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DEVELOPMENT OF AN IDD CONTROL PROGRAM MONITORING AND EVALUATION SYSTEM FOR PAKISTAN

OVERVIEW OF SYSTEM & GUIDELINES

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Development of an IDD Control Program Monitoring and Evaluation System in Pakistan

OVERVIEW OF IDD CONTROL PROGRAM MONITORING AND EVALUATION

The IDD monitoring and evaluation system will include two distinct activities, including 1) program performance and 2) program evaluation. The first of these activities will provide ongoing, continuous information on the process of the salt iodization program, while the second, program evaluation, will allow for an overall assessment of the impact of the program on iodine status, and the magnitude of IDD. These two sets of activities will require different approaches to sampling design, data collection and frequency. Still, taken together, these two activities will provide complementary information necessary to ensure that the IDD control program is as effective as possible. Indeed, the system will aim to identify constraints in the delivery of program activities and provide timely reporting of this information to ensure that corrective action is taken rapidly.

It is proposed to develop a prototype framework of the monitoring system for the Northwest Frontier Province (NWFP) which can be implemented in the next three months. Based on observations of the monitoring activities from this pilot testing, adjustments and modifications may be made, and then the system may be adapted and extended to other areas of the country. The evaluation component may be pilot tested during the same period, if resources permit.

The system is developed to provide principle information at the District level which will then be summarized for Provincial and National reporting requirements. Thus, an important consideration in the success of the system will be the capacity of District level workers to gather (assess), analyze and act upon the information. The system proposed is simple, accessible and will not require a great deal of resources, in terms of manpower, funding and time. In this way, the monitoring system will complement the implementation of program activities and provide the minimal data necessary to continue programmatic efforts to achieve maximum performance and impact.

It is important to emphasize that salt iodization, by its nature, is an activity which engages several sectors, including health, education and industry (food). Therefore, the IDD control program monitoring system should be done as a collaborative venture between industry, health and education sectors. It is proposed that a workshop be held at the Province level and at the District

level to facilitate this collaboration, and to describe the components of the IDD control program monitoring system.

This system calls for the development of a Provincial Salt 'Commissioner' position to be appointed by the Director General of the Ministry of Foods. The role of this Salt Commissioner will be to oversee all aspects of the iodized salt programme, including the availability of iodized salt and its quality for the province as a whole. This person would be responsible to ensure that all aspects of the monitoring system are executed and, in collaboration with the Director General of the Health Directorate, to take prompt actions in response to the information collected.

The indicators to be included in the monitoring and evaluation system are detailed in Table 1.

TABLE 1

INDICATORS FOR IDD CONTROL PROGRAM MONITORING & EVALUATION SYSTEM

No.	Indicator	Target	Frequency of Data Collection
	PROGRAM PERFORMANCE (PROCESS)		
Salt Processor/Wholesaler			
P1	% of all salt processed claimed to be iodized	100 %	Monthly
P2	% of salt processed which is adequately iodized	90 %	Monthly
P3	% of processors/wholesalers with ≥ 10 external monthly checks per year	100 %	Annual
Retail			
P4	% of Markets in Tehsil where > 90% salt is refined	100 %	Quarterly
P5	% of Markets in Tehsil where > 90% salt is iodized	100 %	Quarterly
Consumption			
P6	% of Union Councils where > 90% of salt consumed is adequately iodized	100 %	Quarterly
	PROGRAM EVALUATION (IMPACT)		
E1	Prevalence of Total Goiter Rate in Schoolchildren	< 5 %	Every 2 years
E2	Median Urinary Iodine	> 10 µg/dl	Every 2 years
E3	Percent of salt consumed which is adequately iodized	90 %	Every 2 years

The proposed system suggests that the Food sector be responsible for those activities involved with the primary collection of monitoring data. Information will be reported to the health sector, who will then have the responsibility to act upon the data. In this way, the normal mandated activities and functions of these governmental agencies may be realized. Where the capabilities of these sectors are not able to carry out the specified functions, then it will be necessary to strengthen them through further training and skill development. The importance of the IDD control program will need to be emphasized in such training's and the roles played by the different groups will need to be highlighted and placed into a broad planning context, where each group is made to understand the place and function of other sectors.

1. Program Performance and Process

1.A. Program performance - Salt production and degree of iodization

This activity will evaluate the availability and adequacy of iodized salt at different stages of distribution from production to consumption and will include mechanisms to ensure that timely corrective action take place where constraints are identified. Figure 1 below outlines the four levels at which salt monitoring needs to take place, and characteristics of the salt flows which need to be routinely monitored.

