averaged 4 points lower than those of the children of the 124 matched control women (P=0.06); 15 percent had scores of 85 or less, as compared with 5 percent of the matched control children. Of the 62 women with thyroid deficiency, 48 were not treated for the condition during the pregnancy under study. The full-scale IQ scores of their children averaged 7 points lower than those of the 124 matched control children (P=0.005); 19 percent had scores of 85 or less. Eleven years after the pregnancy under study, 64 percent of the untreated women and 4 percent of the matched control women had confirmed hypothyroidism. [27] Undiagnosed hypothyroidism in pregnant women may adversely affect their fetuses; therefore, screening for thyroid deficiency during pregnancy may be warranted. [28] The link between hypothyroidism caused by iodine deficiency during pregnancy and mental retardation in the offspring has been recognized for nearly 100 years. Iodine deficiency is associated with thyroid deficiency in both mother and fetus [22] a situation that makes it impossible to determine whether the mental retardation of the fetus is due to maternal hypothyroidism or both maternal and fetal hypothyroidism. In developed countries, chronic autoimmune thyroiditis is the most common cause of hypothyroidism among

women in their child bearing years. Antibodies responsible for compromising maternal thyroid function can cross the placenta and, in some instances, compromise fetal and neonatal thyroid function. [12] One such antibody, the thyrotropin-receptor–blocking antibody, has been implicated in cases of transient congenital hypothyroidism that were identified by screening programs for newborns. [27]

In 1969, Man and Jones suggested that mild maternal hypothyroidism alone was associated with lower IQ levels in the offspring; their study involved a cohort of 1349 children, and measurements of serum butanol extractable iodine were used to distinguish between euthyroidism and hypothyroidism in women.[29] A study by Matsuura and Konishi in 1990 documented that fetal brain development is adversely affected when both the mother and fetus have hypothyroidism caused by chronic autoimmune thyroiditis.[30] In such cases, transient neonatal hypothyroidism is present. In an earlier, population-based survey of 2000 pregnancies, serum thyrotropin concentration was measured during the second trimester. [31] The concentrations were high (above 6 mU per liter) in 49 of the women, of whom 6 (3 per 1000) had low serum free thyroxin concentrations. If a lowering of the IQ levels of the offspring were to occur sufficiently often in association with this degree and frequency of maternal thyroid deficiency, then systematically determining the thyroid status of all women before or very early in pregnancy might be justified. The aim of the current study was to determine whether undetected or inadequately treated maternal thyroid deficiency during pregnancy is associated with lower IQ scores in the offspring in the absence of neonatal hypothyroidism. [20]

Chapter III
Methodology

3.1 Research design

This was a non-equivalent group (quasi experimental) type of study design because the study was lacking randomization in the selection of subjects in both the groups and control group was not equivalent to the intervention group in all aspect. The subjects of study, the pregnant women were not selected by randomization but were selected on the basis of natural process of registration in ANC clinics and hospital wards.

3.2 Study site

The site of this study was Sindhupalchok district. All pregnant women of **Sindhupalchok** were taken as the study population. Sindhupalchok is situated in hilly ecological zone of Central Development Region of Nepal. This is bordered by Kavrepalanchok, Katmandu, Nuwakot, Rasuwa, and Dolakha. It is also bordered by an international boundary with Tibet of China in the north.

Study was conducted in the same center to compare the maternal and newborn health status (outcomes) between non-randomly selected pregnant women. The **intervention group** was of 60 pregnant women of first and second trimester those who were registered in Chautara Hospital and district ANC centre. The **control group** was of 60 pregnant women of similar pregnancy status those who were admitted in the maternity ward of same hospital.

3.3 Sample size and sampling

Optimum size of sample was calculated according to the formula. Since the study design was interventional, subjects were compared and tested with appropriate statistical tests.

Total population of Sindhupalchok: 293719, total female population of reproductive age: 68740

No of expected pregnancy: 13550, no of pregnancy with 4 ANC visits: 2324

No delivery conducted by HW: 1220(9 percent), no of delivery in HI: 475 (3.5 percent)

ANC covered by district clinic: 800 (1 in 3), delivery conducted in Hospital / HW: 400

Study period 3 to 5 months, subjects enrolled: Mid trimester

Sample size (n): 100 to 120 [32]

Sample size was calculated according to: $4\ PQ / L^2$

4 X 40 X 60 divided by 10 x 10 equals to 97.44 that is 98

Estimated size of sample would be approximately 100 to 120.

3.4 Selection of study pregnant women

Initially 60 pregnant women of different centers of Sindhupalchowk who had completed first trimester of gestation were screened. Screening was done on the basis of inclusion criteria. All were interviewed with standard questionnaires along with detail general physical and obstetrical examination. Basic blood tests, routine urine tests and especial tests for iodine and thyroid hormones were performed according to standard procedures. Salt iodine estimation of all samples from respective household was performed. Findings were recorded in standard recording forms for further analysis.

3.5 Follow up

All the pregnant mothers in the study group were followed every month for regular consumption (consumption) of iodine, iron and folic acid tablets & ANC care. Findings were recorded in standard forms for further analysis. Special counseling procedures were applied to minimize defaulter. Subjects were educated about MNH care and were referred to appropriate centers for complications and abnormalities.

3.6 Midterm evaluation

All the enrolled subjects were evaluated in the middle of the study with standard study tools. Subjects were followed up for their weight gain, development of fetus and appearance of any abnormal findings. They were counseled about care of pregnancy, delivery and new born. Importance of regular consumption of iodine, iron and folic acid tablets was explained during their visits. Findings of the evaluation were recorded accordingly.

3.7 Outcomes (final) evaluation including study of newborn

Subjects under study were subjected to final interview, general physical & obstetrical examinations, laboratory investigations according to standard study tools (questionnaires, examination forms, iodine estimation forms & lab investigations forms). Study of new born was carried out to find the status of newborn according to standard neonatal examination forms. Information collected was subjected to different stages of standard data management procedures. Finally, raw data was computed, analyzed, compared and tested by appropriate statistical tests.

3.8 Outcome evaluation of control subjects

General physical and obstetrical examination of control subjects was performed when they arrived to the maternity ward of Chautara Hospital. Study questionnaires and examination forms were filled in detail for further analysis. Examination of newborn was carried out in detail and recorded in newborn examination form. Study tools were

similar to intervention group except intervention of oral iodine and regular monitoring of intervention subjects.

3.9 Intervention

Intervention group was provided with a mineral capsule (Komb) containing 150 mcg of iodine to take orally every day from the day of enrolment till delivery along with iron plus folic acid tablets and maternal and neonatal health care package.

Control group was taken from regular attendants of maternity ward of Chautara hospital and assessed for enrollment. Information about pregnancy outcomes was collected only once from the control group. No any intervention was given to the control group. Study group was followed up regularly till the pregnancy was completed with an outcome. Findings were compared between both the groups to get intended outcomes. For comparison, base line data collected from study group was also used as proxy for control group.

3.10 Monitoring and follow up

All pregnant mothers in the study group were followed every month for the regular intake (consumption) of iodine, iron, tablets & ANC care. Findings were recorded using standard tools (questionnaires and examination forms). Standard counseling procedures were applied to minimize defaulters. Subjects were educated about MNH care and were referred to the appropriate centers for any abnormalities.

