Quality aspects of the rapid salt test kit in Indonesia

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ABSTRACT- Indonesia produces a rapid salt test kit that is widely used to provide information for programme decision making in the Control of Iodine Deficiency Disorders. The validity and reliability of the test kit are sufficient for helping programme managers identify high-risk areas and monitor progress towards the goal of Universal Salt Iodization. For salt quality monitoring at production and retail level, it is recommended to use the titration method for the quantitative determination of iodine content.

1. INTRODUCTION

At the turn of the millenium, salt is no longer just a provider of taste and essential electrolytes: throughout the world, it has become the carrier of iodine in a massive attempt to eliminate the devastating consequences of Iodine Deficiency Disorders (IDD). It is estimated that 68% of the world population at risk of IDD is now consuming iodized salt [1]. The proportion of households consuming adequately iodized salt constitutes one of the indicators defined by WHO, UNICEF and ICCIDD for the assessment of the elimination of IDD [2]. It is required that at least 90% of households consume adequately iodized salt.

In response to the need for an instrument to quickly measure iodine content in salt, several rapid field test kits have been developed for the semi-quantitative determination of iodine in salt. It is important to evaluate the quality of these kits, especially when they are used to collect information on the proportion of households consuming adequately iodized salt, one of the indicators for the assessment of IDD elimination.

The first prerequisite for information to be reliable is that the instrument with which it is measured is of good quality. In our case, the rapid test kit (test instrument) should correctly identify salt that is adequately iodized. This article will review two aspects of quality of the test kit that is used in Indonesia [3]:

1. *Validity*, the ability of the test to correctly measure the true value. Validity has two components: Sensitivity and Specificity
2. *Precision (reliability)*, the degree to which the same result can be reproduced consistently when the test is repeated.

2. VALIDITY

2.1 Use of one colour cut off point only

The function of the rapid test kit is based on the formation of free iodine from iodate (in salt) and iodide (in test solution) in an acid environment. This then forms a complex with starch that produces a blue colour that gets darker with higher iodine content [4].

$$IO_3^- + 5I^- + 6H^+ \longrightarrow 3I_2$$

$$I_2 + \text{starch} \longrightarrow \text{Blue Colour}$$

In principle, this allows for the development of a colour scale from light to dark blue, indicating increasing levels of iodine. Most of the early test kits that became available throughout the world contained a multiple colour chart covering a range of iodine contents.

In practice, differentiation between one colour gradient and the next has appeared to be prone to many errors. Moreover, the breakdown of the information on iodine content in many categories provides little additional benefit to the user over the use of just one point. The user is mainly interested in knowing quickly if there is enough iodine or not. Enough iodine or not differs according to the regulation of a country. The Indonesian legal standard for iodized salt stipulates that all salt for animal and human consumption must contain between 30 and 80ppm iodine. Therefore, the Indonesian test kit uses only one cut off point to distinguish between salt with more than (adequate) or less than (inadequate) 30 ppm. Thus, the kit provides for three possible outcomes:

1) no colour change (no iodine)
2) blue colour that is lighter than the reference colour (< 30 ppm or inadequately iodized)
3) blue colour same as or darker than reference colour (>30 ppm or adequately iodized)

2.2 Specificity and Sensitivity

The specificity and sensitivity of the Indonesian test kit have been evaluated by comparing its results with the actual iodine content of salt as determined by titration. The *sensitivity* of the salt test kit refers to its ability to identify correctly all salt that does not have enough iodine (bad salt). The *specificity* is defined as the ability of the test to identify correctly salt that has adequate iodine (good salt). The correct or true iodine content is determined by the titration method. Titration with thiosulfate is the accepted gold standard method for the quantitative determination of iodine in salt. Salt samples in the range of 0 to 100 ppm iodine (titration) have been tested repeatedly by different observers to compare the test kit finding with the true titration content.

The results indicate that the test kit is highly valid for correctly identifying salt without any iodine. Both the sensitivity and specificity of the kit are 100%, meaning that in all cases when the test kit indicates that there is no iodine, the salt indeed has no iodine. Also, that when the kit tells that there is iodine (blue colour), the salt truly contains iodine. Indeed, it is easy for any observer to determine with certainty that there is no change of colour at all.