Consideration of each of these distribution points is critical in ensuring that the salt supply reaches consumers with iodine concentration levels which will provide the required dietary levels to prevent IDD. There are two issues: first, one of the availability of iodized salt, and the second, the adequacy of iodized salt. Both are critical, and obviously to measure quality, it is first necessary to ensure that iodized salt is being processed and that it is available at different distribution points, including retail markets and households.

One may note that there is an important distinction between the terms **'production'**, which will be taken in this document to correspond with 'salt mining', and **'processing'**, which is the process of crushing, milling and refining crude rock salt into small crystals for distribution to retailers. Because all iodine salt is packaged at the point of crushing (processing) in small packages (under 1 kg.), there is only marginal degradation associated with transport and storage.

Figure 1

Salt Distribution Program Characteristics

Production

- Total rock salt production figures
- Transport and availability to processors

Processors

- Total crushed salt, refined salt production
- Proportion of salt iodized
- Internal & external salt quality control
- Storage, transport practices
- Prices

Retail - Markets

- Salt quality control
- Retail practices, i.e., packaging, frequency, quantity
- Storage
- Price: iodized vs. uniodized, rock vs. crushed vs. refined
- Awareness levels among shopkeepers

Consumption - Households, Schools, etc.

- Salt quality control
- Consumption patterns
- Awareness, knowledge, economic rationale

A monitoring system is proposed which assesses iodized salt availability and quality at the point of processing and consumption, and which evaluates market patterns of availability and procurement. Through these functions, it will be possible to determine if the program is progressing well and reaching those at greatest risk of IDD, as well as the general population. Where inadequacies are identified, rapid responses should be made. The following section describes in greater detail the specific monitoring activities, including sampling requirements, field responsibilities and data collection instruments.

Production Level - Register of Salt Production at Province Level

Overview

The first step in addressing the salt iodization activities in NWFP is to gain an overall understanding of raw salt production and distribution statistics. Since all salt mines in the country are under the authority of the Federal Government (Directorate of Industries and Mineral Development) and are regulated by each Provincial Government, it is possible to establish such a chart of salt flows. This activity should be undertaken ***a single time*** by the Province salt Commissioner so that it is clear from where the salt entering the Province originates.

Data Collection

The flows should detail all sources of salt which are available in NWFP, including those from the public sector (primarily Pakistan Mineral Development Corporation (PMDC), Punjab Mineral Development Corporation, and Sarhad Mineral Limited)), as well as those originating from the private sector. There are presently 5 private organizations in NWFP involved in mining, although salt does come to NWFP from the Punjab where there are more private sources of salt. Such information has recently been compiled by Zaidi[1] and UNICEF[2] and will need to be updated as other groups become engaged in salt production. Rock salt is the primary source of all salt in NWFP, and therefore no information on sea/lake salt is necessary for this province (it will be important for Sind).

The salt production register should provide information concerning salt production (mining) statistics, type(s) of rock salt produced, price (per metric tonne) and distribution (to processors). The register should maintain the average production data for all mines providing salt to the Districts of NWFP, regardless of whether they are located in NWFP or not. The data could be gathered by the Provincial Salt Commissioner through solicitation of information from the producers. Form 1 provides an overview of the information to be maintained in a salt production register.

FORM 1

REGISTER FORM FOR MONTHLY SALT PRODUCTION

Name of salt producer (mines)	Location	Type [a]	Production Statistics (metric tonnes)	Price (per mt)	Distribution	
			Total Monthly		Location(s) [b]	Quantity (mt)
		A1, A B C				

[a] Type of rock salt: A1, A = White, transparent, B = Whitish, pink, C = Reddish, white small pebbles

[b] Location (Processors or wholesalers located in NWFP - by District)

1 Zaidi, Zaheer Haider (Utility Stores Zonal Manager - Central). A Study for the Initial Planning of National Strategy for Universal Iodized Salt Utilization for Total Eradication for Iodine Deficiency Disorders (IDD) from Pakistan by the Year 2000. January, 1994.

2 UNICEF Iodized Salt Support Facility. IDD Elimination Report and Salt Production Statistics, 2/94-4/94.

The data included in this form would only be for salt which is being distributed to processors, wholesalers or directly to retail stores located in NWFP. Thus, it will be possible to determine the amount of salt coming from different mines to those processors and wholesalers responsible for the distribution of salt to each District in NWFP. In this way, the total amount of rock salt available for iodization may be ascertained.

Processors - Register of Salt Crushing/Iodization statistics

Overview

Salt which is produced in the mines is sold uncrushed in rock form to processors, who in turn crush, grind and package the salt for distribution to retailers or wholesalers. A small amount of salt is sold wholesale to retailers in rock form (approximately 10%) which is then crushed locally or sold as solid blocks. Thus, the processors are the agents responsible for salt iodization.