3.11 Validity and reliability

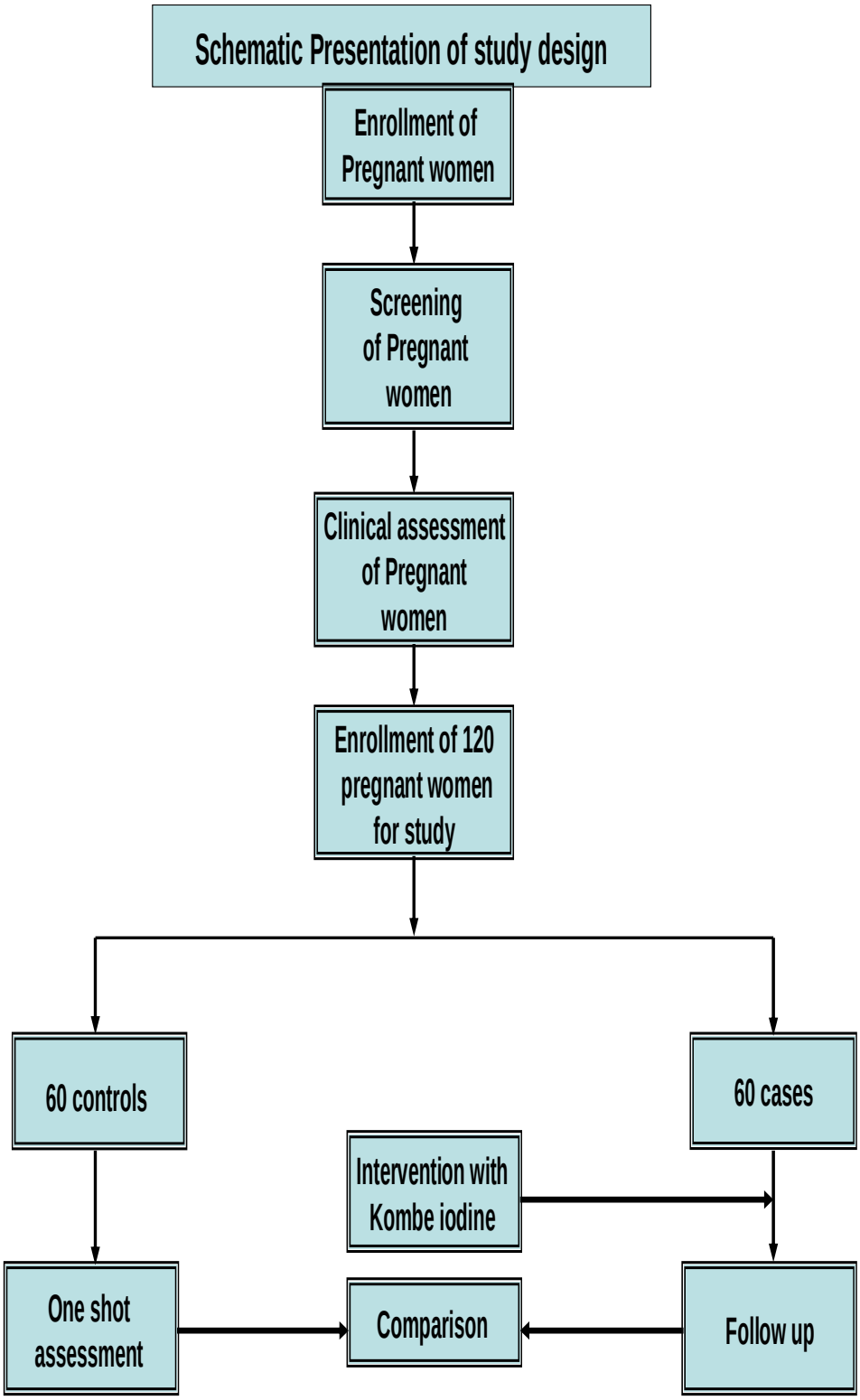
Validity and reliability of the study was considered with high priority to minimize the respective errors.

1. Appropriate sample size was selected
2. Standard study design was applied
3. Pre testing was done in separate area than the study site

4. Standard tools and techniques was developed for data collection
5. Training and orientation for enumerators was conducted as per need and data was collected under strict supervision of researcher
6. Researcher himself supervised data collection through out the study
7. Confounding factors was controlled during design and analysis of the study

3.12 Schematic presentation of study design

First of all pregnant mothers were selected for enrollment in the study. They were screened and appropriate candidates were enrolled in the intervention study. Those who did not meet the criteria were excluded according inclusion criteria. Intervention was given to those selected 60 pregnant women and followed till they deliver. Similarly 60 pregnant mothers who were admitted in the maternity ward of same hospital were taken as control for comparison.

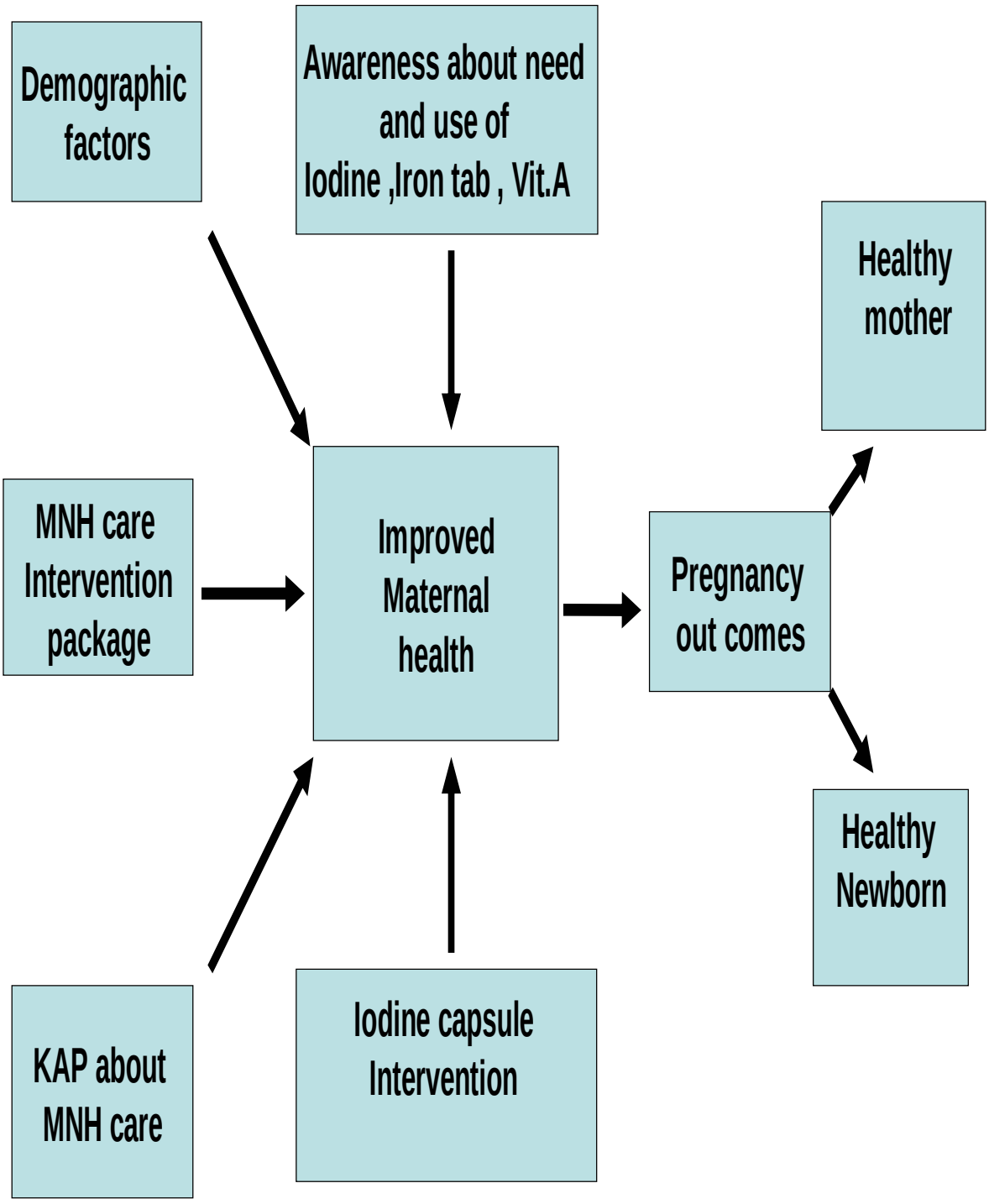

Schematic Presentation of study design
Enrollment of Pregnant women
Screening of Pregnant women
Clinical assessment of Pregnant women
Enrollment of 120 pregnant women for study
60 controls
60 cases
Intervention with Kombe iodine
One shot assessment
Comparison
Follow up

3.13 Exclusion criteria

Following subjects were not included in the study:

1. Pregnant women of more than second trimester of pregnancy
2. Pregnancy of less first trimester of pregnancy
3. Confirmed cases of multiple pregnancy
4. Pregnant cases of more than 3-4 hours far from study site
5. Pregnant women with bad obstetric history for example
6. Subjects with H/O complications who needs intensive obstetric care

3.14 Conceptual frame work



3.15 Operational definitions

Iodine Supplementation- Comb mineral capsules (containing 150mcg of Iodine along with mineral), which was supplied to pregnant mothers for 3 to 5 months as intervention till she delivered.

Iodine- Comb mineral capsules (Iodine capsules):
Specifications (a): Comb mineral has Light brown color, moisture 5.0% , Max pH 6.8+_0.5, Ash 64+_2.0%,NaCl 60.4+_2%,Bacteria count 10000/Gm max ,E.coli Negative Specifications (b):mineral content consists of: I 149.5mcg, Na 25.1, K 5.7,Mg 235.3, Ca 144.3.P 250.9 mcg / capsule

Pregnancy outcome- Results of the pregnancy in consideration to mother & newborn health including maternal and neonatal morbidity and mortality

Maternal- Normal full term delivery, premature delivery, post term delivery, abortions, maternal complications & maternal deaths

Fetal- Fetal death, late fetal deaths, still births, perinatal deaths, neonatal deaths, premature and post term baby

- Normal birth weight: 2.5 Kg or more
- Low birth weight: less than 2.5 Kg
- Small for date baby: birth weight less than 2.5 Kg in a baby who has completed 37 to 42 weeks of gestation.

Maternal and neonatal health (MNH)- State of mother and newborn's health including morbidity and mortality

MNH care service package- Essential health care package especially focused on antenatal, delivery, perinatal and postnatal care developed and implemented by DOHS /MOH Nepal.

Maternal Night blindness- Inability of pregnant women to see properly in dim light after 20 weeks of pregnancy because of deficiency of vitamin A.

