A SHORT TERM EVALUATION OF THE IODIZED SALT SUPPLEMENTATION PROGRAMME TO ANTENATAL MOTHERS IN BACHOK KELANTAN

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FINAL REPORT FOR SHORT TERM IRPA: 304/PPSP/6131172

(1st July 2001 to 30th June 2002)

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GLOSSARY

Definition of terms

Goiter is defined as the enlargement of the thyroid gland of whatever kind but not associated with inflammation or cancer. By palpation, goiter is defined as a thyroid gland whose lateral lobe has a volume greater than the terminal phalanges of the thumb of the person examined. When this criterion is met, overall thyroid volume is at least four to five times greater than normal. (Delange, 1999).

Orang Asli are the aborigines in the Peninsular Malaysia

Abbreviation

TSH	Thyroid stimulating hormone
hCG	Human Chorionic Gonadotropin
T_4	Thyroxine hormone
T_3	Tyrosine hormone
FT_4	Free thyroxine
FT_3	Free tyrosine
TBG	Thyroxine binding globulin
IDD	Iodine deficiency disorders
mcg/l	microgram per liter
mcg I/ g Cr	microgram iodine per gram Creatinine
SD	Standard deviation

95% CI	95% confidence interval
ppm	part per million
ICCIDD	International Council for Control of Iodine Deficiency Disorder
WHO	World Health Organization

ABSTRACT

Iodine is an important micronutrient for physical and mental development. The World Health Organization addressed iodine deficiency disorders as a public health problem as it is endemic in 130 countries all over the world and showed emergence of the condition in some developed country. Malaysia also has some areas endemic for goiter. This study is aimed to determine the prevalence, risk factors, evaluating the knowledge, attitude and practices, as well as to assess the effectiveness of the iodized salt supplement in improving iodine status of the antenatal mothers in Bachok. A cross sectional study was conducted at the Health Clinics and Community Clinics in Bachok, Kelantan from 1st July 2001 to 28th February 2002. A self administered pretested questionnaire was used for assessment on the knowledge, attitude and practices of 342 selected antenatal mothers. The effectiveness of the iodized salt supplement was measured with two samples of spot urine for iodine test. The prevalence of iodine deficiency was 63.0 % (95% CI: 57.8, 68.2). The first sample mean urinary iodine level was 87.3 (SD 58.64) mcg/l and the median was 78.0 mcg/l. The total mean score of knowledge, attitude and practices was 58.6 (SD 7.9), 52.91 (SD) and 42.90 (SD 10.9). However, the subjects showed only minimal effort in gaining knowledge and 65% of subjects had never take iodine supplement before. Potential risk factors were analysed by the logistic regression.in which the smoking husband was the risk factor for iodine deficiency with the odd ratio of 2.0. The effectiveness of the iodized salt supplementation programme were analysed by the general linear regression analysis. Current iodine level in the blood as well as the

level of knowledge and correct method of handling the iodized salt determined the improvement in the iodine status of an individual. In conclusion, Bachok district can still be considered as area prone for iodine deficiency disorders. The condition could be worsen due to the poor level of knowledge on the cause, effect and clinical presentation of the disorders as well as low level of awareness on the disease prevention. However, the iodized salt supplementation programme found was succeed in improving the iodine status among affected antenatal mothers.

ABSTRAK

Iodin merupakan mikronutrien yang penting untuk pertumbuhan fizikal dan mental. Pertubuhan Kesihatan Sedunia (WHO) menekankan penyakit kekurangan iodine sebagai masalah kesihatan memandangkan ia adalah endemik di 130 negara di seluruh dunia dan terdapat sebilangan negara maju menghadapi masalah ini semula. Malaysia turut tergolong dalam kawasan endemik untuk goiter. Kajian ini bertujuan untuk menentukan kadar prevalens, faktor risiko, penilaian pengetahuan, sikap dan amalan, serta penilaian ke atas keberkesanan penggunaan garam beriodin dalam meningkatkan status iodin ibu mengandung di Bachok. Satu kajian hirisan lintang dijalankan di Klinik Kesihatan dan Klinik Desa di Bachok, Kelantan dari 1hb Julai 2001 hingga 28hb Februari 2002. Soal selidik untuk menilai pengetahuan, sikap dan amalan dijalankan ke atas 342 ibu antenatal menggunakan borang yang dijawab sendiri oleh peserta. Keberkesanan penggunaan garam beriodin ini diuji dengan ujian kandungan iodin dalam dua sampel urin spot. Hasil kajian menunjukkan prevalens penyakit kekurangan iodin ialah 63.0% (95% CI: 57.8, 68.2). Min kandungan iodin dalam urin pertama ialah 87.3 (SD 58.64) mcg/l dan mediannya ialah 78.0 mcg/l. Secara umumnya min skor untuk pengetahuan, sikap dan amalan ialah 58.66(SD 7.9), 52.91(SD 7.9) dan 42.90 (SD 10.9). Walaubagaimanapun, peserta hanya menunjukkan usaha yang minima dalam mendapatkan pengetahuan dan seramai 65% peserta tidak pernah mengambil bekalan iodin tambahan. Faktor risiko yang berpotensi terhadap kekurangan iodin dianalisa