There are several hundred processors located throughout NWFP. Many processors have already procured iodization units which use a simple mixing technology, and others have agreed to do so. To facilitate the conversion of processing plants to universal iodization, two alternative modular iodizing units (MIU) have been proposed, each operating at different capacity levels (MIU I for 2000-4000 tonnes per year (tpy) and MIU II for more than 4000 tpy). In the World Bank Nutrition Project Proposal, it is suggested that 260 MIU's would be sufficient to produce all the iodized necessary to meet the requirements nationwide. In addition to the salt processors, there are wholesale agents in NWFP who import crushed salt from outside of NWFP for sale to retailers. It is important to monitor the amount of iodized salt available from the wholesalers, and to gauge what proportion of salt from these sources is iodized.

Data collection

A monthly logbook of all salt processed and available within each District of NWFP should be maintained. For salt processors, this would include information regarding the source of salt, total salt processed, total salt (claimed to be) iodated, distribution channels. In addition to the processors, all salt wholesalers (if applicable) in each District should maintain a simple logbook which details the amount of salt imported to the District, its source, proportion iodized and distribution.

It is proposed that the logo being developed for iodized salt packages be provided to all processors who have been certified as 'provided good quality iodized salt'. The certification process should be dependent upon a number of conditions, one of which is the maintenance of the production logbook. The Province Salt Commissioner would grant use of the logo for all processors in the Province upon confirmation that the various conditions have been met for certification. Distinct criteria will be established for wholesalers, if they are to use their own packaging, and request the logo.

These data would be solicited from the salt processors and wholesalers, and sent to the District Food Controller using a standard form (as in Form 2 below).

FORM 2

MONTHLY SALT PROCESSED / IMPORTED FOR EACH PROCESSOR AND WHOLESALER

Name of Processor (Wholesaler) _____

Location _____

Source(s) of salt [a] _____

[a] Source (Production mine, location)

Total Salt Processed (or Imported) (percentage)	
Iodated	Uniodated

Distribution		
Location [a]	Percent iodated	Percent uniodated
1.		
2.		
3.		

[a] Distribution locations (Tehsils/Union Councils)

Note: It may not be necessary to include information on the percentages of salt distributed to the different Tehsils and Union Councils, but rather just to detail where the salt is distributed.

The data from the individual processors and wholesalers could be summarized by the District Food Controller who would calculate overall monthly results. These data could be used to report the first program performance indicator at the District level:

INDICATOR P1 - PERCENT OF ALL SALT AVAILABLE CLAIMED TO BE IODIZED

From the information on the availability of iodized salt, it will be possible to gain some impression of the general performance of the IDD control program. However, as legislation is enacted which requires iodization of all salt, it will be critical to supplement reported data on the proportion of all salt which is claimed to be iodized with information on the adequacy of the iodine concentration levels at the point of processing. This may be done through a combination of internal and external monitoring activities, which will be the responsibility of both the processors themselves (internal), and the food sector (external).