Thyroid function tests (T3, T4, and TSH)- Biochemical criteria to measure the status of iodine in the blood of the study subjects before and after intervention

Goiter -Globular swelling in front of neck which moves on swallowing grade I to 3. [33]

Anemia

Table: Level of Hemoglobin percent (%) less than WHO cut off points [33]

	Hb% cut-off point (Gm/dl)	
Physiological group	Moderate anemia	Severe anemia
Pregnant women	7.0 -10.9	< 7.0
Non –pregnant women	7.0-11.9	< 7.0
Pre-school children (6-59months)	7.0-10.9	< 7.0

3.16 Data collection

Tools for data collection:

1. Questionnaires
2. Clinical examination forms (mother & newborn)
3. Laboratory investigations forms (routine & TFT)
4. Observation checklists

Health workers at local health institution were hired for data collection, 2 nursing staffs, 1 defaulter tracer, 2 laboratory technicians,1 health assistant , 1 supervisior,1 supporting staff, and 5 FCHVs.

3.17 Data management and analysis

Collected data were edited, cleaned and subjected to statistical analysis with the help of SPSS version 13. Data were analyzed and presented in the forms of descriptive statistics like frequency, percent, mean and standard deviation. Significance of difference between control and intervention and also between pre and post intervention groups was tested by T test and Chi square test. Fetal outcomes like birth weight, length, respiratory rate, heart rate, maternal outcomes like thyroid function test (thyroid hormones) and amount of blood loss during delivery were subjected to T test. Fetal

maturity status, maternal health during delivery and other categorical variables were tested with Chi square test. Rest of the qualitative variables were dealt with Chi square tests.

3.18 Ethical approval and informed consent

Ethical clearance was taken from Institutional Review Board (IRB) of the Institute of Medicine. Formal permission was taken from DHO of Chautara hospital. Voluntary participation requested from mothers and confidentiality and privacy about the information of subjects was maintained. Prior written consent was taken from each subject.

Chapter IV
Results

This chapter deals with the findings of the study obtained from analysis and interpretation of the data. The structural response, physical and biochemical findings of 120 pregnant mothers (60 interventions and 50 controls) have been analyzed according to the objectives of the study. The study was conducted among the pregnant women who were attending the ANC clinic and maternity ward of Chautara Hospital from first week of June to last week of November 2007.

4.1 Demographic profile of respondents

Demographic characteristics of subjects of both the study and control group was described depending upon the findings presented in the table. Three fifth (59.2 percent) of the subjects fell under 20 to 35 years age group. Percentage of adolescent pregnancy was still high (40 percent). But the Percentage of elderly pregnancy was less than 1(0.8) percent. Mean age of pregnant mothers was 22.1 years (SD 3.69).

Table 1: Age distribution of pregnant women

Age category of pregnant mothers	Intervention group (n = 60)	Control group (n = 60)	Total
Less than or equal to 20 years	28(46.7)	20(33.3)	48(40.0)
20 to 35 years	32(53.3)	39(65.0)	71(59.2)
36 years and above	0	1(1.7)	1(0.8)
Mean age	21.7 (S.D. = 3.07)	22.5 (S.D. = 4.22)	22.1 (S.D. = 3.69)

Ethnicity wise population of subjects was distributed diversely. Chhetri had highest percentage (35 percent), others including Dalits had occupied less than two (1.7). The percentage of under privileged group was insignificant. Other privileged casts occupied more than 98 percent. Number of Dalits and other under privileged casts was very low. Giri was a special caste, which comprised one fifth of total population (20 percent).

Table 2: Ethnic distribution of pregnant women

Ethnic distribution	Intervention group (n = 60)	Control group (n = 60)	Total
Brahmin	11 (18.3)	9 (15)	20 (16.7)
Chhetri	20 (33.3)	22 (36.7)	42 (35.0)
Newar	15 (25.0)	11 (18.3)	26 (21.7)
Giri	8 (13.3)	16 (26.7)	24 (20.0)
Tamang ,Gurung	5 (8.3)	1 (1.7)	6 (5.0)
Others	1 (1.7)	1 (1.7)	2 (1.7)

There were only two religions in the study. More than three quarter of population of subjects belonged to Hindu religion (79.2) while Buddhism occupied remaining one quarter. Number of Hindus was more predominant in intervention group than in control group while Buddhists were relatively more in control group than in intervention.

Table 3: Religion distribution of pregnant women

Religion	Intervention group (n = 60)	Control group (n = 60)	Total
Hindu	52(86.7)	43(71.7)	95(79.2)
Buddhist	8(13.3)	17(28.3)	25(20.8)

Occupation of most of study subjects was agriculture (90.8 percent). No of mother having occupation of service, business and house wife was less than 10 percent (9.1 percent). Number of mothers with service was only one (1.7 percent). In total status of service holders was less than one (0.8), percentages of business and housewife was 5.0 and 3.3 respectively.

Table 4: Occupation distribution of pregnant women

Occupation of pregnant women	Intervention group (n = 60)	Control group (n = 60)	Total
Agriculture	54(90.0)	55(91.7)	109(90.8)
Service	1(1.7)	0	1(0.8)
Business	3(5.0)	3(5.0)	6(5.0)
Housewife	2(3.3)	2(3.3)	4(3.3)

4.2 Literacy and educational status of pregnant women

Educational status of study subject was much better than other general pregnant mothers because they were aware of antenatal checkup and care of pregnancy. They were self referred cases attending antenatal clinic of Chautara Hospital for antenatal check up and care of pregnancy. Regarding literacy of study subjects, no of illiterates was only 5 percent, rest of the subjects were literate (95 percent). Among the literates less than four percent were higher secondary graduates (3.3 percent) remaining subjects have completed either primary or secondary level of education both in equal percentages (45.8 percent). There was no significance difference between intervention and control subjects. There is no one in higher secondary level of education in the control group.

Table 5: Literacy and educational status of pregnant women

Literacy Status	Intervention group (n = 60)	Control group (n = 60)	Total
Literate	56(93.3)	58(96.7)	114(95.0)

Illiterate	4(6.7)	2(3.3)	6(5.0)
Educational Status			
Illiterate	4(6.7)	2(3.3)	6(5.6)
Primary (up to grade5)	25(41.7)	30(50.0)	55(45.8)
Secondary (6 to 10 grade	27(45.0)	28(46.7)	55(45.8)
Higher secondary (10 plus 2)	4(6.7)	0	4(3.3)

Type of the family was also similar to the other similar geographical regions. More than 3 families out of five (62.5 percent) were of joint in type, rest of the families were of nuclear in type (37.5 percent). There was very much similarities between intervention and control group. Regarding location of household almost all (100 percent) households were located in rural setting because of sociogeographical situation of the district. Chautara the head quarter of Sindhupalchowk district itself was a rural community.

4.3 Knowledge about iodized salt (Aayonoon) and its use

There was a couple of studies done to find out the status of IDD in Sindhupalchok district in the past. Studies have shown that still the no of house holds using salts other than iodized salt was still very high. This study has shown that the no of subjects who knew about iodized salt (Aayonoon) and its use was very high than previous study. No of study subjects who knew about iodized salt was nearly universal (98.3 percent).Those who didn't know about Aayonoon were less than 2 percent. Considering the percentages of use of iodized salt, four out of five (82.5 percent) study subjects were using iodized salt in their family. Only less than one out of five (17.5 percent) were using salts other than Aayonoon. There was not much difference between subjects of intervention and control group in the use of iodized salt.

Table 6: Knowledge about iodized salt and its use

Characteristics	Intervention group(n=60)	Control group (n=60)	Total
Heard about iodized salt			
Yes	58 (96.7)	60 (100)	118 (98.3)
No	2 (3.3)	0	2 (1.7)
Use of iodized salt			
Yes	50 (83.3)	49 (81.7)	99 (82.5)
No	10 (16.7)	11 (18.3)	21 (17.5)

Percentage wise distribution of duration of use of iodized salt among the families of study subject is depicted in table. Which shows nearly half of the families were using iodized salt for more than 3 years. Percentages of families using less than one year was still one out of five (18.3 percent). Nearly one third of the families were using iodized salt for 1 to 3 years duration.

Table 7: Duration of use of iodized salt by subjects

Duration of use of iodized salt	Intervention group(n=60)	Control group (n=60)	Total
Less than 1 year	11 (18.3)	11(18.3)	22 (18.3)
1 to 3 year	15 (25.0)	24 (40.0)	39 (32.5)
More than 3 years	34 (56.7)	25 (41.7)	59 (49.2)

Similarly persons who advised to use iodized salt to the families of study subject are also presented. Less than half of the families of study subject were advised to take iodized salt by neighbors. Percentages of advice given by health workers and family members to use iodized salt were nearly equal (7.6 and 8.4 percent). Less than 6 (5.9 percent) percent of families of subjects were advised to use iodized salt by the teachers. One third (32.8 percent) of subjects were not advised by anyone to use iodized salt. Neighbors were common source of advice to the families of pregnant women with percentages of 33.9 and 56.7 respectively in both control and intervention group. There was no significance difference between intervention and control group about advice given to use iodized salt to their families.

Table 8: Persons who advised to use iodized salt to subjects

Who advised to use iodized salt	Intervention group(n=60)	Control group (n=60)	Total
None	20 (33.9)	19 (31.7)	39 (32.8)
Health worker	7 (11.9)	2 (3.3)	9 (7.6)

Neighbor	20 (33.9)	34 (56.7)	54 (45.4)
Family members	5 (8.5)	5 (8.5)	10 (8.4)
Teacher	7 (11.9)	0	7 (5.9)

4.4 Pregnancy related characteristics of intervention and control group

Different characteristics related to pregnancy were studied with the help of structured questionnaires and physical examination forms in both the subjects of intervention and control group. Both the subjects belonged to similar circumstances presenting similar characteristics for comparison. Characteristics were compared between intervention and control and also between pre and post intervention in the same study subjects.