The test kit in Indonesia has been developed to identify salt with less than the minimum required level of 30 ppm iodine. With this cut-off point, the test kit will identify correctly 75% of all samples with less than 30 ppm (*sensitivity 75%)*, while it identifies 95% of all salt with more than 30 ppm correctly (*specificity)*. Interestingly, by putting the cut-off point at 15 ppm, the *sensitivity* of the test improves to 96% (the kit is able to correctly identify all samples with less than 15 ppm including 0 ppm). In other words, the kit is supposed to distinguish between above or below 30 ppm, but in fact, performs best for distinguishing between above and below 15 ppm. This is due to the relatively higher amount of errors in the readings for samples that contain between 15 and 30 ppm iodine. In this range, the test kit classifies 50% of salt wrongly as having more than 30 ppm. Figure 1 visualizes the performance of the kit in terms of correct classification as a function of the iodine content.

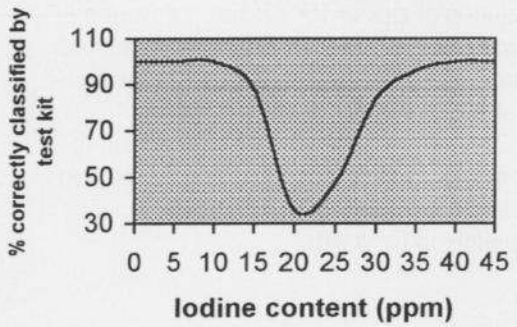


Figure 1. Performance of the test kit varies with iodine content

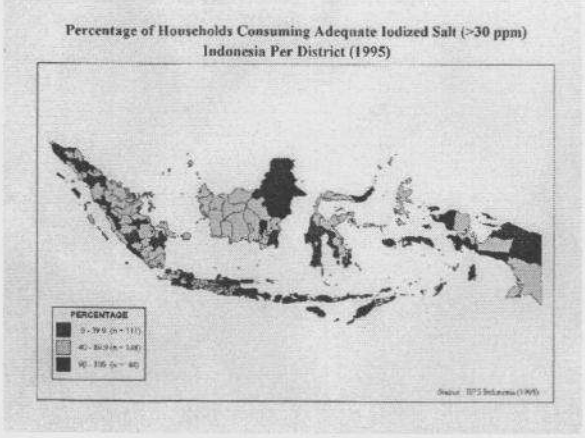
3. PRECISION (RELIABILITY)

3.1 Salt maps-Consistent results over the years

Since 1995, the test kit is used in Indonesia to measure household consumption of iodized salt on a national scale. Measurement of iodized salt consumption has been added to the existing annual Socio-Economic Survey (SUSENAS), conducted by the Central Bureau of Statistics. Including salt testing as an 'add-on' activity to an existing survey is a very cost-effective way for gathering information on household consumption of iodized salt. SUSENAS collects information of a total of 208,000 households covering the whole nation representing the province and district level.

The results of the SUSENAS salt testing over four years (1995-1998) provides evidence that the test kit is highly consistent. This can easily be appreciated when the results are presented in the form of maps. Figure 2 shows the maps of 1995 and 1998. These maps offer the information in an attractive visual format that can be quickly and easily understood without any data analysis skills. The maps have become a powerful tool for advocacy to decision-makers at central and local level. For each district and province the percentage of households using adequately iodized salt is divided in three categories:

1) Green	At least 90% of households use adequately iodized salt
2) Yellow	40 to 90% of households use adequately iodized salt
3) Red	Less than 40% of households use adequately iodized salt



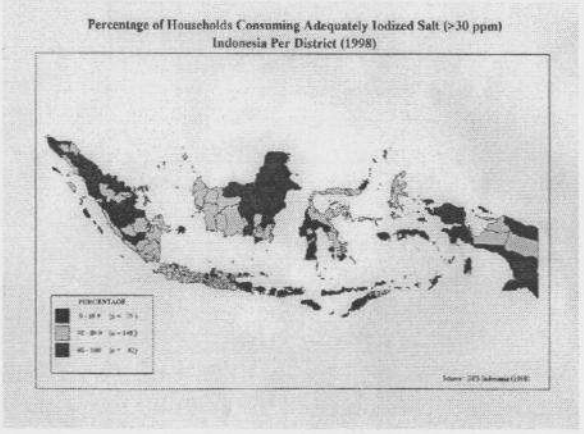


Figure 2. Salt map for 1995 and 1998 showing the percentage of households consuming adequately iodized salt per district.