1.B. Program performance - Availability and adequacy of iodized salt

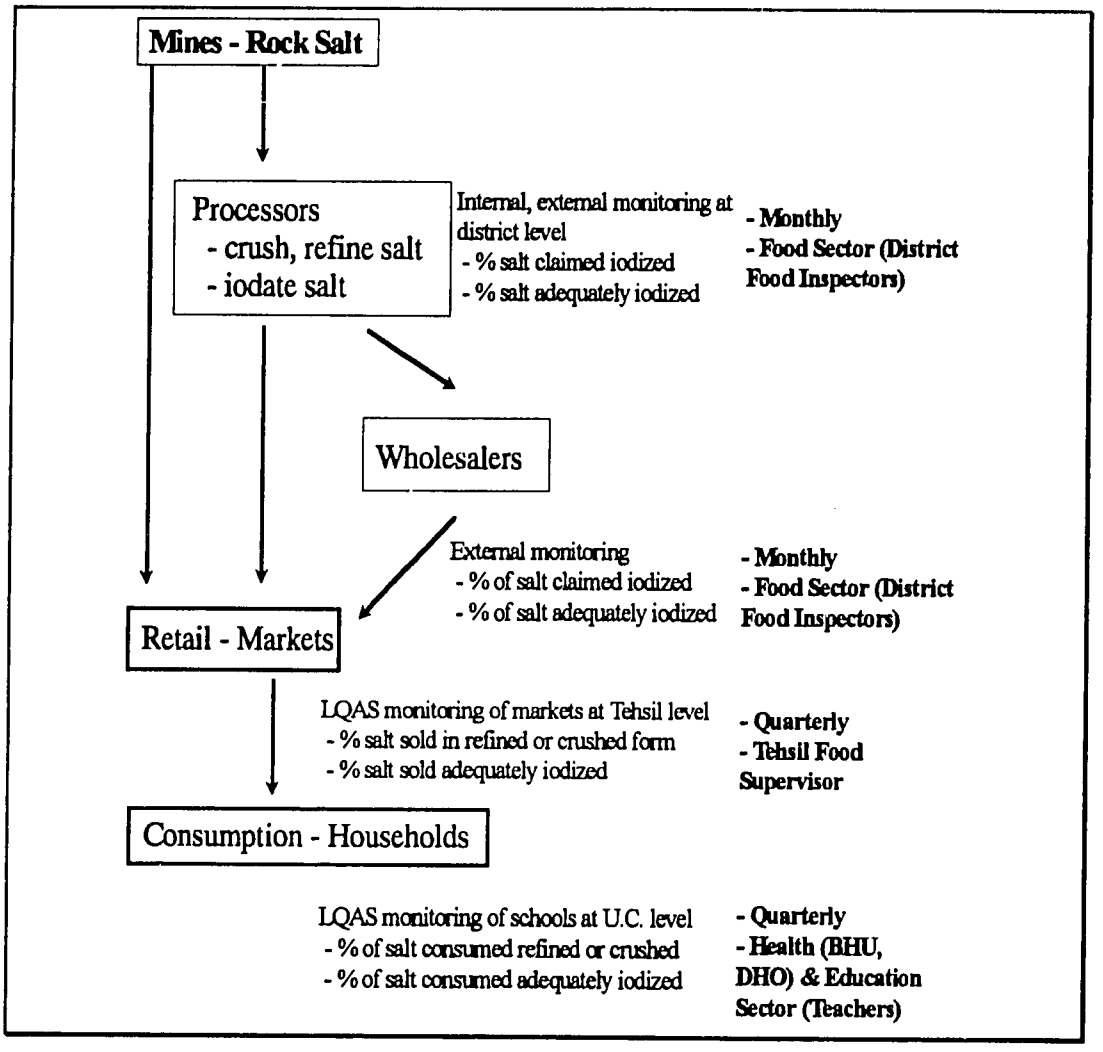
Overview

To complement the salt flow information maintained through forms 1 and 2, a set of operational guidelines for an ongoing monitoring of salt iodine levels at different points of distribution including; processing, retail and consumption, are proposed. Although the timing, frequency and procedures required for the salt quality control at each of these points will differ, it will be essential that these activities are well coordinated and the generation of results and information from each distribution point be linked. It is important to emphasize that the ultimate objectives of this activity are to monitor the availability of iodized salt and to verify that adequate concentrations of iodine are attained in salt, primarily at the point of consumption. If the availability of iodized salt or the concentration of iodine is found to be inadequate at the consumer level, the salt at higher points of the distribution system are to be verified, as detailed below (see Section 1.B.iv.), to determine the distribution point at which losses or program constraints are occurring. Over time, as the situation improves in certain areas, it should be possible to modify the monitoring protocol, so the data may be collected less frequently to ensure that iodized salt remains available and is adequately iodized.

For each of the salt distribution points, different indicators are required, and as the program progresses, modification of targets set for the respective indicators may be necessary. The following section outlines a proposed approach for salt monitoring at the point of iodination which will include both internal (salt processors) and external (GOP) monitoring activities. Figure 2 provides an overview of the salt distribution points to be monitored, along with the indicators, frequency of data collection, and the groups designated to be responsible for the monitoring activities.

Figure 2

Overview of Salt Distribution Points in Monitoring System



1.B. i. Monitoring salt iodine levels at point of processing - Internal

Overview

The routine monitoring of salt iodine levels during processing is the responsibility of the processor and is essentially a quality control issue which assists in verifying that the iodization of salt meets required standards. Indeed once legislation is enacted, each salt processor should iodize all salt at a concentration of at least 50 ppm, and the internal monitoring activity will help facilitate this process.

Data collection

It is recommended that an individual within the processing plant be entrusted with the responsibility of undertaking hourly monitoring of iodine levels in salt using rapid test kits, which provide information of the salt iodine concentration. The interval of one hour is selected so that a constant monitoring on salt iodization may take place, and any variation in the salt processing may be detected and responded to rapidly. While efforts have been taken to standardize iodization at a rate of 50 ppm, such internal monitoring will ensure that the process continues unhampered. The interval and frequency of internal monitoring may be modified as the adequacy of iodized salt processing is found to be sufficient over a sustained period of time.