Parity of intervention and control group is presented in the table. Three out of five pregnant women (59.2percent) were primigravida. Two out of three pregnant women were second gravida and less than 8 percent of pregnant women were multigravida. There was no significance difference between intervention and control group.

Table 9: Parity of subjects

Parity of subject	**Intervention group(n=60)**	**Control group (n=60)**	**Total**
Gravida 1	36(60.0)	35(58.3)	71(59.2)
Gravida 2	21(35.0)	19(31.7)	46(33.3)
More than gravida 2	3(5.0)	6(10.0)	9(7.5)

Status of antenatal check up of pregnant women of intervention and control group is presented in the table, which has revealed that status of antenatal check up in both the groups was universal (96.7 and 96.7 percent). Less than four (3.3 percent) percentage of pregnant women did not have antenatal checkup.

Table 10: Status of antenatal check up of subjects

Ante natal check up	Intervention group(n=60)	Control group (n=60)	Total
Yes	58(96.7)	58(96.7)	116(96.7)
No	2(3.3)	2(3.3)	4(3.3)

More than two third (43.3percent) of subjects had completed second antenatal visit. Nearly one third (30 percent) of the pregnant mothers had completed first visit. Pregnant women those not attending ANC at all and those attending more than third visit were 3.3 and 3.3 percent respectively. Number of subjects those attending at later visits ie third and fourth visits in intervention group were nil while number of subjects attending first and fourth visits were relatively less in control group.

Table 11: Status of antenatal visits

No. of ANC visits	Intervention group(n=60)	Control group (n=60)	Total
None	2 (3.3)	2 (3.3)	4 (3.3)
First visit	35 (58.3)	1 (1.7)	36 (30.0)
Second visit	23 (38.3)	29 (48.3)	52 (43.3)
Third visit	0	24 (40.0)	24 (20.0)
Fourth visit	0	4 (6.7)	4 (3.3)

Pregnant women not vaccinated against tetanus even a single dose were less than six percent only. Pregnant mothers having TT 1 vaccination were nearly three out five (55.8 percent). Numbers of mothers having TT 2 injection were less than two out of three (38.3 percent) with a marked difference between subjects of intervention and control group in TT1 and TT2 injection. Use of iron and folic acid tablets during pregnancy is presented in following table which shows that only less than six (5.8) percent of pregnant women were not taking iron and folic acid tablets at all. So the use of iron and folic acid tablet during pregnancy was universal.

Table 12: Status of TT injection and use of iron tablets

Characteristics of mother	**Intervention group(n=60)**	**Control group (n=60)**	**Total**
No. of TT injection			
Non	5(8.3)	2(3.3)	7(5.8)
TT 1	49(81.7)	18(30.0)	67(55.8)
TT 2	6(10.0)	40(66.7)	46(38.3)
Use of Iron tablets			
Yes	55(91.7)	58(96.7)	113(94.2)
No	5(8.3)	2(3.3)	7(5.8)

Mean height among mothers of intervention group was 158.75 CM with a standard deviation of 2.808. Mean weight of the same group was 56.12 Kg with a standard deviation of 3.284. Similarly mean height of mothers of control group was 159.73 CM with a standard deviation of 1.103 while weight of the same group was 57.87 Kg with a standard deviation of 2.960.

Table 13: Mean weight and height of subjects

Characteristics	**Intervention group(n=60)**	**Control group (n=60)**	**Total**
Mean height in CM	158.75 (SD 2.808)	159.73 (SD 1.103)	159.24 (SD 2.181)
Mean weight in KG	56.12 (SD 3.284)	57.87(SD 2.960)	56.99 (3.235)

4.5 Maternal outcomes among intervention and control group

Maternal out comes were described as types of delivery , duration of third stage , amount of blood loss , any complications , status of referral and duration of pregnancy at delivery. These were considered as the standard indicators of maternal out come. Each component of maternal outcomes were analyzed and presented according to the objectives. Less than half of the deliveries were normal (45 percent), one out of three deliveries were combined with episiotomy followed by normal delivery with tear which was 15.8 percent. Only five percent of deliveries were complicated needing assistance. There was no significance difference between the deliveries of intervention and control group.

Table 14: Type of delivery of intervention and control subjects

Type of delivery	**Intervention group (n=60)**	**Control group(n=60)**	**Total**
Normal delivery	27(45.0)	27(45.0)	54(45.0)
Normal delivery with episiotomy	21(35.0)	20(33.3)	41(34.2)
Normal delivery with tear	10(16.7)	9(15.0)	19(15.8)
Assisted delivery	2(3.3)	4(6.7)	6(5.0)

Four out of five (80.8 percent) deliveries had third stage of less than 30 minutes while one out of five (19.2 percent) had prolonged third stage (more than 30 minutes). The difference between intervention and control group was not significant. Amount of blood loss was measured in milliliter. Nearly 90(89.2) percent of deliveries had lost less than 200 and more than 50 ml of blood while less than eight (7.5) percent had lost more than 200 ml of blood during delivery.

Table 15: Duration of third stage and amount of blood loss

Duration of third stage in minutes	**Intervention group (n=60)**	**Control group(n=60)**	**Total**	**P-value**
10 to 30 minutes	50(83.3)	47(78.3)	97(80.8)	
More than 30 minutes	10(16.7)	13(21.2)	23(19.2)	
Amount of blood loss in ml				
Less than 50	2(3.3)	2 (3.3)	4 (3.0)	0.582
50 to 200	55(91.7)	52(86.7)	107(89.2)	
More than 200	3(5.0)	6(10.0)	9(7.5)	

More than ninety (92.5) percent of the mothers had delivered between 38 to 42 weeks of pregnancy which is considered as normal. Only less than 7.5 five percent pregnant women had delivered before 38 weeks of gestation. None had delivered before 29 and after 42 weeks of gestation. The difference in duration of pregnancy is statistically significant between intervention and control group. The difference in weight of pregnant mother before and after intervention of at least three months duration is also statistically significant**.**

Table 16: Period of gestation at delivery and mean weight of subjects

Period of gestation in weeks	Intervention group (n=60)	Control group(n=60)	Total	P-value
29 to 37	0	9(15)	9(7.5)	0.002
38 to 42	60(100)	51 (85.0)	111(92.5)	
More than 42	0	0	0	
Mean weight in Kg	**Pre intervention**	**Post intervention**	**-**	
Mean weight in KG	56.12	59.62)	-	0.000
Standard deviation	SD = 3.284	SD = 3.325	-	

4.6 Perinatal outcomes

Perinatal outcomes comprises of fetal maturity, weight of newborn, general condition of fetus, fetal length perinatal morbidity and mortality. These indicators were analyzed, computed and compared to find out the difference between intervention and control group. Mean weight of newborn in intervention group was 3.333 Kg with a standard deviation of 0.2515; similarly weight of newborn in control group was 3.046 Kg with a standard deviation of 0.4408. Weight of newborn was highly significant between intervention and control group. Similarly length of newborn was also statistically significant.

Table 17: Mean weight and length of newborn

Weight of newborn	Intervention group (n=60)	Control group(n=60)	Total	P-value

Mean weight (SD)	3.333 (0.2515)	3.046 (0.4408)	-	0.000
Mean length (SD)	51.00 (1.507)	50.18 (1.546)	-	0.004

More than half of newborn (55.8 percent) had fair general condition during birth. More than one third of new born (35.8) had good general condition and less than nine (8.3) percent had poor general condition. Regarding cry of the new born , nearly four out of five babies (78.3 percent) had active cry while one out of five babies had moderate and less than three(2.5) babies had poor cry. There was no significant difference in general condition and cry of newborn between babies of intervention and control group.

Table 18: General condition and cry of newborn

Characteristics of newborn	**Intervention group (n=60)**	**Control group(n=60)**	**Total**	**P-value**
General condition of newborn				
Good	26(43.3)	17(28.3)	43(35.8)	0.221
Fair	30(50)	37(61.7)	67(55.8)	
Poor	4(6.7)	6(10)	10(8.3)	
Cry of newborn				
Active	50(83.3)	44(73.3)	94(78.3)	0.152
Moderate	10(16.7)	13(21.7)	33(19.2)	
Poor	0	3(5.0)	3(2.5)	

Almost three quarter (75.8 percent) of newborns were pink in color at birth. Less than one quarter (23.3 percent) newborns were pale at birth and less than one (0.8) percent of newborns were blue at time of child birth. Similarly four out of five (78.3 percent) babies newly born were sucking well while less than six (5) percent newborn were sucking poorly. Color of newborn and sucking were not statistical significant between intervention and control group.

