Quality Assurance Procedures in Laboratory Monitoring of Iodine Deficiency Disorders and Quality Assurance in Salt Iodization Programme - Experience from India

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'Fact finding is more effective than fault finding - CARL LOTUS BECKER'

1. INTRODUCTION

Most of the countries all over the world has initiated iodine deficiency disorders elimination programmes (IDDEP). It is essential that IDDCP should have on-going continuous monitoring and evaluation programme. ICCIDD/WHO/UNICEF has recently described indicators to be used for monitoring and evaluation of IDDEP (WHO/NUT/94.6). These indicators include clinical and laboratory parameters for which Quality Assurance is a must. This article describes Quality Assurance programme to be followed for laboratory parameters.

Quality Assurance Program is a must for all laboratory procedures. There are two terminologies used Quality Assurance and Quality Control. These terms are not strictly interchangeable as they have different definitions which are given below:

2. QUALITY ASSURANCE

Definition: A proactive and continuous process of monitoring a system for reproducibility and reliability by -

1) Setting standards of performance and designating possibility
2) Defining corrective actions taken when criteria are not met.
3) Performing measurements within a stated level of confidence.

3. QUALITY CONTROL

Definition: An indicator system for documented performance and actions.

1) Provides a record of consistency of performance.
2) Records actions taken when performance fails to meet the standard.
3) Uses a non-blinded system with potential for bias.

There are two types of Quality Assurance/Control

1) Internal Quality Assessment
2) External Quality Assessment

WHO/UNICEF/ICCIDD has identified the indicators for monitoring the progress of IDD control programmes. These include laboratory parameters like-

1) Iodine content of salt at production and household levels
2) Urinary iodine levels
3) Neonatal TSH.

For the first two parameters i.e. iodine content of salt and urinary iodine levels, the Quality Assurance programmes is on similar levels. Neonatal TSH is carried out by ligand binding assays, the procedure to be followed varies from other two parameters. Recent studies indicate that in developing countries Neonatal TSH screening is not feasible. Hence the quality assurance assessment for neonatal TSH is not described.

4. INTERNAL QUALITY ASSURANCE PROGRAMME FOR URINARY IODINE AND IODINE CONTENT OF SALT.

4.1. General Principles/Guidelines:

1) To run one sample with known value with every batch of test sample analysis. Usually one known value sample should be analysed with a batch of 25 to 30 unknown samples.

2) Known value sample can be obtained commercially or can be prepared in the laboratory.
3) For urine iodide estimation, known value samples are not available commercially.
4) Known value samples can be prepared in the laboratory.

Preparation of known value samples for urinary iodine estimation:

1) Pooled urine samples from the samples received in the routine lab. analysis or collect from one individual (250 ml.)
2) Analyse iodine in the pooled samples by the method to be used by all participating laboratories for 25 times.
3) Calculate: mean ± 2 S.D.
4) Divide the pooled sample in small aliquot of one ml.
5) Preserve in cold (4 C to 8 C.)
6) Take out one aliquot every time for internal quality assessment.
7) After using this aliquot is discarded
8) Aliquots are stable at this temperature for six months.

5. Procedure for Internal Quality Assessment

1) By running the known value sample along with every batch of test sample analysis (A batch of 25 to 30 unknown samples)

2) Draw levy - Jenning plot.

+ 2 S.D.
+ 1 S.D.
Mean
- 1 S.D.
- 2 S.D.

3) If the value falls within ± 2 S.D. of Mean

- indicates consistency of the method

- reagents quality

- performers ability

4) If the value falls outside ± 2 S.D.

- Check stored aliquots for internal quality
- Check reagents for contamination
- Pipetting error
- Any other

6. EXTERNAL QUALITY ASSESSMENT

6.1. General Principles/Guidelines:

1) Analysis of samples with unknown value supplied by reference laboratory.
2) Once in two or four weeks
3) To be analysed along with test sample analysis.
4) No special treatment or precaution for this sample.
5) Send the value obtained to reference laboratory along with internal quality assessment chart (Levy Jenning plot)

7. QUALITY ASSURANCE FOR IODINE CONTENT OF SALT BY TITRIMETRIC METHOD

The similar quality assurance programme can be run for iodine content of salt by titrimetric method.