Each factory should be provided with rapid test kits which can distinguish iodine levels of 30, 50 and 80 ppm.[3] These are used to determine whether the recommended level of 50 ppm is being reached or surpassed, so that corrective action can be taken to guarantee consistent salt iodine levels.

The information gathered from this internal monitoring should be recorded in a logbook register, which should detail the date, time of testing, batch number and the observed iodine concentration. Furthermore, the log should provide a section for notes to comment on what modifications were made to correct the iodization mixing method in those cases where the iodine concentration was too low (< 30 ppm) or too high (> 70 ppm). An example is provided below:

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3 Please note that the MBI chemical test kits are only discriminating of salt iodine levels at each of four intervals, 0, 7, 15 and > 30 ppm. These are inadequate for the internal quality control programme. The level of iodization stipulated as being necessary in Pakistan is 50 ppm. Therefore, it is necessary to procure a different set of rapid testing kits which are sensitive and discriminating of iodine concentration levels above 30 ppm. For example, Bangladesh has developed a filter paper technology which detects the presence of KIO_3 at levels of 30, 50 and 80 ppm iodine.

The base kit of filter paper is sufficient for 500 checks, or 2 months (assumes 8 checks per day over 60 days) which includes a case, plastic bottles, solutions and iodine-sensitive filter papers (cost = $ 25 or Rs.750). For subsequent supplies, only the acid solution and iodine-sensitive filter papers are necessary (cost = $5, Rs. 150 / 500 tests). Thus, it is possible to provide each processor with the materials required to routinely test salt samples internally on an hourly basis at a cost of $ 50, or Rs. 1500/year.

Date	Time	Batch Number[a]	Iodine level[b]	Notes
June 1	8:00 am	125	2	
	9:00 am	129	3	
	10:00 am	133	3	
	11:00 am	137	2	
	12:00 am	141	1	Added 10 g more KIO_3
	13:00 am	144	3	
	14.00 am	148	3	
	15:00 am	152	3	
	16:00 am	156	4	Added 10 kg. more refined salt
	17:00 am	160	3	

a Batch numbers - assume 4 batches per hour, with 12-15 minute dry mixing time per batch

b Iodine level (based on Bangladesh kits, e.g. 1 = < 30, 2 = 30-50, 3 = 50-80, 4 = > 80)

Analysis and Response

The daily summary could then be calculated (assuming 100 kg per batch) and recorded in a separate book, as:

Date	Number of batches produced	Total iodized salt produced (mt)	Number of recordings	Number < 30 ppm	Number > 80 ppm
June 1	40	4.0	10	1	1
June 2	45	4.5	11	0	1
June 3	38	3.8	9	1	1

For the internal monitoring of salt iodine levels at the processor, it is recommended that a series of clear guidelines be developed from which it will be possible for the processors themselves to take corrective action in cases where inadequate salt iodine concentrations are detected. For example, how much KIO_3 should be added to the 100 kg. of salt mixing when a level of < 30 ppm is detected, or how much salt should be added if a level of > 80 ppm is observed during the internal monitoring process.

The data from the register reviewed by the District food inspectors on a monthly basis, who will then summarize the information, as in Form 3. Perhaps the food inspector can review the logbook when visiting for the external monitoring activity, and provide positive reinforcement where records have been kept well, and support those processors where there are deficiencies in the logging procedures. In this way, the quality assurance function (external monitoring) may serve to confirm the quality control activity (internal).

FORM 3

MONTHLY SUMMARY OF DAILY SALT IODIZATION - PROCESSOR LEVEL (INTERNAL)

Name of Processor _____

Location _____

Total salt produced (MT) _____

Total iodized salt produced (MT) _____

Total number of internal monitoring checks (recordings) ? _____

Number of recordings < 30 ppm ? _____

Number of recordings > 70 ppm ? _____

1.B. ii. Monitoring salt iodine levels at processors (and importers) - external

Overview

To supplement the process of internal monitoring, there should be random, unannounced checks of each salt processor and importer once a month to collect salt samples which will be transported to an appropriate laboratory at the Province level for analysis by titration[4]. According to the World Bank proposal, a series of standardized nutrition and food quality laboratories will be strengthened throughout the country and could be standardized to conduct titration, and perhaps also analyze iodine concentration in urine samples (see section on evaluation). At the present time, a nutrition laboratory exists in Peshawar and could serve this function for NWFP. The District Food Controller (DFC), or other designated official (NGO ?), should be responsible for developing a schedule to collect random salt samples from every processor (and importer) at least once a month and send these to laboratories for testing by titration to determine the precise level of iodine in salt.