Table 19: Color and sucking of newborn

Characteristics of newborn	**Intervention group (n=60)**	**Control group (n=60)**	**Total**	**P-value**
Color of newborn				
Pink	44(73.3)	47(78.3)	91(75.8)	0.434
Pale	16(26.7)	12(20.2)	28(23.3)	
Blue	0	1(1.7)	1(0.8)	
Sucking				
Well	48(80.0)	46(76.7)	94(78.3)	0.233
Moderate	11(18.3)	9(15.0)	20(16.7)	
Poor	1(1.7)	5(8.3)	6(5.0)	

Initiation of breast feeding to feed colostrums was studied in recently delivered mother during their hospital stay to know the status of knowledge of importance of early breast feeding. Three quarter (76.7 percent) of mothers had first breast fed their babies with in 10 to 30 minutes of delivery. Nearly one out of five (18.3 percent) babies was breast fed with in 30 to 60 minutes of child birth. Percentage of newborn who were breast fed before 10 minutes and after one hour of birth was less than five. The difference in

initiation of breast feeding to their babies was statistically significant between intervention and control group.

Table 20: Initiation of breast feeding of newborn

Breast feeding of newborn	Intervention group (n=60)	Control group (n=60)	Total	
Less than 10	5(8.3)	0	5(4.2)	P-value
10 to 30	50(83.3)	42(70.0)	92(76.7)	0.004
30 to 60	5(8.3)	17(28.3)	22(18.3)	
More than 60	0	1(1.7)	1(0.81)	

4.7 Laboratory characteristics of study subjects

To know the status of thyroid hormones of study subject, biochemical indicators were used. To know the difference in thyroid profile before and after intervention thyroid function tests of intervention subjects were performed, data collected, analyzed and compared. Among the three hormones thyroxin (T4) was significantly different between pre intervention and post intervention. Rest of the hormones, triiodothyronin (T3) and thyroxin (T4) did not show significant difference between pre and post intervention.

Table 21: Laboratory characteristics of study subject

Thyroid function test	Pre intervention mean value	Post intervention mean value	P-value
Triiodothyronin (T3) pg	2.660 (0.7019)	2.798 (0.6407)	0.097
Thyroxin(T4) ng	1.115(0.1777)	1.220 (0.1870)	0.000
Thyroid stimulating hormone(TSH) IU	1.570 (1.1282)	1.655 (0.9143)	0.554

Chapter V
Discussion

IDD is an important micronutrient deficiency disorder in Nepal. Long back in some isolated mountainous areas of Nepal, most of the adult women had goiter and 10 percent of were cretins (severest IDD) population. [4]

Status of IDD has been improved a lot in last 3 decades. Since the introduction of iodized salt prevalence of using of Aayonoon has been improving. A couple of studies done in Sindhupalchok and neighboring district Kavre (Current IDD status assessment) 2004 has shown increasing trend in use of iodized salt and decreasing trend of iodine deficiency disorders but not to the satisfactory level. Reports of those studies have pointed out Sindhupalchok as a district of iodine deficiency disorders with fairly high prevalence. Different national and sub national level studies done in past and some of the recent studies have identified IDD is still prevalent in most of the mountainous districts of Nepal. [35] Depending upon the reports of those studies we have selected Sindhupalchok as a study district. Our objectives of doing study in Sindhupalchok is to find out the status of iodine deficiency disorders among pregnant women and impact of iodine intervention during pregnancy to the perinatal outcomes in the same group. Demographic characteristics of subjects were studied to know the relation of those factors with the pregnancy outcomes. Age distribution of pregnant mothers showed that 59 .2 percent of mothers belonged to 20 to 35 year age group, 40 percent of the respondents were below 20 years. This is greater than national figure. Pregnant women having age of more than 35 year were less than 1(0.8) percent which is better than national figure. There were similarities in age distribution between both groups. Number of adolescent pregnancy was still high as compared to national context. Mean age of pregnant mother was 22.1 years. Ethnically, distribution of subjects is diverse. Majority of study subjects belonged to Chhetri, followed by Newar (21.7 percent), Giri (20 percent) and Bramin (16.7 percent). Tamang and Gurung were 5 percent. Others minorities were less than 2 (1.7) percent. Hindu was the most common religion (79.2 percent) followed by Buddhism (20.8 percent). Agriculture was most important occupation of subjects (90.8 percent). Service, business and housewife altogether comprised 9.2 percent. Almost (95 percent) of subjects were literate, among them

completing primary and secondary level education were 45.8 percent each. Number completing higher secondary level was less than 4 percent. Three out of five (62.5 percent) pregnant women lived in joint family while 37. 5 percent lived in nuclear family. Being mountainous district almost all (100 percent) households were located in rural area. Knowledge about iodized salt was universal (98.3percent) which was better than previous report. [35] Use of iodized salt (salt with two children logo) was fair (82.5 percent) among the subjects which was fairly good than 2004 report. [35]

Among those who were using iodized salt, 49.2 percent were using it for more than 3 years shows that awareness about iodized salt is not that old. Majority of advice to take iodized salt was given by neighbors (45.4 percent). 32.8 percent of respondents did not get advice from any means. Role of health workers in giving advice was minimal (7.6 percent).

Pregnancy characteristics of subjects were described in terms of parity of mother, status and number of ANC visit, number of TT injection and use of iron plus folic acid tablets. Three out of five (59.2 percent) pregnant were primigravida, one out of three (33.3 percent) were gravida 2 and less than 8 percent were multi gravida (more than 2 gravida). Almost all (96.7 percent) subjects had attended ANC which was extremely high than national figure (Annual report FY 2062 -63). Percent of completing second visit was 43.3 percent. Percentages of subjects those who had completed fourth visit was 3.3 percent which was significantly less than national figure. [36] Majority (55.8 percent) of pregnant women were vaccinated against tetanus for once only while the number vaccinated twice for tetanus was 38.3 percent. Most of the subjects had taken iron and folic acid tablets (94.2 percent) for 1 to 5 months. Mean height of pregnant mothers was 159.73 cm with a standard deviation of 2.181.

Maternal outcomes were described in terms of type of delivery, duration of third stage, amount of blood loss in milliliters, period of gestation at delivery in weeks and mean weight in kg before and after implementation of iodine capsule. 45 percent of deliveries were normal followed by normal delivery with episiotomy, normal delivery with tear and complicated assisted delivery. A percentage of complicated assisted delivery was 5.8.Eight percent of deliveries had normal third stage (10 to 30) minutes. Majority of deliveries had lost moderate amount of blood (50 to 200ml). More than 90 (92.5)

percent deliveries had completed weeks of gestation (38 to 42 weeks), which was statistically significant. Mean weight of mothers before and after intervention was 56.12 Kg with a standard deviation of 3.284 and 59.62 Kg with a standard deviation of 3.325 respectively with great statistical significance. One of the most exciting studies done in Italy has come out with a finding that the rate of preterm delivery and miscarriage was four to eight times higher in the mothers whose thyroid deficiency disorder was not corrected. That was first study to demonstrate that in intervention makes difference. [12]

Perinatal outcomes were described in terms of mean weight, mean length, general condition, cry, color and sucking of newborn. Those outcome indicators were compared and tested statistically between intervention and control group. Mean weight of newborns of intervention and control group were 3.333 Kg (SD= 0.2515) and 3.046 Kg (SD=0.4408) respectively with a high statistical significance. Similarly mean length of newborns of intervention and control group were 51.00cm (SD=1.507) and 50.18cm (SD=1.546) respectively with a statistical significance. Majority of newborns(55.8 percent) had fair degree of general condition, 35.8 percent had good and 8.3 percent had poor degree of general condition. Four out five (78.3 percent) newborns had active cry, 19.2 percent had moderate and 2.5 percent of the newborns had poor cry. Regarding color of newborn at delivery, 75.8 percent had pink, 23.3 percent had pale and 0.8percent of newborn had blue color at birth. Four out of five (78.3 percent) newborns sucked well, 16.7 percent had sucked moderately and 5 percent of babies had very poor sucking. Three quarters (76.7 percent) of the babies were breast with in 10 to 30 minutes of birth while 18.3 percent of babies were breast with in 30 to 60 minutes of child birth. Percentage of newborns that were breast fed beyond 60 minutes was 0.81.

Laboratory investigations were also performed to find out the significant biochemical difference between pre and post intervention. TFT was performed as an indicator to identify the difference in thyroid hormone level of study subjects. Mean value of three hormones, Tri-iodothyronin (T3), thyroxin (T4) and thyroid stimulating hormone (TSH) were computed to compare and test statistically. Mean values of T3 during pre and post intervention period were 2.660 pg (SD=0.7019) and 2.798(SD=0.6407). In this study there was no statistical significance in the mean difference of T3 between pre and post intervention study.

