Salt as a Vehicle for Fortification

Report of a WHO Expert Consultation

World Health Organization

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1. Background

A WHO Forum and Technical Meeting on Reducing Salt Intake in Populations was organized in October 2006 in Paris, France with the overall goal of developing recommendations for Member States and other stakeholders on how to reduce the salt intake of populations with the long-term goal of preventing chronic diseases (WHO, 2007). The experts participating in this meeting recommended WHO to further discuss the use of salt as a vehicle for iodine fortification, as this could originate a potential conflict between two major public health goals – reducing average population salt intake, and tackling iodine deficiency.

As a follow-up of the meeting in Paris, WHO organized an Expert Consultation on salt as vehicle for fortification. This Consultation was convened by WHO Headquarters jointly with the WHO Regional Office for Europe, with the support of the Ministry of Health of Luxembourg, and took place in Luxembourg on 21-22 March 2007.

The overall goal of the Expert Consultation was to discuss how to reconcile the policy of reducing salt consumption to prevent chronic diseases and the policy of universal salt iodization (USI) to eliminate iodine deficiency.

The specific objectives of the meeting were to review and discuss:

- the benefits and disadvantages of using salt as a vehicle for micronutrient fortification;
- the public health significance of mild-to-moderate iodine deficiency;
- the public health significance of cardiovascular disease;
- the impact of the message «Use iodized salt» on the overall salt consumption of the population;
- the best way to deliver to the public a message addressing both the reduction of salt consumption and the consumption of iodized salt.

On the first day of the meeting, presentations were made by experts addressing the following topics: public health significance of mild-to-moderate iodine deficiency; public health significance of cardiovascular diseases and excessive salt consumption; advantages and disadvantages of using salt as a vehicle for micronutrient fortification; and country experiences on reducing salt intake policies and USI interventions (Switzerland, Finland, China, Costa Rica and Poland).

After the presentations, the participants were divided into working groups to discuss three main topics: evidence of iodine deficiency disorders (IDD) and cardiovascular diseases (CVD) as major public health problems; salt as a vehicle for fortification; and how to integrate policies to reduce salt consumption and promote USI. On the second day, a plenary session was organized. The groups presented the results of their work, and these results were discussed and used as the basis to make recommendations along with the plenary presentations by the experts.

2. Public health significance of cardiovascular diseases and iodine deficiency disorders throughout the world

2.1. Magnitude

- CVD are the leading cause of death, responsible for 30% of all deaths globally. They also contribute 10% to the global disease burden (WHO 2005).

- Worldwide, 7.1 million (13%) of deaths are estimated to be associated with high blood pressure (>115 mmHg systolic blood pressure). About one third of disability adjusted life years (DALY) attributable to high blood pressure occur in developed countries, one third in developing countries with a high mortality rate and one third in developing countries with a low mortality rate. Thus strategies for blood pressure control are a public health priority around the world and not just in developed countries (WHO, 2002).

- Iodine deficiency is one of the world's most important nutritional deficiencies, and produces a spectrum of disorders – impaired cognitive development and function; hypothyroidism; congenital abnormalities; cretinism and endemic goitre – known as IDD (WHO, UNICEF, ICCIDD, 2007). These disorders are endemic in many countries around the world. Iodine deficiency affects one third of the global population, including 260 million school-age children. Although pockets of severe iodine deficiency still exist, probably more than 80% of the current iodine deficiency is of mild-to-moderate severity. More than half of the population in Western and Central Europe is at risk of iodine deficiency, and about one fourth of the countries where iodine deficiency is a public health problem still have weak or non-existent public health programmes to address this problem (Delange F and Zimmerman M, 2004).

2.2 Dietary salt intake, blood pressure and cardiovascular disease

- There is a significant variation in the levels of salt consumption between countries, and also significantly different patterns of consumption. In European and North American countries, about 70-80% of sodium consumed comes from processed foods, restaurant services and catering.

- In Asian as well as in many African countries, salt added in cooking and present in sauces and seasonings still represents the major source of sodium in the diet.

- High levels of dietary salt intake have been associated with high blood pressure, with a higher prevalence of hypertension and a greater rise in blood pressure with age both within and between populations (INTERSALT Cooperative Group, 1988). These observations suggest a direct link between the levels of salt intake and high blood pressure and the prevalence of hypertension. The body of evidence linking salt intake to blood pressure comes from a variety of studies: animal, ecological, epidemiological and clinical including randomized control trials.