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4 Standard titration methods are conducted in biochemical laboratories where the iodine is liberated with sulphuric acid. The free iodine is then titrated using sodium thiosulphate, and starch is used as an indicator. The technique to be used will detect the presence of potassium iodate and will provide precise results which are sensitive to 0.1 ppm. For purposes of national monitoring, standardization of all laboratories to be used in this system will be executed to ensure that consistent results are generated.

Data collection

The samples may be collected by the District Food Inspector. In cases where more than one brand of salt is being processed or imported, then individual samples of all brands should be collected and analyzed. The salt samples should be clearly identified, dated and sealed in moisture-free envelopes which will limit any possible degradation for transport.

Analysis and Response

Following laboratory determination, these data should be recorded and maintained by the District food controller, eventually entering them into computerized database files. Results of the external monitoring should be generated on a monthly basis, providing information as to the proportion of all salt samples (1 per brand) which reached standard iodine levels (> 50 ppm), as well as more detailed descriptive statistical analysis documenting the distribution of the salt iodine levels observed in the processors and the importers. These data could be summarized and then sent to the Provincial and Federal industry and health authorities, also on a monthly basis. It is critical to identify appropriate mechanisms to take action when the external monitoring results differ from the internal monitoring data being reported.

The results from the external monitoring should be printed as a one-page newsletter by the Provincial Salt Commissioner and distributed to all salt producers, DHO's, educators Province, Federal authorities, multilateral agencies and others involved in the National IDD control programme. Furthermore, a quarterly update will also be prepared which summarizes the laboratory results and the monthly internal monitoring data provided by the processors to provide an impression of the adequacy and changes in salt iodine levels at the point of processing. These quarterly reports could also include any supplementary information generated from market or consumption surveys. The proposed IDD Newsletter in NWFP may be an appropriate vehicle through which to disseminate the information and track progress over time. The data from these reports may be used to generate the program performance indicator # 2 on a monthly basis, and program performance indicator # 3 on an annual basis.

INDICATOR P2 **PERCENT OF SALT PROCESSED WHICH IS ADEQUATELY IODIZED**

INDICATOR P3 **PERCENT OF PROCESSORS WITH ≥ 10 EXTERNAL MONTHLY CHECKS**

1.B. iii. Monitoring salt iodine availability and adequacy - retail market

Overview

As the salt monitoring system is established, the availability of iodized salt and of the adequacy of salt iodine concentrations should be assessed at the point of retail. This is especially important in those areas where transportation results in a long time lag between processing and consumption, or where stocks of salt are maintained and not constantly replenished. It is recommended that every three months, the DHO, or some other District level health or nutrition worker, should coordinate a market survey which will include information on the availability and sale of iodized salt, relative to other types of salt. This ongoing retail monitoring should be supplemented by a less frequent survey of markets which should collect information on prices, awareness of retailers concerning the importance of iodized salt, etc. and will be conducted in conjunction with the IDD evaluation (see Section 2).

Concept of Lot Quality Assurance Sampling (LQAS)

For monitoring at the point of retail (and for consumption), it is recommended that conventional survey techniques not be used. It is of greater interest to use alternative sampling techniques to ascertain whether or not the salt supply in several areas is adequate or not. Such approaches, including lot quality assurance sampling (LQAS)[5], determine whether a threshold has been reached or not in a specific geographic or administrative area (regardless of the degree to which the threshold has been surpassed) are more useful for purposes of ongoing salt monitoring. This technique will be described briefly as it will be used for monitoring at retail markets and at the point of consumption.

In the present context, use of LQAS aims to identify areas based on whether a 'threshold' has *not been reached* for some program indicator, e.g., whether less than 75% of retail markets have iodized salt when it is expected that 90% of markets have iodized salt, so that resources may be targeted to those areas to improve program performance. It is important to emphasize that a monitoring system which employs LQAS does not provide information concerning the actual level below the threshold, but rather just that the threshold has not been reached. In this way (using the example above), it is not important the proportion of markets with access to iodized salt is 74.9 %

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5 Lanata, C.F. and Black, R.E. Lot quality assurance sampling techniques in health surveys in developing countries: Advantages and current constraints. *World Health Statistics Quarterly* (1991) 44: 133-139.

or 25 %, but rather that it is known with some degree of confidence that the threshold level of 75 % has not been attained and the area requires further support.