dengan regressi logistik mendapati suami yang merrokok merupakan factor risiko kepada ibu untuk mengalami kekurangan iodine dengan 'odd ratio' sebanyak 2.0. Keberkesanan program penggunaan garam beriodin dianalisa dengan linear regressi umum. Kajian mendapati tahap iodine dalam darah serta tahap pengetahuan serta cara yang betul dalam penggunaan garam beriodin menentukan peningkatan tahap iodine seseorang individu. Kesimpulannya daerah Bachok masih dianggap sebagai kawasan yang berisiko untuk penyakit kekurangan iodine. Keadaan ini akan menjadi lebih buruk dengan tahap pengetahuan yang rendah terhadap sebab. akibat dan tanda-tanda klinikal penyakit serta kurangnya kesedaran terhadap kepentingan pencegahan penyakit. Program pemberian garam beriodin didapati telah berjaya untuk memperbaiki tahap iodin di kalangan ibu-ibu mengandung..

1. INTRODUCTION

Micronutrients are essential for proper body function. Our body needs them in a very small amount, as they cannot be synthesized in the body. One of important micronutrient is iodine. Iodine deficiency is probably the first nutritional disease recognized by man, as the physical effects of iodine deficiency in the form of goitre and cretinism and its dietary treatment have been known centuries ago.(Hetzel, 1990) when a French man named Courtois was first discovered iodine about 200 years ago in dried seaweed or kelp. (Davidson *et al*, 1986).

Goiter is an enlargement of the thyroid gland of whatever kind but not associated with inflammation or cancer. By palpation, goiter is defined as a thyroid gland whose lateral lobe has a volume greater than the terminal phalanges of the thumb of the person examined. When this criterion is met, overall thyroid volume is at least four to five times greater than normal. (Delange, 1999). Goiter was the most visible consequence of iodine deficiency. In fact, it was only the tip of the iceberg because about 90.0% the effects of iodine deficiency were hidden in the form of minimal brain damage in children or loss of energy in adults. (ICCIDD, *www.tulane.edu*).

In 1983 Dr Basil S.Hetzel developed the term iodine deficiency disorders to describe the spectrum of physical and mental deficiencies whether congenital or acquired secondary to iodine inadequacy. Iodine deficiency disorders is a global public health problem. The statistical data by the World Health Organization in 1998, estimated that 340 million people are affected with goitre. At least 1500 million people,

or 29.0% of the world's population, live in areas at risk of iodine deficiency. (World Health Organization, 1999). About 30 000 babies are stillborn every year and over 120 000 are born cretins because their mothers are iodine deficient. (The State of the World's Children, 1994, UNICEF).

IDD is still a public health problem in many developing countries and in some developed countries. The decline in the median urinary iodine level in the population in the developed countries was found in several studies; Burgi (1989) in Germany, Netherland and Austria. Hollowell *et al* (1998) in the United States and Li.M. *et al* (2001) found that there is re-emergence of IDD in Australia.

In Malaysia, there were many studies on IDD have been conducted.(Kementerian Kesihatan, 2002). Goiter was not a serious health problem in Peninsular Malaysia but there was existence of small pockets of the endemic. (Ramalingaswami, 1973). In Peninsular Malaysia, goiter was reported in the inland mountains to an extent of 40.0%. (Polunin, 1951; Mafauzy *et.al* 1995). Rozia, H. *et al*(1987) reported that an overall goiter prevalence in late 1980's in Kedah was 35.1%. Mafauzy *et al* (1995) found that in Kelantan, 31.4% goiter prevalence was in coastal area and 45.0% among the inlands in which grade II and III goitre was 2.0% in coastal area and 3.2% in the inland area respectively.

Pregnancy, parity, food habits, socioeconomic status and smoking were factors that may induced iodine deficiency or formation of goiter as found in many studies. Few studies showed that the prevalence of goiter was higher among pregnant women from lower socioeconomic strata.(Sakinah, Khalid &Aishah(1993), Dodd & Madan (1993),

Kapil *et al*(1997)). Pregnancy could induced goiter formation secondary to an increase in body requirement for thyroid hormone and iodide (Glinoer, 2001).The increased in thyroid volume during pregnancy was related with the place of residence. Rotondi *et al*(2000) noted in iodine deficient areas, the thyroid volume increase with gestation and reverts to the initial size 12 months post partum whereas in areas with severe iodine deficiency, the thyroid volume are only partially reversible. Berghout *et al* (1994) found there is no increase in the thyroid volume of pregnant women in iodine replete areas. Smyth *et al* (1997) noted multiparous women were more likely to have a significant enlargement of thyroid gland than the primigravida.