- The consensus is that by lowering salt intake blood pressure is lowered. The blood pressure-lowering effect is dependent on the degree of reduction of dietary salt intake (He FJ and MacGregor GA, 2003). This effect is dose-dependent (Cook NR et al, 2005) and does not present a threshold effect (Sacks FM et al, 2001; MacGregor GA et al, 1989), at least within the ranges tested in clinical trials (as low as 3 g of salt per day). The higher the starting blood pressure, the greater the effect (He FJ and MacGregor GA, 2003; Cappuccio et al, 1997). In older people (Cappuccio et al, 1997) and in those of black African origin (Bray GA et al, 2004), this effect is sustained over many years (TOHP I, 1992; TOHP II, 1997; Kumanyika SK et al, 2005).

- This evidence has led to the suggestion that, if sustained over many years and applied to populations, a reduction in salt intake would lead to a reduction in the incidence of cardiovascular outcomes (coronary events, strokes, cardiac and renal failure) with a significant reduction in the burden of cardiovascular disease worldwide (He FJ & MacGregor GA, 2003).

The argument is strengthened by the concept that the majority of cardiovascular events attributable to blood pressure would occur in those with a moderately raised blood pressure, representing the majority of the cases, for whom drug therapy would not be recommended by national and international guidelines (WHO/ISH Hypertension Guideline 2003; Murray C et al, 1997).

- A few prospective studies (Sasaki S, Zhang X-H, Kesteloot H, 1995; He J et al, 1999; Tuomilehto J et al, 2001; Nagata C et al, 2004) have indicated a direct relationship between the levels of salt intake and the incidence of fatal and non-fatal cardiovascular events. One study has raised concerns about possible adverse effects of low salt intake on cardiovascular outcomes (Alderman MH et al, 1995; Alderman MH et al, 1998; Alderman MH, 2004; Cohen HW et al, 2006). The results and the analysis of this study, however, have been challenged as flawed.

- A recent report from the Trials of Hypertension Prevention I and II (TOHP I, 1992; TOHP II, 1997) has shown a significant 30% reduction in the 10-15 year incidence of cardiovascular events amongst participants originally randomized into the sodium reduction arms of the above trials for a period between 18 months and 36-48 months (Cook NR et al, 2007).

- The efficacy of reduced sodium intake in lowering blood pressure is well established. An average reduction of 77 mmol/day in dietary intake of sodium has been shown to reduce systolic blood pressure by 1.9 mmHg and diastolic blood pressure by 1.1 mmHg.

- A modest, long-term reduction in population salt intake has the potential to reduce stroke deaths by about 14% and coronary deaths by about 9% in people with hypertension, and by approximately 6% and 4%, respectively, in those with normal blood pressure.

- On the basis of the above evidence, current recommendations on salt intake for the prevention of cardiovascular disease is <5 g (90 mmol) per day or, for persons with high blood pressure, African Americans, and middle-aged or older adults, <1500 mg of sodium per day (WHO/FAO 2003; USDA Guidelines for Americans 2005; AHA Guidelines, 2007, WHO Guidelines 2007).

2.3 Iodine deficiency and salt iodization

- Iodine deficiency is the result of insufficient dietary iodine intake.
- At the population level, the best indicator of iodine status is median urinary iodine (UI) excretion. It is an indicator of recent dietary intake and is used as criteria to define the severity of iodine deficiency (WHO/UNICEF/ICCIDD, 2007).
- The physiological consequence of iodine deficiency is hypothyroidism. The health effects of iodine deficiency vary according to the stage of the life cycle, including reproductive failure (e.g. infertility, stillbirth etc.), infant mortality, pregnancy and fetal mental retardation, cretinism, fetal and postnatal growth retardation, impaired cognition (e.g. reduced IQ), and endemic goitre, including toxic nodular goitre.
- Iodine-induced hyperthyroidism (IIH) is a result of an excessive intake of iodine, which affects mainly (but not only) older people with nodular goitres (Delange F, 1998) and it has been reported in almost all iodine supplementation programmes. The risk of hyperthyroidism is increased for UI concentrations above a median of 200 ug/l in susceptible individuals like those with pre-existing nodular goitre, and depends on the rapidity of the increase in iodine intake and the severity of pre-existing iodine deficiency.
- The prevention of IDD is possible with the addition of iodine to the diet. Of the various methods used to add iodine to the diet, fortification of salt with iodine for human and animal consumption has been recommended and is being implemented worldwide (WHO/ICCIDD, 1995; WHO, 1999).