7.1. Internal quality assurance

1) Analyse 20-25 times one sample of iodised salt
2) Find Mean + S.D.
3) Store the samples in small aliquots of 10 gm in plastic bag in non-humid condition.
4) Analyse on aliquot of this everytime along with batch of 25-30 unknown samples.
5) Levy Jenning Plot for internal assessment should be maintained.

7.2. External quality assurance

1) Analysis of samples with unknown value supplied by reference laboratory.
2) Once in two or four weeks
3) To be analysed along with test sample analysis.
4) No special treatment or precaution for this sample.
5) Send the value obtained to reference laboratory along with internal quality assessment chart (Levy Jenning plot)

8. SETTING OF REFERENCE LABORATORY

- To be recognised by participating laboratories.
- One for each zone / area depending on the number of participating laboratories.

8.1. Functions of Reference Laboratory:

- Prepare samples periodically on the same line as internal quality assessment (Mean + 2 D.D.)
- Send one sample to each participating laboratory.
- Send the computed chart to each participating lab. once a month.
- Training of Laboratory staff at periodic interval
- Providing quality reagents
- Providing external quality assessment samples which are prepared fresh every time.
- Analyse certain number of samples from each participating lab. on regular basis.
- Coordination of all laboratories.

For the past two years, ICCIDD South East Asian regional laboratory situated at AIIMS New Delhi. India has been maintaining quality assessment programme for few private salt producers in India for their product iodised salt. In addition ICCIDD is involved in monitoring iodine content of salt collects from retailers all over the country and at house hold level in Delhi.

The quality Assurance for iodised salt at production site

ICCIDD helped the private salt manufacters to establish a laboratory at each production site with in built internal quality assurance programme. The production site laboratory analyses iodine content of salt using titrimetric method every half an hour or, In some cases at least 3 or 4 times a day. During the day, these laboratoris also analyse a known value sample and maintain Levy Jenning plot. The details of obtaining known value sample and Levy Jenning plot are given above.

In addition the laboratories at production site send in a month six salt samples to ICCIDD Laboratory at New Delhi. These samples are randomly selected from production site on different days and analysed induplicate by the laboratory at production site. The ICCIDD Lab analyses these samples in duplicate by titrimetric method and the results are exchanged.

The ICCIDD laboratory at New Delhi purchases six iodised salt samples from the market of different brands. Each sample is analysed six times for iodine by titrimetric method. The mean and S.D. of each sample is calculated. Fifty grams of these salt samples labelled as salt sample 1 to 6 of each month are sent to laboratories at production site. These laboratories analyse these samples in duplicate and the results are exchanged.

Thus a strict quality assurance is maintained at production sites to maintain the adequate level of iodine in the salt samples. In case of deficiencies. The corrective action is taken immediately.

Monitoring of iodised salt at retailers level

India has a vast network of Non-Governmental Organisations (NGO). These NGO's have excellent track record as a creditable and committed partners for providing health and developmental inputs. There is also a nationwide presence of Bharat Scouts and Sports - The Indian Chapter of International Scouts & Guides. With the help or these two channels we collected a total of 875 iodised salt samples over the period of one year from different parts of India. These samples were collected from retailers. Out of 875 samples analysed by titrimetric method 60% of the samples had iodine content of more than 15 ppm.

Monitoring of iodine content of household

The salt samples were collected from students of different schools situated in New Delhi. Initially the contact was made through the principals of the schools and on one appointed day children from each school was asked to bring salt samples from their house holds. Each sample was analysed by kit method in the school and representative samples were brought to ICCIDD Laboratory to analyse iodine content by titrimetric method. A total 1712 samples were analysed by kit method and 1475 samples were analysed by titrimetric method. About 96% of the salt samples shewed iodine content to be more than 15 ppm.

"QUALITY ASSURANCE IS NOT A FAULT FINDING MISSION BUT A METHOD TO ENSURE QUALITY RESULTS FROM EACH LABORATORY."