1.3 Knowledge, Attitude and Practice

Knowing the causes and effects of a disease will influence a person's attitude and practices, towards the disease. Improvement in knowledge of medical doctors and nurses lead to a change in their perception towards breastfeeding.(Musa *et al*, 1994). It is supported further by the health belief model by Rosenstock (1974) that described actions to avoid the disease will be performed if the benefits of the behaviour outweigh the disadvantages. Fernandez (1988) in Spain, show that the belief of members of the larger society who belief goiter is the hereditary causationism gave a great impact to the dietary prophylaxis programme. The false cultural belief in this society said that goiter was due to bad blood, causes the dietary intervention useless and wasteful. Fernandez also found that the belief or attitude of some influential people invites some controversies such as, a physician who believes the iodine invites hazardous abuse or who fear of the loss of a pool of potential patients may not encourage the iodine prophylaxis. Mohapatra *et.al* (2000) described the major factor contributing to the

failure of iodine supplementation programme in India was the cost of iodized salt, which is usually more expensive than ordinary salt.

The education level of an individual is not a key factor for better knowledge on iodine deficiency. Factors that might contribute to improvement in knowledge on IDD are the interest in learning new subjects and the effort that was put in searching them. However, the factor that has been described was closely related to the attitude of an individual. The attitude and belief of a person is one of the most difficult attribute to change especially if that attitude or is culturally accepted and practiced by the community.

The Ministry of Health, Malaysia have implemented IDD control programme such as water iodination in schools and iodized salt supplementation to antenatal mothers with the aim of eliminating IDD as announced by the International Council for the Control of Iodine deficiency Disorders (ICCIDD) that IDD should be eliminated by the year 2000. This study was conducted to evaluate a part of this programme. There is currently no continuous monitoring of iodine content done by the authority during the manufacturing of the iodized salt nor continuous community assessment on the practice was done so far. The results of the study may help us to review the weaknesses that can be corrected. In addition this study will also estimate the prevalence of IDD in the study area. The author hope that the results obtained will help the Ministry of Health in strengthening the IDD prevention programme in Malaysia.

2. OBJECTIVE

2.1 Research questions

This study plan to answer the following research questions

1. Are the mothers aware of the consequences of iodine deficiency?
2. Are the mothers consuming and storing the iodized salt correctly?
3. Is the iodized salt supplied to the antenatal mothers able to improve the iodine status?
4. What are the factors that influenced the level of iodine in the second urine sample?

2.2 General objective

To evaluate the effectiveness of the iodized salt supplementation programme within 2 months duration among antenatal mothers in Bachok Kelantan

2.3 Specific objectives:

1. To determine the prevalence of iodine deficiency among antenatal mothers in Bachok
2. To evaluate the knowledge, attitude and practices of the mothers regarding iodine deficiency and supplementation in pregnancy.
3. To determine risk factors associated with iodine deficiency in pregnant mothers
4. To assess the effectiveness of the iodized salt supplement to antenatal mothers in improving iodine status.

5. To determine factors that associated with the change in the mean urinary iodine level

2.4 Research hypothesis

1. The mean urinary iodine level in the iodine deficient mothers increase significantly after consumption of the iodized salt compared to mothers without iodine deficiency.

3. METHODOLOGY

The study consists of two phases. The first phase is to study the prevalence and risk factors of iodine deficiency disorders among antenatal mothers as well as their knowledge, attitude and practice regarding iodine deficiency and iodine supplementation. The second phase is to study the effect of iodized salt supplementation after two months.

3.1 Background of study area

The author has selected the district of Bachok as the study area out of ten districts in the State of Kelantan at convenient. It is situated at the coastal area, facing the South China Sea in the east, with Kota Bharu district in the north and Pasir Puteh district in the south. It is about 264.5km square which is divided into 8 sub-districts. The total population is 109,786 people (Malaysia Census 2000). The ethnic composition is 98.6% Malays, 1.1% Chinese and 0.3% other races. About 51.4% of the populations are farmers, fishermen or hunters. In term of educational level, only 6.6% of those above 23 years of age entered the higher institution like universities or colleges. There are 6 Health Centres (Klinik Kesihatan) and 22 Community Clinics (Klinik Desa) to serve Bachok . *Klinik Kesihatan* was a centre supervised by a doctor and served for 20 000 population whereas *Klinik Desa* run by Jururawat Masyarakat (community nurse) or Bidan (midwife) and served for 5 000 population.

The total antenatal attendees for the year 2000 in Bachok were 26 504 mothers with the mean number of visits per antenatal mothers of 7 times each. The total annual

deliveries in the year 2000 were 4016. Bachok has already implement the iodized salt supplementation programme since the late 1996. In the year 2000, number of iodized salt distributed to antenatal mothers were 4 645 packets. (Annual Report 2000, Health Department of Kelantan). Therefore the mean packet of salt distributed to each antenatal mothers was 1.15.

3.2 PHASE 1

3.2.1 In the first phase, the objectives 1, 2 and 3 have to be covered

3.2.2 Study design: Cross sectional study

3.2.3 Reference population : Antenatal mothers in Kelantan

3.2.4 Target population: Antenatal mothers in Bachok Kelantan

3.2.5 Source population: Antenatal mothers attending antenatal examination in the Health Clinics and Community Health Clinics in Bachok

3.2.6 Sample size

1. Using the single proportion formula.

$$N=[z/\Delta]^2 p(1-p)$$

z= 1.96 for 95.0% confidence interval

precision (Δ) = 0.05

p= proportion of the disease in the population.