2.4 Dietary salt reduction and salt iodization

- Current recommendations indicate that in order to prevent chronic diseases, the population average consumption of salt should be <5 g/day (<2 g/day of sodium) (WHO, 1983; WHO/FAO, 2003).

- Some countries have set quantitative recommendations limiting the daily salt intake converging with the international recommendations of <5 g of salt per day. These national recommendations have been aimed at the general public and manufacturers, and few countries have taken action to translate these recommendations into policies and programmes.
- Few countries, like the United Kingdom of Great Britain and Northern Ireland and the DACH countries (Germany, Austria and Switzerland) have separate recommendations for children and adolescents.
- Recommended daily iodine intakes are set at 250 µg/day for pregnant and lactating women, 90 µg/day for children <6 year of age, 120 µg/day for children 6-12 years of age and 150 µg/day for children >12 years of age and nonpregnant, nonlactating adults. Such intakes in children >12 years of age and in nonpregnant adults should result in a median urinary iodine of 100-200 µg/l and in pregnant women, in a median urinary iodine of 150-250 µg/l (Andersen S et al, 2001; Hess SY et al, 1999; Hollowell JG et al. 1998).
- As the most devastating consequences of iodine deficiency occur during intrauterine development and in the first few months of life, adequate iodine nutrition in pregnant women and in infants and young children is fundamental.

3. Salt as a vehicle for fortification

3.1 Iodized salt

- Salt is the most widely used food vehicle for iodine fortification. USI, that is iodization of all salt for human (food industry and household) and livestock consumption, is the strategy recommended by WHO for the control of iodine deficiency (WHO, 1999). Salt iodization programmes are currently implemented in over 70 countries around the world where IDD is a public health problem (Delange F, et al, 1999).

- The choice of salt as the preferred vehicle for the delivery of iodine is based on the following factors: salt is one of the few commodities consumed by everyone; consumption is fairly stable throughout the year; salt production is usually limited to a few geographical areas; salt iodization technology is easy to implement and available at a reasonable cost throughout the developing world; the addition of iodine to salt does not affect its colour, taste or odour; the quality of iodized salt can be monitored at the production, retail and household levels (Allen L, et al, 2006).

- Some obstacles to the implementation of USI are: difficulties in enforcing legislation on iodized salt; problems caused by having a high number of small-scale salt producers and the absence of an effective operational monitoring system; the lack of monitoring of the salt quality may result in variations in the iodine content of salt, inadequate supply of fortificants, inadequate supply and use of iodized versus noniodized salt, and population levels of salt intake (measured versus estimated) (Allen L, et al, 2006). These are important to understand given the risk of iodine-induced hyperthyroidism (Stanbury JB, et al, 1998).

- The current recommendation that salt be fortified with iodine at a level of 20-40 ppm is based on the assumption of an average salt intake of 10 g per day at the population level. This assumption may no longer be valid because salt intakes in populations may vary substantially between countries (INTERSALT Cooperative Group, 1988) and the level of intake is being reduced as a result of public health policies aiming to attain the population average intake of 5 g of salt per day (WHO, 2007). The level of iodine fortification may need to be adjusted by national authorities responsible for the implementation and monitoring of USI in light of their own data regarding dietary salt intake. The national level of average salt consumption must provide key guidance for the concentration of iodine in salt.

- The large diversity in national circumstances and public health goals has resulted in the development of many different approaches to the regulation of food fortification. In most industrialized countries, food fortification parameters are established by law or through cooperative arrangements. In many developing countries, the role of the government in regulating food fortification may not be predominantly enforced. Since it is the role of the government to protect the public's health, it is generally recommended that all forms of food fortification be appropriately regulated in order to ensure the safety of all consumers and provide the maximum benefit to the target groups (Allen L, et al, 2006).

3.2 Other vehicles for iodine fortification

- Alternatives to the use of salt for the delivery of iodine to populations include: bread, water, milk, and possibly edible oil and wheat flour.

- From a technical point of view, adding iodized baker's salt to bread has been shown to be an effective way of ensuring a constant supply of dietary iodine in countries where bread is staple food. However, limitations for the worldwide use of bread as a preferred vehicle include: non-centered chain of production for bread, which makes it difficult to monitor fortification processes and levels in the final product; wide variations in bread consumption at the population level; great variety of breads offered to the population (Allen L, et al, 2006).