Mean values of T4 during pre and post intervention period were 1.115 (SD=0.1777) and 1.220 (SD = 0.1870) respectively with high statistical significance (P-value=0.000). Similarly values of TSH in study subjects during pre and post intervention period were 1.570(SD=1.1282) and 1.655(SD=0.9143) respectively. This study did not show significant difference in TSH level between pre and post intervention study though elevated serum TSH, unless exceptional pathological situations indicates the potential risk of iodine deficiency on brain development. There was no logical and biochemical co-relation among the changes in hormonal level between pre and post intervention period. Immediate effects may not be detected even if there is significant decrease in thyroid hormone level. This was recently reported by Haddow et al. [12, 20] The effects will be detected in the mental development of their children, which needs to be tested by IO of school age children. A population-based survey of 2000 pregnancies for thyroid function test during second trimester was performed which showed high concentration of TSH (above six mu per liter) in 49 of the women, of whom 6 (3 per 1000) had low serum free thyroxin concentrations. [31]

Chapter VI
Conclusion and Recommendations

6.1 Conclusion

We conclude that regular supplementation of iodine along with iron and folic acid tablets during pregnancy preferably in first and second trimester, following systematic screening for iodine deficiency disorders (especially for hypothyroidism) may be worth while even when the degree of deficiency is mild and does not cause immediate clinical manifestations in the women. If routine screening were to be introduced, the most conservative policy would be to perform at the first prenatal visit preferably in the first trimester. Intervention with standard maternal and neonatal health care package, regular supplementation of iron folic should also be incorporated to achieve desired perinatal outcomes. 93 percent of deliveries were full term, less than 5 percent deliveries were complicated, significance difference in mean weight gain during third trimester of pregnancy following intervention, significance difference in mean weight and length of newborn and significance difference in thyroxin hormone level all these findings supported to conclude the study. Finally regular supplementation of iodine in oral form for more than three months during pregnancy preferably during early stage along with regular intake of iron and folic acid and intervention of standard maternal and neonatal health care package will bring significant positive changes in perinatal (maternal and neonatal) outcomes . Intervention in early pregnancy is the important factor to achieve expected out comes in the development of nervous system of newborn.

6.2 Recommendations

- Program of regular supplementation of iodine in oral form in iodine deficient area during early stage of pregnancy can be implemented to avoid birth of iodine deficient new born.
- Integrated intervention of standard maternal and neonatal health care package and oral iodine supplementation can be implemented to bring better perinatal outcomes.
- Regular intake iron and folic acid tablets and iodine capsules can jointly be run together to get intended maternal and neonatal outcomes.
- Early systematic screening of women in early stage of pregnancy during prenatal visits to find out iodine deficiency disorders is recommended.
- Campaign to raise awareness about the use of iodized salt especially in iodine deficient areas is also recommended.
- Regular monitoring of salt iodization in those iodine deficient areas should be strengthened.
- Further research on iodine intervention and pregnancy outcomes in a large scale in early stages of gestation followed by assessment of IQ of school age children in the same subjects is recommended.

References

1. ICCIDD, UNICEF. Progress towards the Elimination of Iodine Deficiency Disorder (IDD).
2. WHO, the world Health Report 2002, was reducing Risks, Promoting Healthy Life Geneva 2002.
3. Dunn JT. Glinoer D. 1993 Specific recommendations on iodine nutrition for mothers and infants in Europe. In: Delange F, Dunn JT, Glinoer D, eds. Iodine deficiency in Europe: a continuing concern. New York: Plenum Press; 478.
4. HMG, Ministry of Health (1967). *Endemic Goiter in Nepal, WHO/SEA/26, October 1967.*
5. HMG/N, New ERA, Micronutrient Initiative, UNICEF Nepal, and WHO.
6. NMSS (1998). *Nepal Micronutrient Status Survey 1998*. Katmandu, Nepal: Ministry of Health, Child Health Division,
7. MoHP Department of Health Services National Nutrition Policy and Strategy (NNPS), 2004.
8. Glinoer D. The regulation of thyroid function in pregnancy: pathways of endocrine adaptation from physiology to pathology. Endocr Rev 1997; 18:404-433.[Free Full Text]
9. Glinoer D, De Nayer P, Delange F, et al. 1995 A randomized trial for the treatment of mild iodine deficiency during pregnancy: maternal and neonatal effects. J Clin Endocrinal Metab. 80:258–269.
10. Hetzel, B.S., and Pandav, C.S. 1996. S.O.S. for a billion. The conquest of Iodine
11. Gardner LI. Historical notes on cretinism. In: Gardner LI, ed. Endocrine and genetic diseases of childhood and adolescence. 2nd ed. Philadelphia: W.B. Saunders, 1975:234-8.
12. Haddow JE, Palomaki GE, Allan WC, et al. Maternal thyroid deficiency during pregnancy and subsequent neuropsychological development of the child. N Eng J Med 1999; 341:549-555.
13. Karmakar, M.G. & C.S. Pandav (1885). Iodine Deficiency Disorders in Nepal: Monitoring and Quality Control of Iodated Salt, A Report, All India Institute of Medical Sciences, New Delhi, May-June 1985.

14. WHO, the world Health Report 2002, was reducing Risks, Promoting Healthy Life Geneva 2002.
15. MOH, MI, New ERA, 2005, Nepal Iodine Deficiency Disorders Status Survey
16. Pharoah POD, Connolly KJ, Ekins RP, Harding AG. Maternal thyroid hormone levels in pregnancy and the subsequent cognitive and motor performance of the children. Clin Endocrinol (Oxf) 1984; 21:265-270.[Medline]
17. Corinne R. Fantz, Samuel Dagogo-Jack, Jack H. Ladenson and Ann M. Gronowski Thyroid Function during Pregnancy 45: 2250-2258, 1999 Maternal Thyroid Deficiency during Pregnancy and Subsequent Neuropsychological Development of the Child
18. VOA. com. 13 December 2006, Physician Urges Tests for Thyroid Disease during Pregnancy, News; Voice of America, New York
19. Matsuura N, Konishi J. Transient hypothyroidism in infants born to mothers with chronic thyroiditis -- a nationwide study of twenty-three cases. Endocrinol Jpn 1990; 37:369-379. [Erratum, Endocrinol Jpn 1990; 37:767a.][Medline]
20. Utiger RD. Maternal hypothyroidism and fetal development. N Engl J Med 1999; 341:601-602.
21. Reinhardt W, Kohl S, Hollmann D, et al. 1998 Efficacy and safety of iodine in the postpartum period in an area of mild iodine deficiency. Eur J Med Res. 3:203–210
22. Nøhr SB, Laurberg P. 2000 opposite variations in maternal and neonatal thyroid function induced by iodine supplementation during pregnancy. J Clin Endocrinal Metab. 85:623–627
23. Pedersen KM, Laurberg P, Iversen E, et al. 1993 Amelioration of some pregnancy-associated variations in thyroid function by iodine supplementation. J Clin Endocrinol Metab. 77:1078–1083.
24. Daniel G, Nayer PD, Delange F, Lemone M. A Randomized Trial for the Treatment of Mild Iodine Deficiency during Pregnancy. *Journal of Clinical Endocrinology and Metabolism*
25. Maternal and Neonatal Effects, 1995, by U.S.A
26. Mandel SJ, Larsen PR, Seely EW, Brent GA. Increased need for thyroxin during pregnancy in women with primary hypothyroidism. N Engl J Med 1990; 323:91-96.
27. Dussault JH, Fisher DA. Thyroid function in mothers of hypothyroid newborns. Obstet Gynecol 1999; 93:15-20.

28. WHO. A statement by the WHO. Safe use of iodized oil to prevent iodine deficiency in pregnant women.
29. Delange, F., Dunn, J.T., and Glinoer, D. 1993. Iodine Deficiency in Europe. A continuing concern. New York: Plenum Press publ. 1-491 pp.
30. Laurberg P, Pedersen KM, Hreidarsson A, Sigfusson N, Iversen E, Knudsen PR. 1998 Iodine intake and the pattern of thyroid disorders: a comparative epidemiological study of thyroid abnormalities in the elderly in Iceland and in Jutland, Denmark. J Clin Endocrinal Metab. 83:765–769.
31. Klein RZ, Haddow JE, Faix JD, et al. Prevalence of thyroid deficiency in pregnant women. Clin Endocrinol (Oxf) 1991; 35:41-46.[Medline]
32. Department of Health Services, MoH, Nepal. Annual report (2061/62)
33. UNICEF /WHO. Website available at
34. WHO. Iodine Status Worldwide, WHO Global Database on Iodine Deficiency, 2004
35. Joshi AB, Banjara MR, Rikimaru T and Pandey S. Assessment of Current Status of IDD for the Development of Future Control program JICA Nepal. 2004.
36. DOHS, UNFPA .Annual Report 2004 -2005. 2006, Nepal
37. ACC / SCN. Micronutrient update, 4th Report on the world Nutrition situation, 2000
38. DOHS, NPHA, WHO. National Health Prevention and Treatment protocols 2005, Nepal
39. Deficiency Disorders. 2nd Ed. Delhi: Oxford University Press publ. 1-466 pp.
40. Hetzel, B.S. The Story of Iodine Deficiency: An International Challenge. New York: Oxford University Press, 1989.
41. http://indorgs.virginia.edu/iccidd/www.thyroidmanager.org. (Micronutrient Initiative, Kiwanis International).
42. MOH, UNICEF, WHO, MI, New ERA Ltd.1998, Nepal Micronutrient Status Survey.
43. MOHP, New Era. Demographic Health Survey 2006, Nepal
44. MoH, WHO, UNICEF, New ERA. Nepal Micronutrient Status Survey, 1998.
45. Pop VJ, Kuijpens JL, van Baar AL, et al. Low maternal free thyroxin concentrations during early pregnancy are associated with impaired psychomotor development in infancy. Clin Endocrinol (Oxf) 1999; 50:149-155.[CrossRef][Medline]

46. Susanne B. Nøhr A. Jørgensen K. Pedersen M. and Peter L.The Journal of Clinical Endocrinology & Metabolism: Vol. 85, No. 9 3191-3198 Copyright © 2000 by the Endocrine Society
47. UNICEF. State of the Worlds Children 2004
48. UNICEF. Indicators for assign iodine deficiency disorders & their control through salt iodization, New York, 1994.
49. Zulewski H, Muller B, Exer P, Miserez AR, Staub JJ. 1997 Estimation of tissue hypothyroidism by a new clinical score: evaluation of patients with various grades of hypothyroidism and controls. J Clin Endocrinol Metab. 82:771–776. Delange F, Dunn.