Based on the prevalence of goitre among the coastal people in Kelantan that was 23.0% (Mafauzy *et.al,* 1993), at 95.0% confidence interval and the precision of 0.05, the calculated sample size was **272** subjects.

3.2.7 Sampling method : Multistage sampling

Based on the year 2000 records, the total annual delivery in Bachok was 4016 in which 68.0% were from the area covered by the Klinik Desa whereas another 32.0% were from the area covered by the Klinik Kesihatan. The primary sampling unit was the Klinik Kesihatan (Health Centres) in which four out of six were selected at random and the secondary sampling unit was the Klinik Desa (rural health clinic) in which two clinics under the supervision of each Klinik Kesihatan, were selected to ensure enough number of subjects could be obtained within the period of 1st July 2001 to 28th February 2002. Each Klinik Kesihatan and Klinik Desa has an equal chance to be selected. Here is the list of Klinik Kesihatan with the Klinik Desa under their supervision in Bachok (the clinics that involved in this study with * and number of subjects involved from each clinics in bracket):

i. Klinik Kesihatan Bachok* (33 subjects)
   - Klinik Desa Kandis* (33 subjects)
   - Klinik Desa Jelawat* (44 subjects)
   - Klinik Desa Beris Lalang
   - Klinik Desa Pantai Baru
   - Klinik Desa Rekang

ii. Klinik Kesihatan Beris Kubor Besar* (47 subjects)
   - Klinik Desa Pauh Sembilan* (22 subjects)
   - Klinik Desa Kuau
   - Klinik Desa Bekelam* (38 subjects)
   - Klinik Desa Belukar

iii. Klinik Kesihatan Gunong* (49 subjects)

- Klinik Desa Kepala Batas* (32 subjects)
- Klinik Desa Telaga Ara
- Klinik Desa Beoh
- Klinik Desa Pauh Lima* (16 subjects)
- Klinik Desa Kuchelong

iv. Klinik Kesihatan Balai* (13 subjects)

- Klinik Desa Melawi* (11 subjects)
- Klinik Desa Perupok* (4 subjects)

v. Klinik Kesihatan Mahligai

- Klinik Desa Alor Bakat
- Klinik Desa Kolam
- Klinik Desa Pak Badol

vi. Klinik Kesihatan Beris Panchor

- Klinik Desa Tawang
- Klinik Desa Wakaf Aik
- Klinik Desa Pintu Gerbang

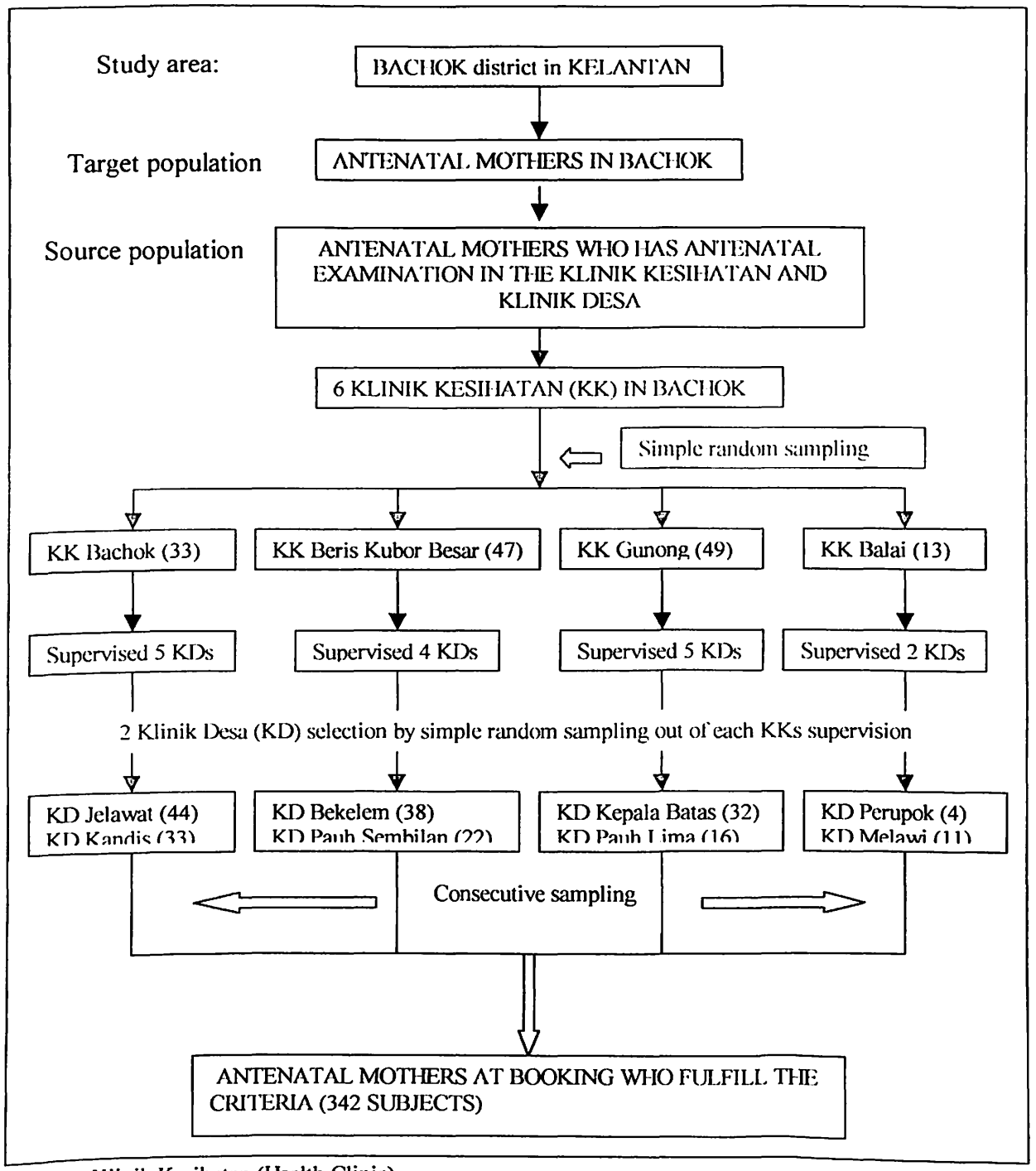
Altogether the author managed to get **342** antenatal mothers involved in this study within the period of data collection despite the calculated sample size of **272** subjects.