- Because water is consumed daily, it too has the potential to be a useful vehicle for iodine fortification. Its major limitation, compared with salt, is that sources of drinking water are so numerous and ubiquitous that iodization would be difficult to control. Moreover, iodine has limited stability in water (no longer than 24 hours) such that continuous daily dosing of the water supply would be necessary. A review of the efficacy and cost-effectiveness of the different procedures used to iodize water concluded that while efficacious for the most part, there is no doubt that the cost, and the monitoring systems needed, are more problematic than those required for iodized salt. Although the use of water as a vehicle for iodine fortification is technically more difficult than the use of salt, there are certain conditions where water iodization could be a suitable method for the correction of iodine deficiency and some countries have successfully used it [e.g. Thailand (northern), the Central African Republic, Mali, Sudan, Malaysia, and Italy (Sicily)] (Allen L, et al, 2006).

- Iodine in milk, either added by providing extra iodine to dairy cows or adventitiously through use of iodine-containing cleaning agents has been instrumental in the control of iodine deficiency in several areas/countries (e.g. Northern Europe, the United Kingdom of Great Britain and Northern Ireland, the United States of America). However, the variability in the amount of milk consumed by the population does not make it a suitable vehicle for iodine fortification.

3.3 Monitoring

- In view of the salt reduction programme to prevent cardiovascular diseases, the surveillance of iodine status is reinforced as an important tool. However, no available monitoring of salt intake and blood pressure is currently in place.

- Ideally, salt intake should be estimated initially by measuring sodium excretion in 24-hour urine collections in a representative subsample of the population stratified by sex and age. This will give absolute estimates of baseline salt intakes for comparison across different population groups and different regions. The 24-hour urine collections are considered the "gold standard" method to measure sodium (salt) intake as they can capture 85-90% of the ingested sodium. This method presents the advantage of not being affected by subjective reporting of dietary intakes, but shows some limitations: high participant burden; problems of completeness; collection must be accurately timed to avoid over- and under-collection.

- In addition to a 24-hour urine collection, several methods can be used to estimate salt intake: duplicate diets, dietary surveys and spot urine collections. But these present significant limitations.

- The use of median UI and 10th and 90th percentiles of the distribution may improve the interpretation of iodine status, in particular the potential impact of excessive iodine provision.

4. Integrating public health policies for the prevention and control of CVD and IDD

- To reconcile the existing WHO policies aimed at reducing the intake of salt and delivering adequate dietary iodine to populations, it is necessary to consider the concentration level of iodine in salt that would provide sufficient iodine, given salt intakes <5 g/day, or lower, as recommended. Because iodization methods permit adequate concentrations of iodine to provide recommended levels within this range of salt intake, these two policies are not in direct conflict.

- The interaction with food manufacturers is fundamental to the success of salt reduction strategies and to USI. Food industries should be encouraged to harmonize the salt content of their products according to the lowest threshold possible to avoid unnecessary variations in salt content of the same food product commercialized in different countries. In addition, the use of iodized salt in countries implementing USI should be considered.

- The current recommended strategy for IDD control is based on correcting this nutritional deficiency by increasing iodine intake through food fortification. Salt is the most commonly used vehicle for this purpose. In order to meet iodine requirements of a population it has been previously recommended to add 20-40 ppm iodine to salt, assuming an average salt intake of 10 g per capita per day (WHO, 1996). This figure of 10 g per day may no longer be valid and the recommendation will need to be adjusted if the goal to reduce average population salt intakes to <5 g/day is achieved.

- Following WHA resolutions 57.17 and 58.60, the recommendation of the report of the WHO Forum and Technical Consultation in Paris of 5-7 October 2007, on Reducing Salt Intake in Populations, the report of the Joint WHO/UNICEF committee, further WHO publications (WHO, 1982; WHO, 1983; WHO/FAO, 2003; WHO 2005, WHO, 2007) and given the desirability of ensuring maximum health benefits for all, the recommended average consumption of <5 g/day of salt (<2 g of sodium), except where lower levels have already been set, it is reaffirmed that all salt intended for food consumption should be iodized.

