Field Validation of salt iodine spot testing kit using multiple observers to assess the availability of iodised salt : Experience from India

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1. INTRODUCTION

Universal Salt Iodisation (USI is the most widely practiced intervention for elimination of Iodine Deficiency Disorders (IDD).(1) Salt iodine testing is an important "Process" indicator for monitoring progress towards USI. Under the National Iodine Deficiency Disorders Control Programme in India, iodisation of salt is the recommended strategy with the level of iodisation fixed at a minimum of 15 parts per million (ppm) at consumer level and 30 ppm at production level.(2) The salt department and the state governments are responsible for monitoring the salt iodine content at both production and consumption levels.(2)

The iodometric titration, the traditional method for testing iodine content is accurate.(3) However, it is time consuming, requires capital infrastructure and trained manpower. The time lapse between collection of sample and the availability of result for feedback and corrective action is considerable. The iodine spot testing kits do not require any infrastructure, are low cost and most importantly, provide immediate feedback. The kit gives only a qualitative or semiquantitative estimation of the iodine content. Qualitative means that salt samples are classified as (adequately) iodised or uniodised. It gives no indication of the actual level of iodine in the salt. Some kits give an approximate estimate of iodine content in the salt. These are called semiquantitative tools and categories salt samples as having an iodine content of 0 ppm, 7 ppm, 15 ppm or 30 ppm.

Previous studies on validity of the salt iodine spot test kit have been largely laboratory based or used a single observer. (4,5,6) However, there is a need to test the kits in a field situation where multiple observers are involved in its use. In this paper we address the issues of validity and agreement of the spot testing kit used in actual field conditions in two Indian states, as compared to iodometric titration method.

2. METHODOLOGY

The data for the present study was collected during two USI surveys carried out by our team in the state of Madhya Pradesh (Central India) in 1995 and National Capital Territory of Delhi (Northern India) in 1996.

The survey in Madhya Pradesh was a part of the "Independent Survey Evaluation of Universal Salt Iodisation (USI) which was carried out in November 1995 (7). An "EPI 30 cluster sampling" method based on probability proportionate to size (PPS) was followed (1). The state was divided into rural and urban strata. In each strata, 300 households were selected i.e. 10 in each cluster. The study team comprised of 15 senior physicians from different national institutions and medical colleges in India. In each cluster, salt samples were collected from the selected households and all the retail shops in that village/ urban cluster. The samples were tested by the salt testing kit in the field by the physicians.

The survey in the National Capital Territory of Delhi was a school based survey carried out to estimate the of use of iodised salt at the household level (8). Thirty schools from South Delhi were selected using the "EPI 30 cluster" sampling methodology. After orienting the school principals, teachers and students to IDD and the importance of consuming adequately iodised salt in the household, the children from class 6 to 8 were requested to bring salt samples from their

homes on a pre-fixed day. On that day, a public health nurse from the project visited the school and tested the salt samples using the salt iodine spot testing kit. The results were communicated to the students and teachers and the opportunity was also used to further reinforce messages about IDD.

About 20 grams of salt samples in all cases were collected in airtight plastic envelopes and brought to the Iodine Monitoring Laboratory (IML) of the International Council for Control of Iodine Deficiency Disorders (ICCIDD) located at the Centre for Community Medicine (CCM), All India Institute of Medical Sciences (AIIMS), New Delhi for iodometric titration.

3. LABORATORY PROCEDURES

To estimate the iodine content of salt iodometric titration was used as the reference method. It uses thiosulfate and starch as an external indicator (9).

The kit, produced by MBI chemicals, Chennai (India) is a starch based test. In case the test showed "no iodine" on the first testing, the test solution was added again after-acidifying the salt sample. This was required to neutralise the presence of alkali in the salt. The kits were used well within the expiry date mentioned on the pack.

4. DATA ANALYSIS

The data was processed and analysed using EpiInfo 6 (10). Tests for proportion, and 95% confidence intervals were estimated as appropriate. To estimate validity of the spot testing kit, sensitivity and specificity were calculated. The agreement was assessed using Kappa statistic.

5. RESULTS

The results of the study are presented separately for single and multiple observers.

5.1. Single Observer (Delhi Data)

A total of 1258 salt samples were collected from schools of Delhi and tested both by titration and by kit (Table - 1). The proportion of salt samples with iodine $\geq$ 15 ppm were similar by both the methods (63.6% by kit and 64.4% by titration). However, most of the samples found to have 0 ppm by the kit had some iodine in them. The sensitivity (ability to correctly identify salts with adequate iodine content) and specificity (ability to correctly identify salts with inadequate iodine content) of the kit to detect adequately iodised salt was high (Table - 3). The agreement, in classification as adequate and

Table 1.
Single Observer data: Comparison of iodine content of salt between spot testing kit and iodometric titration (Delhi data - 1996)

Kit (PPM of Iodine)	Titration (PPM of Iodine)			Total
	0	0.1 to 14.9	≥ 15	
0	6	287	27	320 (25.4%)
7	0	111	27	138 (11.0%)
15 & 30	0	43	757	800 (63.6%)
Total	6 (0.5%)	441 (35.1%)	811 (64.4%)	1258

inadequately iodised, between the two method was 92.3% with a kappa value of 0.83 (SE; 0.028).