3.2.8 Subjects selection

New antenatal mothers attending the selected clinics were chosen by consecutive sampling depending on the fulfillment of both the inclusion and exclusion criteria.

The antenatal mothers included in this study were those at less or equal to 20 weeks period of amenorrhea at the first antenatal booking. Preferably the author would like to choose those in the first trimester (less than 12 weeks period of amenorrhea) so that the physiological changes that the mother has is almost similar and comparable as the physiological changes were more pronounced during this period. But, due to limited number of antenatal mothers who booked within the first trimester, 20 weeks POA was chosen as a cut off point. Only those antenatal mothers who booked during the period of 1st July 2001 to 28th February 2002 were selected to join the study. Mothers who have not taken iodized salt for the current pregnancy were included because the effectiveness of the salt supplementation is assessed in this study. Lastly, only those who permanently live in the selected area were included so that the follow up could be made and the probability of drop out could be reduced.

Unfortunately 5 mothers were excluded from this study due to abortion before the second urinary sample could be collected. Another 6 mothers were also excluded when the retrospective calculation of the expected date of delivery showed that the period of amenorrhea was more than 20 weeks.



KK : Klinik Kesihatan (Health Clinic)
KD : Klinik Desa (Community Health Clinic)
Number in bracket: Number of subjects involved from each selected clinic

Figure 3.1: Flow chart showing a summary of subject selection

3.2.8 Questionnaire

The questionnaire consists of several items:

1. Personal data
2. Sociodemographic characteristics
3. Potential risk factors for iodine deficiency disorders:
    a. Family history of goitre
    b. Personal and spouse smoking habit
    c. Present obstetric history: Last normal menstrual period, gravida, para and period of amenorrhea at first antenatal visit
    d. Past obstetric history: Year and history of complication in previous pregnancy.
4. Thyroid gland status

    Examination of the thyroid gland was done by the author in order to eliminate inter observer bias. All subjects were examined during the first visit. The thyroid size was graded according to WHO/ICCIDD (1994) classification.

    Grade 0, no palpable or visible goiter

    Grade 1; goiter is not visible and it moves upward in neck as the subject swallows

    Grade 2, goiter is visible when the neck is in normal position. Subject with grade 1 or 2 thyroid gland enlargement with a low urinary iodine level were classified as endemic goiter whereas those with normal thyroid gland size but low urine iodine level was considered as iodine deficient.

5 First and second urinary iodine results

The first urine sample is the one taken at the beginning of the study, before the iodized salt consumption. The second urine sample was taken 2 month after the iodized salt consumption.

6. **Knowledge**: Forty four structured questions of knowledge regarding iodine deficiency disorders, the cause and effects (items listed below) were used to measure the subject's level of knowledge. Each statement is followed by a "yes", "no" or "unsure" response. Each correct answer is given score of two, one for unsure and none for the incorrect. The range for total score was 0 to 88 and classified into 'poor' (0-29), 'average' (30-59) and 'good' (60 and above). (refer table 4.1 for sub domains)

7. **Attitude:** Twenty-one questions regarding the perception and belief on the use of iodized salt towards elimination of iodine deficiency disorders. Each response was based on a 5-point Likert scale of "strongly agree", "agree", "unsure", "do not agree" and " strongly disagree". A maximum score of four for positive attitude and minimum of zero for negative attitude were given to each subjects. The range for total score was 0 to 84 and classified into 'poor' (0-29), 'average' (30-59) and 'good' (60 and above). (refer table 4.1 for sub domains)

8. **Practice:** Twenty-eight questions regarding the health provider practices in giving health education and how are the mothers react on it. A maximum score of three for good practice and a minimum of zero for poor practice was given. The range for total score was 0 to 84 and classified into 'poor' (0-29),

'average' (30-59) and 'good' (60 and above). (refer table 4.1 for sub domains)

The author or the research assistant did the interview on the sociodemography, history of goitre, smoking habit, present and past obstetric history (refer appendix). The Knowledge, Attitude and Practices portion of the questionnaire were self-administered. However, for the illiterate mothers, the author did the interviews.