- USI is a very cost effective, feasible and sustainable method of preventing iodine deficiency, but it is fundamental to recognize that specific population groups (e.g. pregnant women and children) may also need to be targeted in other ways for the adequate consumption of iodine (e.g. potassium iodide tablets or iodized oil).
- The iodine concentration in salt should be determined considering both the level of salt consumption and median UI of the population.
- Monitoring of UI through existing programs is essential. Countries need to periodically adjust the levels of iodine fortification within the goal of salt consumption <5 g/day, depending on their own local data.
- Monitoring UI is also of value to detect a median UI >200 µg/l and therefore prevent any risk of iodine excess by adjusting the level of iodine fortification accordingly.
- Policies for salt iodization and reduction of salt to <5 g/day are compatible, cost effective and of great public health benefit. At the country level, close collaboration between salt iodization and salt reduction programs as a coalition is urgently required so that their aims are congruent.
- Ministries of health should make sure that the message to consume iodized salt does not promote excessive salt consumption and does not conflict with salt reduction policies.
- Advocacy with policy makers will be necessary for implementation and appropriate legislation and regulation on salt iodization and salt reduction.
- Fortification of salt is currently the most feasible approach for the elimination of IDD, but research is needed to identify other possible vehicles for delivering iodine.

- Best practices from countries that have developed both salt reduction and iodization policies should be considered when ministries of health are developing and implementing policies with similar goals.

5. Recommendations

- The participants of the Expert Consultation agreed on the statements and recommendations given below:

- National policies should commit to reducing the average salt consumption of the adult population to <5 g/day, except where lower levels have already been set. Policy makers should develop a clear strategy to achieve this goal. This should include measurable objectives, targets, indicators (including those for population subgroups), and a time frame for their accomplishment in the shortest possible time.

- The prevention of IDD is possible by increasing dietary iodine intake. Salt is the most widely used vehicle for iodine fortification. USI as the recommended strategy to control iodine deficiency is reaffirmed. Salt iodization programmes that are currently being successfully implemented in over 70 countries around the world should continue and be sustained.

- Policies for salt iodization and reduction of salt to <5 g/day are compatible, cost effective and of great public health benefit. At the country level, close collaboration between salt iodization and salt reduction programs as a coalition is urgently required so that their aims are congruent.

- Reliance on salt as a vehicle for the delivery of dietary iodine should not be used to justify promotion of salt intake to the public, and additional vehicles to salt for micronutrient fortification should continue to be explored.

- The current recommendation that salt be fortified with iodine at a level of 20-40 ppm is based on the assumption of an average salt intake of 10 g/day at the population level. This assumption may no longer be valid because salt intake in populations may vary substantially between countries and the level of intake is being reduced as a result of public health policies aiming to achieve a population average intake of 5 g of salt per day (WHO, 2007).

- The level of iodine fortification needs to be adjusted by national authorities responsible for the implementation and monitoring of USI in light of their own data regarding dietary salt intake. The average national level of salt consumption must provide key guidance for the concentration of iodine in salt.
- The iodine concentration in salt should be determined considering both the level of salt consumption and median UI of the population.
- Ministries of health should ensure that health promotion messages do not inadvertently promote excessive salt consumption. This should be clearly reflected in the development and implementation of policies to prevent iodine deficiency and promote reduced salt intake.
- Lessons from successful experiences in countries that have implemented both reduction of salt consumption and salt iodization policies should be considered when ministries of health plan to implement these policies.
- Advocacy from International Organizations (e.g. WHO, UNICEF, FAO), NGO's and academia with policy makers is recommended in order to promote the development and implementation of policies that aim both at safe salt iodization and effective reduction in salt intake.
- Food fortification, including salt iodization, should be appropriately regulated by governments to ensure that fortification is both safe and effective.
- Specific regulatory measures on the use of iodized salt intended to food producers and distributors should be taken by governments where the main source of dietary salt are processed foods and meals consumed outside the households.
- Multinational food industries are encouraged to harmonize the salt content of their products according to the lowest threshold possible to avoid unnecessary variations in salt content of the same food product commercialized in different countries.

- The benefits of correcting iodine deficiency far outweigh the potential risk of fortification. Iodine-induced hyperthyroidism and other potential adverse effects can be almost entirely avoided by adequate and sustained quality assurance and monitoring of iodine fortification.
- The use of salt as the vehicle for new fortification initiatives, other than iodine and fluoride, should be discouraged.
- The monitoring of salt quality is essential to ensure both efficacy and safety of the process of iodine fortification.
- Changes in population salt intakes need to be assessed over time via monitoring of urinary sodium excretion and, where appropriate, in conjunction with the established WHO programme for monitoring UI levels.
- Use of spot urine collections to monitor changes in salt intake over time should be considered as a possible alternative to repeated 24-hour urine collections to increase the feasibility of monitoring, despite expected requirements for substantially greater sample sizes with this approach.
- Where possible and the resources permit, blood pressure measurements should be added to the monitoring tools alongside iodine and sodium.

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