5.2. Multiple Observers (Madhya Pradesh Data)

A total of 682 salt samples were collected from the retail shops and households in Madhya Pradesh. The kit overestimated iodine content as compared to titration due to the high false positive rate (Table - 2). The proportion of samples classified as iodine level of more than 15 ppm was 83.4% with kit as compared to 69.5% with titration method. As observed in Delhi, most of the samples tested as 0 ppm by the kit had some iodine in them. With multiple observers, the spot testing kit had high sensitivity but poor specificity (40.4%) in detecting adequately iodised salt (Table - 3). The agreement between the two methods in detecting adequateness of iodisation was 77.6% with a kappa of 0.393 (SE;0.035).

Salt samples were also dichotomised as iodine present or absent. The results were similar to above with specificity and agreement decreasing in multiple observers as compared to a single observer. However, there were very few samples in the not iodised category.

6. DISCUSSION

This study analyses the performance of spot testing kits in evaluating the status of salt iodisation in two states of India using single observer and multiple observers. There are two limitations of the study which have to be kept in mind. First is that the data used for analysis was not originally collected for this comparison. However, this has also resulted in avoiding any bias which could have been introduced if the investigators had prior knowledge of the hypothesis. The second limitation is that there were very few samples with no iodine in the study area. However, this is to be expected in any area which has introduced salt iodisation for a certain period of time.

Briefly, the result of the study showed that the use of multiple observers resulted in a sharp decline in the agreement between titration and kit when iodine content was used either as qualitative (adequate/ inadequate) or as a semiquantitative tool (four levels

Table 2.
Multiple observer study: Comparison of iodine content of salt between spot testing kit and iodometric titration (Madhya Pradesh data - 1995)

Kit (PPM of Iodine)	Titration (PPM of Iodine)			Total
	0	0.1 to 14.9	≥ 15	
0	1	38	9	48 (7.1%)
7	2	43	20	65 (9.5%)
15 & 30	4	120	445	569 (83.4%)
Total	7 (1.0%)	201 (29.5%)	474 (69.5%)	682

: 0, 7, 15, 30). The sensitivity of the kit to differentiate adequate and inadequate iodine content of salt, with multiple and single observers was almost similar. However, the false positivity rate was much higher with multiple observers. We have observed that there is an overlap of actual iodine content of salt : sample for the values assessed as 0 ppm, 7 ppm and 15 ppm by the kit. Thus many samples with adequate iodine (15 ppm) may be labelled as inadequate (0 or 7 ppm). This problem is accentuated by the use of multiple observers. Multiple observers simulate the actual field conditions.

For the monitoring of salt iodisation, the objective is to ensure that the community consumes adequately iodised salt. False positivity in the monitoring tool would lead to overestimation of the "actual" situation. This could result in complacency on the part of the programme managers.

In Madhya Pradesh, before the current survey was done, the program managers claimed the availability of adequately iodised salt to be 84.21% on the basis of their internal monitoring system. They had collected and tested over 80,000 salt samples in 42 districts through over 4000 health workers. This was an overestimate of adequately iodised salt availability to the community by over 20%. Because of the high false positivity rate, the program performance was over-rated and resulted in complacency among program managers and field staff. In addition, if tests with unacceptable validity are used for monitoring a public health program, the community as well as program managers may lose faith in the effectiveness of intervention or in the kit. Such results might lead to slackening of efforts to control IDD and consequent persistence of iodine deficiency disorders in the community.

We have presented results of performance of one particular kit which is extensively used in India. However, there are many other kits available and being used worldover.(11) Also, the recommended level of iodisation varies from country to country. The performance of a particular kit at relevant levels of iodisation needs to be assessed for each country separately. Our study emphasizes the need for a full evaluation of the kit using multiple observers before introducing it for monitoring the programme at national level.

Programmatically, salt iodine spot testing kits are very useful. Hence, efforts should be made to improve the currently available kits. Till a valid alternative is

Table 3.
Validity of the spot iodine testing kit when used as a qualitative tool

Indicators	Iodine present Vs Iodine absent		Iodine adequate Vs Iodine inadequate	
	M.O.* data	S.O.@ data (Delhi)	M.O.* data (MP)	S.O.@ data (Delhi)
Sensitivity % (95% CI)	93.0 (90.0 - 95.0)	74.9 (72.4-77.3)	93.9 (91.2-95.8)	93.3 (91.3-94.9)
Specificity % (95% CI)	14.3 (0.3-57.8)	100.0 (54.0-100.0)	40.4 (33.7-47.4)	90.4 (87.2-92.9)
Kappa (S.E.)	0.018 (0.024)	0.028 (0.007)	0.393 (0.035)	0.83 (0.028)

*M.O. - Multiple Observer

@S.O. - Single Observer

available, the titration method should be continued for monitoring iodine content of salt collected from the production site, distribution points (retail shop keepers) and households.

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