3.3 Pre test and questionnaire development

Structured questionnaire on knowledge, attitude and practice on iodine deficiency disorders was developed in the Malay language. The author identified the sub domains and items herself, based on KAP study done in India (Mohapatra *et al*, 2001) and the questionnaires that was used in a study in Kelantan (Norhaizan, 1998). Questionnaires were built up through literature review and discussion with the supervisor. Pre test were carried out twice at the Klinik Desa Bayu Bayam, Kota Bharu involving one hundred antenatal mothers. The first pilot study was in February and March 2001. Following that, some of the questions were reviewed and reconstructed. The author did the second pilot study in June 2001. Data were entered into the SPSS version 10.0 software and were analysed for reliability and validity of each domain. Cronbach alphas for knowledge, attitude and practice are shown in Table 4.1

Table 3.1:The Cronbach alphas for knowledge, attitude and practice questions of the second pre test study

No	Question	Corrected item total correlation	Alpha if item deleted
	Questions on Knowledge		
1.	Iodine deficiency as a disease and perception on the swelling in the neck	0.3954	0.8436
2.	The causes of IDD	0.6969	0.8356
3.	Clinical presentation of iodine deficiency	0.5169	0.8404
4.	The effects of iodine deficiency	0.4214	0.8431
5.	Food rich in iodine	0.5768	0.8387
6.	Food that could interfere iodine absorption	0.4350	0.8442
7.	Use of iodized salt	0.3958	0.8436
8.	Method of storing the iodised salt	0.0893	0.8516
9.	Availability of iodized salt	0.4586	0.8420
	Cronbach alpha for knowledge = 0.8		
	Questions on Attitude		
10.	Iodine deficiency disorder	0.1828	0.5913
11.	Prevention of iodine deficiency	0.3182	0.5600
12.	Importance of knowledge on iodine deficiency	0.1931	0.5926
13.	The use of iodized salt	0.2279	0.5841
14.	The use of iodized salt in non pregnant condition	0.3117	0.5653
	Cronbach alpha for attitude=0.6		
	Questions on Practices		
15.	The clinical staffs frequency in giving health education	0.7540	0.7528
16.	Mothers practices in gaining health information	0.5730	0.7787
17.	Taking iodine supplement previously	0.5301	0.7830
18.	Dietary intake	0.0910	0.8256
19.	Frequency of using the iodized salt supplied	0.5463	0.7812
20.	Daily practice of when to add the salt	0.5396	0.7823
21.	How the salt was keep at home	0.5297	0.7845
	Cronbach alpha for practices = 0.8		

3.4 Training of the research assistant and laboratory technologist

A female research assistant was trained to assist in the interviewing of the antenatal mothers and fill up the questionnaire. It took few sessions including the pilot study. She was explained about the study objectives and the content of the questionnaires. The author showed the way to ask an illiterate mother in answering the questions. Evaluation of the research assistant questioning skill was done by direct observation during the pre test study session. The laboratory technologist involved was trained at the Institute of Medical Research (IMR) Kuala Lumpur for urine analysis.

3.5 Iodised salt and iodine rapid test

All subject was supplied with 500 gram iodized salt a month, which contained 70 ppm (70mcg/g) potassium iodate, wrapped in an unlaminated polyethylene, since first antenatal visit. At least 5 out of 100 packets from each batch of the iodized salt to be supplied to the subject was first tested at random for the iodine content with a semi quantitative test, iodine rapid test kit. A small amount of the salt was tested by mixing it with 3 drops of starch solution and 3 drops of hydrochloric acid solution onto a saucer. If the salt contains iodate, the salt should immediately turn grey / blue, and remain this colour for several minutes before turning brown. The intensity of the colour produced can be used as a rough estimate of the iodine content:

Table 3.2 : The rough estimate of iodine content in the salt (Foo, L.C., 2000)

Colour change (indicator)	Iodine content
No colour	no iodate present
Very light purplish or greyish tinge	< 5 mg iodine/kg salt
Light purplish or greyish tinge	5 - < 20 mg iodine /kg salt
Medium grey	20 - < 35 mg iodine/kg salt
Dark grey or bluish black	≥ 35 mg iodine/kg salt

3.6 Statistical analysis

Data was entered and analysed with the SPSS version 10.0 software at the CAI laboratory Universiti Sains Malaysia.

3.6.1 Descriptive analysis

Data were checked and cleaned. The distributions and frequencies were examined. Numerical variables with normal distribution were presented as mean and standard deviation whereas those with non normal distribution were presented as median and interquartile range. The categorical variables were presented as frequency or percentages distribution.