Annexes

Survey Questionnaire for Pregnant women

(*Questions need to be asked to all pregnant women & general physical & obstetrical examination of the same should be performed)*

1. General information

Date (dd/mm/yy): / / 2064

ID no.

Name of respondent: Age: …… (In completed years)

Religion: Caste/ Ethnicity:

District: Village/Tole

VDC/ Municipality: Ward number

Occupation (write clearly type in brief):

Education:

1) Can't read write
2) Can read and write
3) Primary level school (up to 5grade)
4) Secondary level school (6 to 10 grade)
5) Higher Secondary education (10 plus grade)
6) University education

1. Type of family

1) Single (nuclear) 2) Joint

2. Location of the household

1) Rural
2) Urban

2. Knowledge on iodized salt

3. Have you ever heard about iodized salt?

1) Yes 2) No

If yes, what was the source?

1) Radio 2) T V 3) News Papers 4) Others ……

5) Don't know

4. Do you use iodized salt?

1) Yes 2) No

5. Since when are you using iodized salt?

……. (Years/months)

6. Who suggested you to use iodized salt?

1) Health personnel
2) Neighbor
3) Family members
4) Teachers
5) Others (specify)

3. Knowledge on IDD

7. Do you know any symptoms or disease caused by iodine deficiency?

1) Yes 2) No

If yes, what are they?

a)

b)

c)

8. Is any member of your family has been suffering from goiter?

1) Yes 2) No

Q.N.	Questions and filters	Answers	Answer or Code	Skip
9.	How many times did you conceive?	Number of conceptions		
10.	How many times did you have live births	Number of live births		
11.	What is the number of living children?	Number of living children		
12.	What is the period of amenorrhea of last pregnancy?	Period of amenorrhea (in months)		
13.	What is the date of your last menstruation?	LMP:(dd/mm/yy) / / 2064		

If yes mentions relation to the pregnant women ……

Age (in years)……

4. Knowledge about Maternal care:

14.	**Did you see anyone for ANC (antenatal care)?**	1 Yes 0 No	_____	**If No, Skip**
15.	Whom did you see? **Only one answer**	1 Doctor 2 ANM 3 MCHW 4 Other	_____	
16.	Do you have a maternal health card?	1 Yes 0 No	_____	**If No, Skip**
17.	Record from the card A Number of ANC visits B Number of TT vaccines	Number of visits Number of TT vaccines	_____ _____	
18.	How many times did you see someone for care during the Pregnancy? **For woman not having card**	Number of times	_____	
19.	During your ANC were you counseled on the following? **Multiple answer possible** **Read the options**	1. Delivery preparation 2. Breast feeding 3. Child spacing 4. Immunization 5. Danger signs of pregnancy 6. No counseling	_____ _____ _____ _____ _____	
20.	For how long did you consume iron pills/folic acid?	Number of ---------days	_____	

21.	Do you know about danger signs /symptoms during pregnancy?	1 yes 0 no		**If no skip**
22.	What danger signs/symptoms require immediate medical assistance during delivery? **Multiple responses possible Record all responses** **Don't read the options**	O Do not know A Fast and difficult breathing B Bleeding from genital tract C Swelling of legs, arms, face D High fever E High blood pressure F Blurred vision G Anemia H Persistent vomiting I Fainting/fitting X Others----------		
23.	Do you have any difficulty to see in dim light during this pregnancy? **(Question regarding Night blindness during pregnancy)**	1 Yes 0 No Don't know		

24. Iodine content in the Salt sample

1. Sample I 1)10 PPM 2)Below 15 PPM 3)Above 15 PPM
2. Sample II 1) 0 PPM 2) Below 15 PPM 3) Above 15 PPM

Name of enumerator: Designation:

Signature: Name of the clinic:

Date:

Iodine Supplementation and Pregnancy Outcomes among Pregnant Women in Sindhupalchok

Consent Form

Thank you for agreeing to participate in this study and being interviewed. The examination results of the study will be shared with you. You have agreed to answer a few questions, perform physical and laboratory examination. You have the right to stop the interview and examinations at any time.

……..yes, I agree to be interviewed and examined

……..No, I do not agree to be interviewed

Print Name: ……..

Participant's Signature:……..... Date: ……..

Respondents' initial Physical Examination Form

ID No. Date of examination
Name of the respondents Age in Yrs.
Address: ……. VDC/Municipality ……..W.No
No of visits ……. District

1. Vitals
   BP
   Pulse
   Temperature (F)
   Height (CM)
   Weight (Kg)
   BMI

2 General
   Skin color, Pallor, Jaundice
   Edema

3 Neck:
   Thyroid swelling
   Stage I
   Stage II
   Stage III

4 Abdominal
   Height of the fundus (in weeks)

   Fetal parts palpable or not
   Presentation
   Lie
   Head of the fetus
   FHS
   Liquor adequate
   not adequate

5. Other examination if any:

6. Advice given to the mother

   About care of pregnancy, delivery, newborn

   About Iodine supplementation

Diagnosis (along with POG)
……..

Lab. Investigation

Blood: HB …gm%
   Group
   Rh typing
   Sugar (R)
   VDRL
Serum:
   HBsAg
   HIV
Serum thyroid profile:
   T3,
   T4,
   TSH

Urine:
   routine
   Sugar
   Albumin
   Urine iodine estimation in mcg

Name of the enumerator: Designation:
Name of the clinic signature
Location:

Respondents' Follow up Physical Examination Form

ID No. Date of examination: / /

Name of the respondents: Age in Yrs…….

Address: ……. VDC…….Ward No……..……District

No of Follow up visits (Following Iodine capsule introduction): 1 2 3 4 5

1. Vitals
   BP
   Pulse
   Height (CM)
   Weight (Kg)
   BMI

2 General
   Skin color, Pallor, Jaundice
   Edema

3 Neck:
   Thyroid swelling
   Stage I
   Stage II
   Stage III

4 Abdominal
   Height of the fundus (in weeks)

   Fetal parts palpable or not
   Presentation
   Lie
   Head of the fetus
   FHS
   Liquor adequate Not adequate

5. Other examination if any:

6. Advice given to the mother

   About care of pregnancy, delivery, newborn

   About Iodine supplementation

   Diagnosis (along with POG)
   ……..

Name of the enumerator: Designation:
Name of the clinic signature
Location:

Respondents' final Physical Examination Form (Post Intervention)

ID No. Date Name of the respondents
Age (Yrs). Address: Dist: …… VDC/Municipality ……..W.No
No of visits ……. Name of the Hospital/ Institution:

History of medication (months): iodine capsule Iron folic acid others

1. Vitals
   BP mm of Hg Pulse per minute Temperature 0 F

   Height CM Weight Kg BMI

2. General
   Skin color Pallor Jaundice Oedema

3. Neck for thyroid swelling
   Grade I Grade II Grade III

4. Abdominal examination

   Fundal height weeks Presentation Position of fetus

   Head of the fetus engaged fixed free

   FHS per minute regular irregular absent

   Liquor adequate Polyhydramnous oligohydramnious

5. Other examination if any:

6. Obstetric findings (including PV findings):

   Dilation of os CM Effacement Membrane

   Station Liquor clear thin muconeum frank muconeum stained

   Presentation Cephalic Breech Compound

7. Complete Diagnosis (including Period of gestation):

8. Delivery findings:

   Type of delivery Date of delivery Time of delivery

   Sex of baby M / F Weight of baby: Kg Gm Length of baby cm

   Condition of baby: Poor / Fair / Good Delivery of placenta (3 rd stage):

   Amount of blood loss ml Condition of Mother: Poor fair Good

9. Condition at discharge Mother Baby

10. Lab investigation (Post intervention): T3 T4 TSH

11. Delivery conducted by: Name Designation

12. Name of the institution:

Respondents' final Physical Examination Form (Control)

ID No. Date Name of the respondents
Age (Yrs). Address: Dist: …… VDC/Municipality ……..W.No
No of visits ……. Name of the Hospital/ Institution:

History of medication (months): Iron folic acid others

1. Vitals
   BP mm of Hg Pulse per minute Temperature 0 F

   Height CM Weight Kg BMI

2. General
   Skin color Pallor Jaundice Oedema

3. Neck for thyroid swelling
   Grade I Grade II Grade III

4. Abdominal examination

   Fundal height weeks Presentation Position of fetus

   Head of the fetus engaged fixed free

   FHS per minute regular irregular absent

   Liquor adequate Polyhydramnous oligohydramnious

5. Other examination if any:

6. Obstetric findings (including PV findings):

   Dilation of os CM Effacement Membrane

   Station Liquor clear thin muconeum frank muconeum stained

   Presentation Cephalic Breech Compound

7. Complete Diagnosis (including Period of gestation):

8. Delivery findings:

   Type of delivery Date of delivery Time of delivery

   Sex of baby M / F Weight of baby: Kg Gm Length of baby cm

   Condition of baby: Poor / Fair / Good Delivery of placenta (3 rd stage):

   Amount of blood loss ml Condition of Mother: Poor fair Good

9. Condition at discharge Mother Baby

10. Lab investigation (Post intervention): T3 T4 TSH

11. Delivery conducted by: Name Designation

12. Name of the institution:

Respondents' initial Blood Examination Form

ID No. Date of examination: / /

Name of the respondents: Age in Yrs…….