LQAS is efficient in screening many areas with a small number of samples and provide some information on each of these areas as independent 'lots'. It is then possible to identify those populations at greatest risk, and to focus resources on improving the implementation of salt iodization activities to those areas. A primary advantage of LQAS is that it requires a comparatively smaller number of samples to be collected than more robust survey sample designs, and once developed, an LQAS scheme may be used for multiple indicators. Thus, it may be possible to gain information on different aspects of the iodized salt activity other than the adequacy or availability of iodized salt by employing the same LQAS sample frame. It is important to recognize that LQAS is appropriate to monitor programmes such as salt iodization in areas which are going to be measured repeatedly to assess progress, and is not as useful for single community-level surveys. Rather, for less frequent surveys, alternative sampling approaches should be used which provide more precise prevalence estimates (See Section 2).

Precision and Threshold

One of the important requirements of the LQAS approach is the specification of an upper (P_0) and lower (P_a) limit of programme performance, and serves as the basis for calculating the number of monitoring samples to be collected. These two limits should be based on some understanding of the anticipated rates of different indicators (P_a), from which an upper limit of inadequate performance is set (threshold) where, if surpassed, it is deemed imperative to intervene and provide further programmatic inputs.

In addition to these two limits, there are two statistical considerations which need to be discussed briefly in order to determine the sample size requirements for a LQAS design.

α - Statistical significance of the test. This is the ability of the test to avoid a type-I error (identify a community as not having a problem when in fact it does have a problem). This level should be set as low as necessary to limit the probability of failing to identify an area with low levels of iodized salt in markets. Most commonly, this is set to 5% (0.05), but in extreme cases, it may be of interest to set the α to 1 % (0.01) where it is essential to identify all groups which are truly at risk.

β - Power of the test. The power determines the level where type-II errors are made, where areas are identified as having a poor market supply of iodized salt when in fact they do not have a problem. The power can be set somewhat less rigid, as this type of error is not as serious, i.e. if an area is falsely identified as having inadequate access to iodized salt, then resources would be focused there when they may not be necessary. While inefficient, it is less critical than a type-I error where areas which require intervention are not identified. For the LQAS design for monitoring, the β should be set to 80% in almost all cases, although it may be desirable to establish the β at 90% where certain information is critical and where programming resources are limited. Thus, it is of importance to ensure that activities are aimed towards those Tehsils that have low access rather than targeting Tehsils not really at-risk.

Annex 1 provides a series of threshold limits and sample size requirements which may be considered for the monitoring of retail markets. It is proposed to use different indicators and to set distinct threshold limits for the retail market monitoring based on the progression of the program. For example, in the early stages of monitoring, it may be more important to identify those areas where the proportion of refined salt sold in markets is low. Later, as refined iodized salt penetrates the markets, the focus could be to detect areas where the iodine concentration in the salt does not meet standards levels. Similarly, the threshold points used for these indicators may vary as well. Initially, the objective of the monitoring may be to identify areas where less than 50% of the retail salt is adequately iodized. Then, as areas improve and iodized salt becomes more widespread, the threshold could be modified to take action in those areas where only 75% of the salt is found to be adequately iodized (when it is expected that 90% of the market samples will be adequate). In this way, monitoring may ensure that areas are identified which require further programmatic support at different stages of program development.

In the next section which describes the steps for the data collection, the indicator to be used is the proportion of markets which sell no salt in rock form. The expected level of performance is 90%, which is to say, at least 90% of the markets sell no rock salt at all. The threshold level used for targeting program support will be those Union Councils (U.C.) where less than 75% of the markets sell exclusively refined salt (or more than 25% of the stalls still sell salt in rock form). With these parameters, 42 market stalls will be visited, and a threshold will be reached if 5 stalls (samples) are found to have any rock salt. The same procedures will be followed for different indicators, and different threshold levels, with only the number of markets to sample changing.

Annex 2 suggests a proposed schedule and time frame for the use of alternative indicators and threshold points for the market monitoring. The indicators to be used, and the corresponding threshold levels for the different parameters of program performance should be determined at the District level through collaborative meetings between the District Food Controller and District health officials (DHO, medical superintendent). It may be useful to form a small Committee of these individuals and others who would be involved with the IDD control program, including IDD coordinators, industry representatives (salt processors), educators, etc. who could determine the specific monitoring requirements.

Administrative level

The use of LQAS to monitor salt in retail markets should be done to provide meaningful information from which action may be taken. Ultimately, the area for which data are collected should be considered with the following four points in mind:

a) The nature of the responses which may be taken from the information,
b) The expected variation in salt supply within areas,
c) Resources available for data collection, processing and reporting, and
d) Existence of infrastructure used for monitoring of other health programmes or activities

There are four administrative levels in NWFP for which representative information may be considered relevant, including the District, subdivision (Tehsil), Union Council, and village. It should be borne in mind that monitoring at any of these levels will require separate sampling and reporting frames, and in turn, as the level of interest moves to smaller administrative areas, the resources and logistics required will increase proportionally.