3.6.2 Simple and multiple logistic regression

Categories with small number of subjects and skewed distributions were noted. Meaningful combination of categories was done when it was indicated. The dependent variable was the first urinary iodine level, in which the level of 0 – 99.9 mcg/l (low) was label as 1, and the level of ≥ 100 mcg/l (normal) was label as 0. Simple logistic regression was done for all variables. All independent variables were analyzed by using both forward and backward stepwise variable selection methods to obtain preliminary models. Variables excluded by automatic procedures were added to the model one at a time and tested by log-likelihood ratio (LR) test. With all significant and important variables, the *"Preliminary main-effect model"* was obtained. The fitness of model was tested with the Hosmer and Lemeshow test, classification table and ROC curve.

3.7 PHASE 2

3.7.1 The second phase objectives were objectives 4 and 5

3.7.2 Study design: Prospective study

3.7.3 Sample size:

Sample size was calculated with the PS software.

1. For objective 4, the paired sample calculation was used. Number of subjects needed were **63**, to be able to detect the population mean of the difference (post - pre intervention urine iodine level) of 25 mcg/l within type I error of 5% and the power of 80%. The following parameter was applied in above calculation, i.e: SD of difference in urine iodine level between pre and post intervention of 70 mcg/l.

2. For objective 5, with independent sample calculation, 123 subjects for each group were needed to be able to detect the difference of 25 mcg/l in population mean of the chamge in urine iodine level (post – pre intervention urine iodine level) within the type I error of 0.05 and the power of 80%. The following parameter wad applied in above calculation, ie: SD of urine iodine change in each group was estimated as 70 mcg/l.

Therefore from above calculation, the biggest sample size that was **123** subjects in each group of iodine deficient and non-iodine deficient was used in the second phase of the study.

3.7.3 Sampling method: All subjects (**126**) with normal first urinary iodine level were included whereas those with low first urinary iodine level (**126** out of **216**) were selected at random using the randomization table.

3.8 Urine analysis

3.8.1 Urine sampling

All subjects received salt, which contains 70 ppm (70mcg/gm) of potassium iodate. Each subject was required to supply two urine samples about 3 ml each time for urine iodine analysis. Urine was placed in a well-capped plastic container and stored in a refrigerator at 0 - 5°C before analysis. First sample was collected during the first visit to the antenatal clinic. The next sample was required two months later that is after the second months of salt consumption.

3.8.2 Urinary iodine determination

The urine samples were sent to the chemical pathological laboratory, Hospital Universiti Sains Malaysia for analysis. A single laboratory technologist was responsible in handling the urinary analysis.

1. Principle of analysis:

Small sample of urine (250 to 500 mcl) are digested or purified with 70% chloric acid solution at 110 to 115°C. Then arsenious acid solution was added, and the mixture was left for 15 minutes. Lastly the ceric ammonium sulphate solution was added. Iodide act as catalyst in the reduction of ceric ammonium sulphate (yellow colour) to the cerous

form (colourless) in the presence of arsenious acid. This is known as the Sandell-Kolthoff reaction. The decrease in yellow colour over a fixed time period is measured by a spectrophotometer and plotted against a curve constructed from standards with known amounts of iodine run in the same assay. The corresponding iodine concentration was read in mcg/L by finding its absorbency from the standard curve. The result was interpreted with $\pm$ 2 standard deviation.

2. Urinary iodine level

The median urinary iodine was used as reference. The measurement is classified as, **mild** : 50.0 –99.9 mcg/L, **moderate:** 20.0 – 49.9 mcg/L, **severe** : less than 20.0 mcg/L. and **normal**: $\geq$ 100.0 mcg/l. (WHO/ICCIDD, 1999)