Address: ……VDC…… W.No……..District

No of Follow up visits (Following Iodine capsule introduction): 1 2 3 4 5

Serum thyroid profile:

T3,

T4,

TSH

Name of the enumerator: Designation:
Name of the clinic signature
Location:

Respondents' Final Blood Examination Form

ID No. Date of examination: / /

Name of the respondents: Age in Yrs…….

Address: ……VDC…… W.No……..District

No of Follow up visits (Following Iodine capsule introduction): 1 2 3 4 5

Date of delivery …… Sex of baby M F .weight of baby ……Kg…..Gm

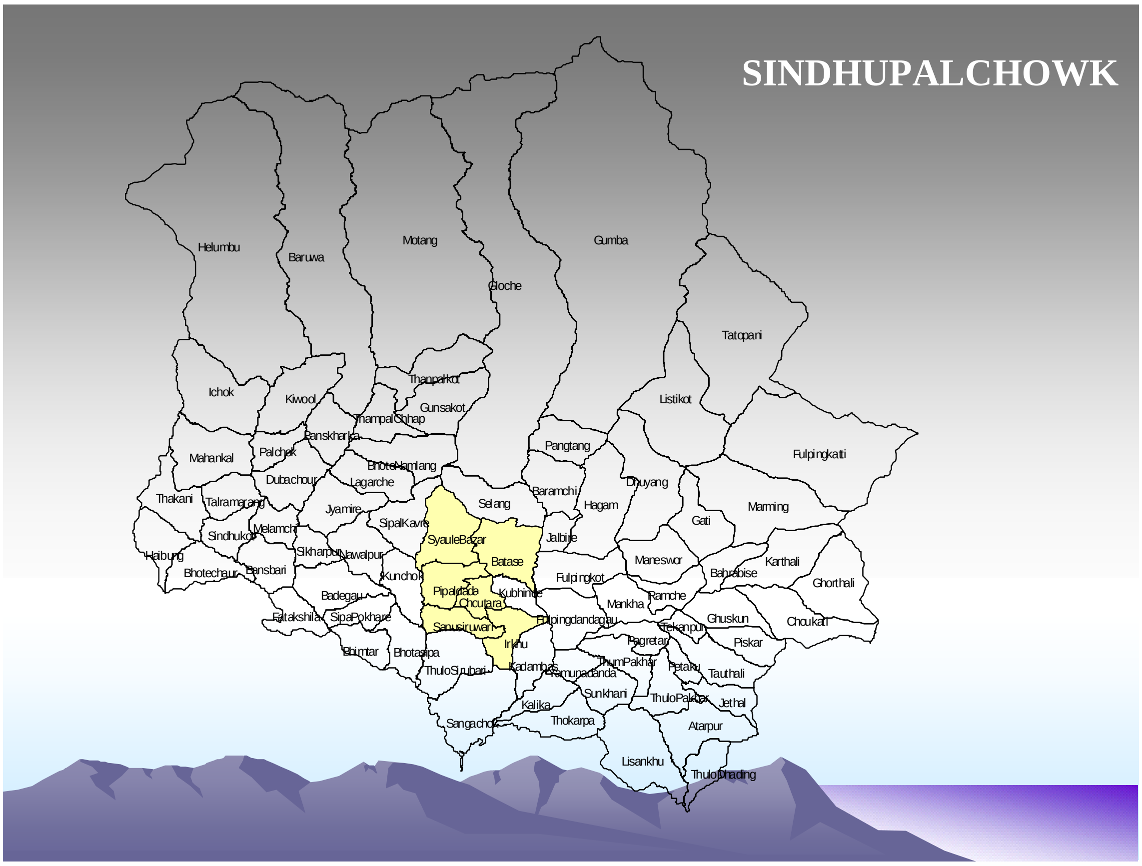
Serum thyroid profile:

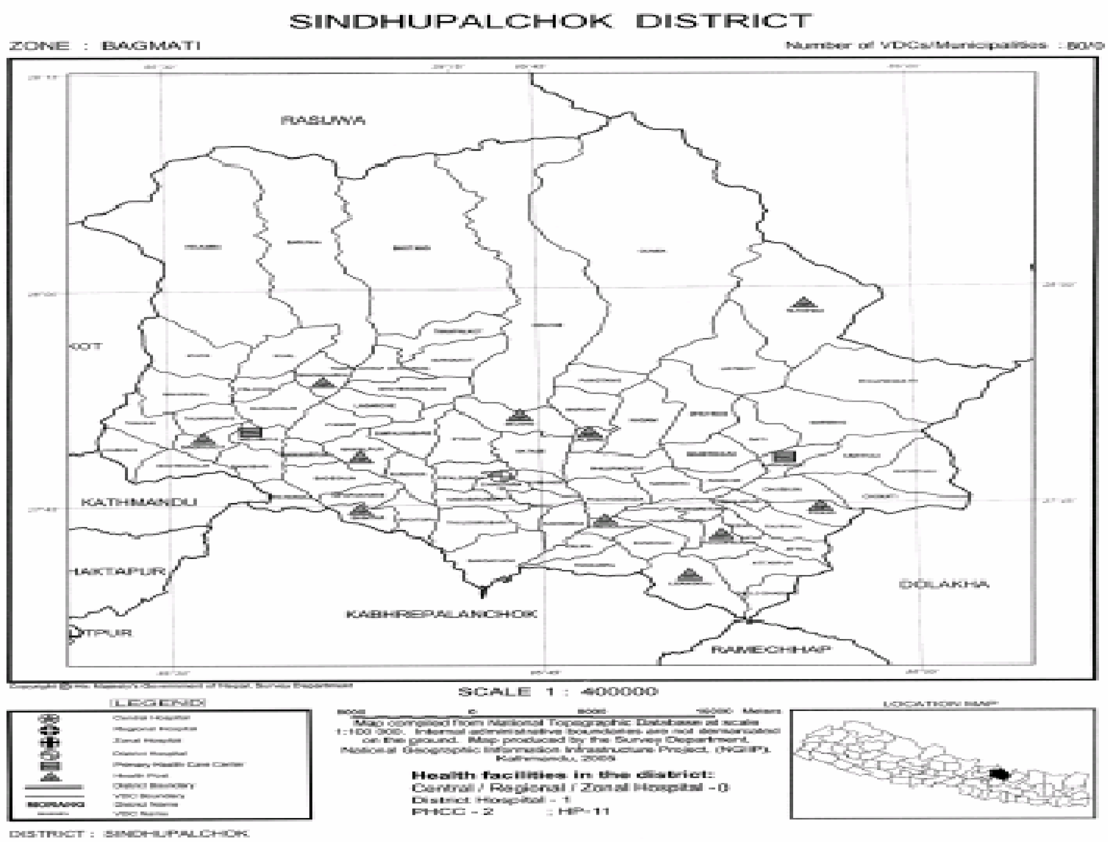
T3,

T4,

TSH

Name of the enumerator: Designation:
Name of the clinic signature
Location:


SINDHUPALCHOWK
Helumbu
Baruwa
Motang
Gumba
Tatopani
Ichok
Kiwool
Listikot
Fulpingkatti
Mahankal
Palchok
Pangtang
Thakani
Jyamire
Selang
Hagam
Gati
Marming
Syaule Bazar
Batase
Jalbire
Maneswor
Karthali
Ghorthali
Bahrabise
Ramche
Mankha
Ghuskun
Choukati
Piskar
Irkhu
Sunkhari
Kalika
Thokarpa
Tauthali
Jethal
Atarpur
Lisankhu
Sangachok
Bhotechaur
Bansbari
Badegau
Kunchok
Fatakshila
Bhimtar
Bhotasipa
Melamchi
Talramarang
Sindhukot
Haibung
Lagarche
Dubachour
Gunsakot
Thangpalkot
Listikot
Dhuyang
Fulpingkot
Golche


SINDHUPALCHOK DISTRICT
ZONE : BAGMATI
RASUWA
KATHMANDU
KABHREPALANCHOK
DOLAKHA
RAMECHHAP
SCALE 1 : 400000
LEGEND
LOCATION MAP
Health facilities in the district:
Central / Regional / Zonal Hospital - 0
District Hospital - 1
PHCC - 2 ; HP - 11
DISTRICT : SINDHUPALCHOK