Figure 2 shows that over the years, the salt test kit is consistent in replicating the same pattern of red, yellow and green. There are some provinces turning from red in yellow or from yellow to green which is consistent with the improvement that can be expected as a result of the programme. Moreover, the red areas are not scattered in a random way, but clustered and they overlap exactly with those areas where most of the raw salt farming in Indonesia takes place. It is a common phenomenon in many countries that the consumption of iodized salt is low in areas with raw salt farming, simply because it can not compete with the abundant local supply of raw salt. The test kit can identify those areas.

3.2 Correlation with other IDD indicators

Another indication of the quality of the test kit is that there is a strong correlation between the proportion of households using adequately iodized salt and the prevalence of goitre as well as the urinary iodine excretion.

Data on household salt consumption, the prevalence of goitre, and urinary iodine excretion from all districts of the province of Central Java and Nusa Tenggara Timur were collected in the same year(1996).

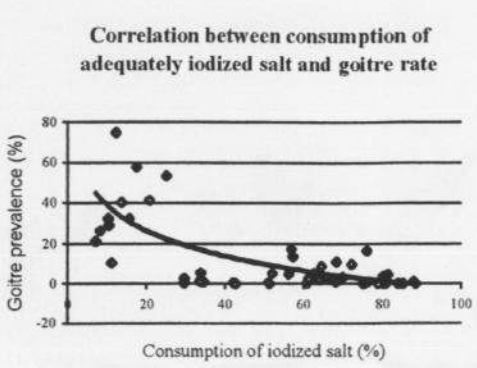


Figure 3. Correlation between salt consumption and prevalence of goitre.

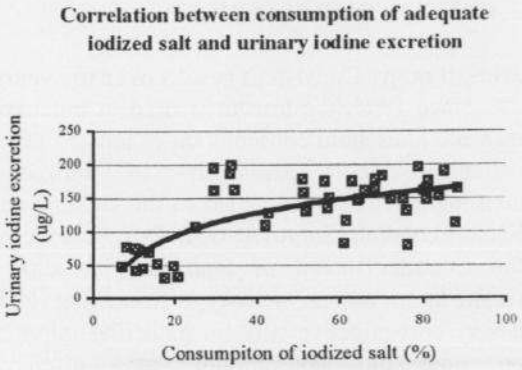


Figure 4. Correlation between salt consumption and urinary iodine excretion.

It can be observed that districts with high consumption of adequately iodized salt tend to have a low prevalence of goitre and the other way around. It can indeed be expected that the prevalence of goitre will be low in a given area if the intake of iodine (from iodized salt) is sufficient among a large proportion of the population in that same area. This correlation would not have been found if the test kit was not able to correctly distinguish adequately iodized salt. Similarly, increased consumption of adequately iodized salt results in higher urinary iodine levels in the population.

4. CONCLUSION

The Indonesian rapid salt test kit is a valid and reliable instrument that provides valuable information to IDD programme managers in a cheap and timely manner. It is particular useful for the regular measurement of the proportion of households consuming adequately iodized salt and thus the monitoring of progress towards the goal of Universal Salt Iodization. Equally, it can identify high-risk areas for targeting programme interventions.

For quality control purposes it also provides a cheap instrument suitable for quickly checking large numbers of samples. Samples with less than 15 ppm will be correctly identified in 96% of cases. Caution is required, when a cut-off point of 30 ppm is used, because in the range of 15 to 30 ppm many samples are wrongly classified as adequately iodized. It is recommended, in case of doubt or dispute, to always check the sample with the titration method.

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