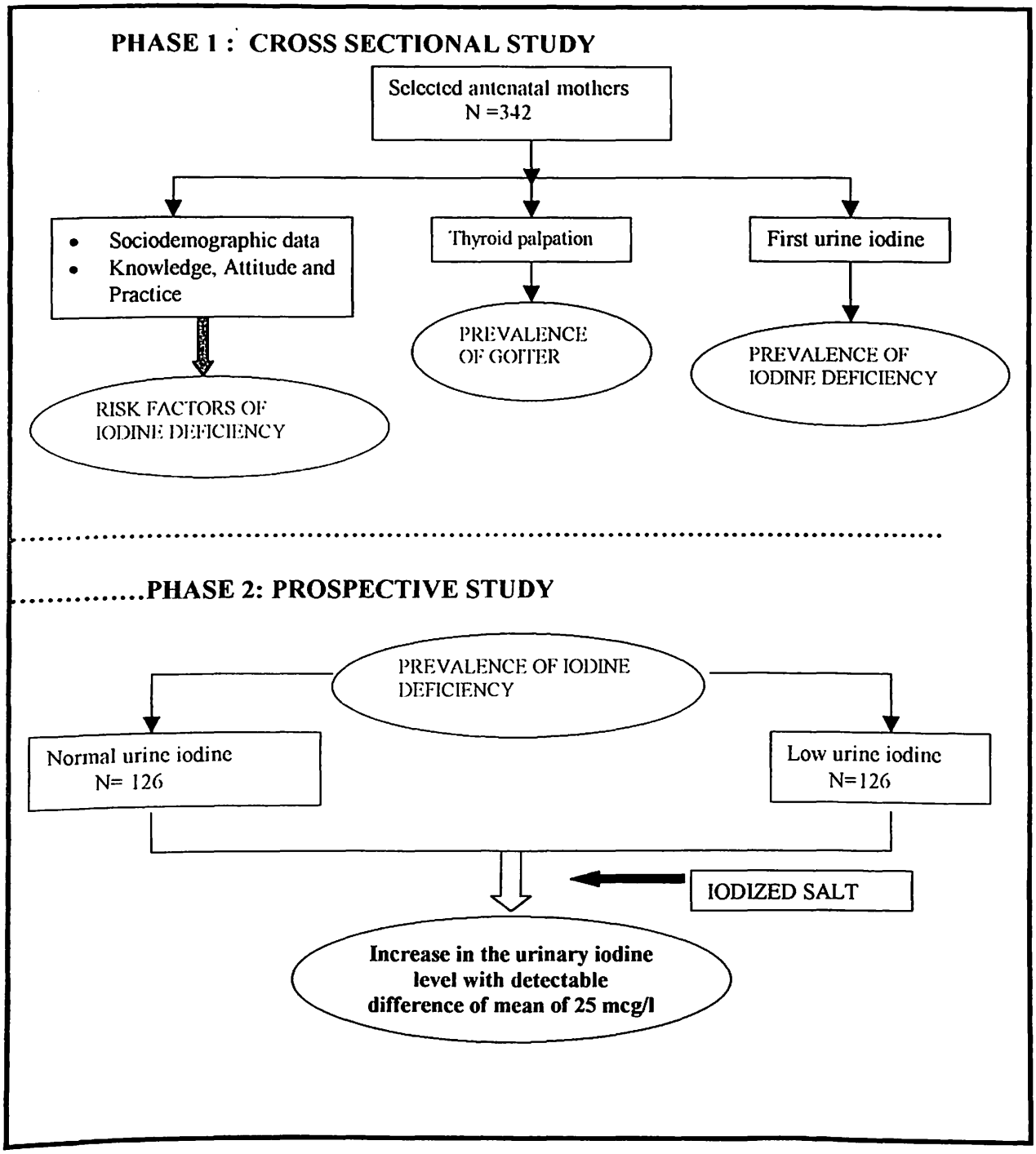


Figure 3.2: Flow chart of the study

3.9 Statistical analysis

Data was entered and analysed with the SPSS version 10.0 software at the CAI laboratory Universiti Sains Malaysia. STATA version 7.0 software was used in analysing influential statistics for the general linear regression analysis.

3.9.1 Univariate analysis.

The distribution of mean of difference in the urinary iodine level was tested for normality. The effectiveness of the iodized salt supplementation was assessed with the paired sample t test.

3.9.2 General linear regression analysis

Data were explored in each group. Univariate analysis was performed, for both numerical and categorical variables with independent t test. The variables, which may have interaction were checked with forward approach. The predicted and residual value with the model was saved and scatter plot was performed to check for residual. Equality of variance and the fitness of model were checked. Linearity was checked by plotting residual versus predicted. The scatter plot showed income and urinary iodine level was not in linear distribution. Therefore the cut of point at 0-150 mcg/l and >151mcg/l for urinary iodine were made to ensure the residual is in linear relationship. The final model was developed by forward approach.

3.10 Research protocol and ethical approval

The research proposal was approved on 1st November 2000 by the research committee and approval from the research ethical committee was attained 7th June 2001. This research was funded under short term grant, Universiti Sains Malaysia: 304/PPSP/6131172, from 1st July 2001 to 30th June 2002.

4.RESULTS

4.1 Sociodemographic characteristics

Table 5.1 shows the socio-demographic characteristics of 342 mothers involved in this study. Most of the subjects were Malays, majority of them has attended secondary school and were housewives.

Table 4.1: The socio-demographic characteristics of 342 mothers .

Characteristics	n	%	Mean (SD)	Median (IQR)
Age (years)				
17 – 26	92	26.9	30.6 (6.22)	
27 – 36	187	54.7		
37 - 46	63	18.4		
Ethnic group				
Malay	339	99.1		
Indian	1	0.3		
Others	2	0.6		
Educational level				
No formal education	13	3.8		
Primary school	35	10.2		
Secondary school	276	80.7		
Institution / tertiary	18	5.3		
Duration of schooling (years)				11.0 (2.0)
Literacy				
Literate	318	93.0		
Illiterate	24	7.0		
Mother's occupation				
Housewife	271	79.2		
Employed	58	17.0		
Self employed	13	3.8		
Total family income (RM)				
100 – 500	154	45.0		
501 – 1000	111	32.5		RM600.00
1001 – 1500	36	10.5		(RM 600.00)
1501 – 2000	11	3.2		
> 2000	30	8.8		
No of family member				
2 – 5	159	46.5		6.0 (3.0)
6 – 10	165	48.2		
11 – 15	16	4.7		
16 - 20	2	0.6		