The District is the largest administrative region, where the Government maintains a considerable cadre of health and industry personnel. However, it may be that by designating the District as the administrative level for which representative information is gathered, disparities within Districts may not be identified, and therefore could constrain the ability to target specific population groups within each District who may have the lowest or poorest access to IDD program activities.

While the collection of information in markets from all villages could identify pockets where there is poor access of iodized salt, this is clearly unrealistic and costly. One alternative which is proposed is to identify certain discriminating characteristics of villages at some administrative level, e.g., Union Council or Tehsil, and group together all villages which share common qualities.

From these groupings, select a (subset of) village(s) and designate these for the ongoing monitoring to represent the area as a whole (Sentinel site monitoring). The(se) village(s) will then provide the sample frame for monitoring, and will generate information to determine how well the program is progressing in the area. This approach is only relevant if the selected villages lead to reliable information from which action may be taken and targeted for all other villages in the area.

Once the administrative level for the retail monitoring is decided upon, e.g. Tehsil, the procedure for data collection can be outlined. In the following section, it will be assumed that the market monitoring data will be representative of each Tehsil. The same procedures may be adopted if information is to be collected to represent the entire District by making the necessary adjustments in the selection process.

Data collection

For each Tehsil in the District, characterize villages into two distinct groups based on; urban or rural area, population size and access to paved roads. Develop lists of all villages which fall into each of these two groups, Group I and Group II (if possible include population figures). Randomly select 2 villages from each of these lists. Visit the selected villages and ask what the primary location is the markets used by the villages for all subsistence shopping. In most cases, this will be located not more than a few kilometers away. It will be important to visit a market with at least 20 stalls selling salt and thus local stalls in villages will not prove adequate to satisfy sample requirements.

For all selected villages for Groups I and II, it will be necessary to randomly select a total of 42 market stalls which sell salt. It is suggested that 21 of these are taken from each of the markets associated with the two villages selected for Group I and repeating the process for Group II.

There are several ways in which stalls may be selected within each market area included in the sample, and necessitates some creative balance between cost and precision. What is essential is that a degree of randomness is incorporated into the selection process, and that all market stalls have roughly the same equal probability of being selected. One approach which may be taken is that adopted by EPI coverage surveys. In this, the data enumerators move to a central point of the village for Group I, and then selects a random number between 1 and 4, where each number is associated with a direction, e.g. north, south, west or east.

Once chosen, the team moves in the direction selected, counting the total number of market stalls (which sell at least some salt) until the perimeter of the village is reached. Next, a random number is selected between 1 and the total number counted. The team moves to the stall which corresponds to the chosen number, and then begins the data collection with this first stall, moving to the next closest stall which sells salt, repeating this process until the total number of 21 stalls have been visited and enumerated. For each round of monitoring, a different set of stalls should be selected to limit the possibility that behaviors and stocking patterns will be altered as a consequence of the monitoring and may no longer represent the 'real' situation.

Tehsil Food Supervisors should visit the selected markets., perhaps in collaboration with local village health workers and community health volunteers from the selected village. This team should take a random sample of 21 stalls, repeating this process in the second market. The team would ask each selected shopkeeper if all salt sold in the stall is iodized. If the answer is yes, then the stall would be taken as a positive responder. If the stall sells uniodized salt, then the stall will be a negative response.

Data analysis and response

From the total of 42 samples (from markets for both selected villages), if more than 5 are 'negative responders', then the Tehsil as a whole will be considered to have not yet made available an exclusive supply of refined salt and corrective action should take place. It would be important to ascertain if the problem is one of supply, e.g. processors are not providing crushed salt, or of demand, e.g., consumers do not request the salt so the retailers continue to stock rock salt.

It is important to emphasize that the market monitoring work should be done to educate and empower the retailers. By informing the retailers about the importance of iodized salt, and providing them with rapid testing, they can be important vehicles through which the message of iodized salt could be promoted to consumers. The collection of these data should also provide insight into the overall market dynamics for iodized salt, including its availability, pricing and purchase. It will also lead to the generation of the program performance indicators designated at the retail level:

INDICATOR P4 **% U.C.'S WHERE > 95% OF SALT SOLD IS CLAIMED TO BE IODIZED**

INDICATOR P5 **% U.C.'S WHERE SALT SOLD IS ADEQUATELY IODIZED (> 30 PPM)**

1.B. iv. Monitoring salt iodine levels - consumption

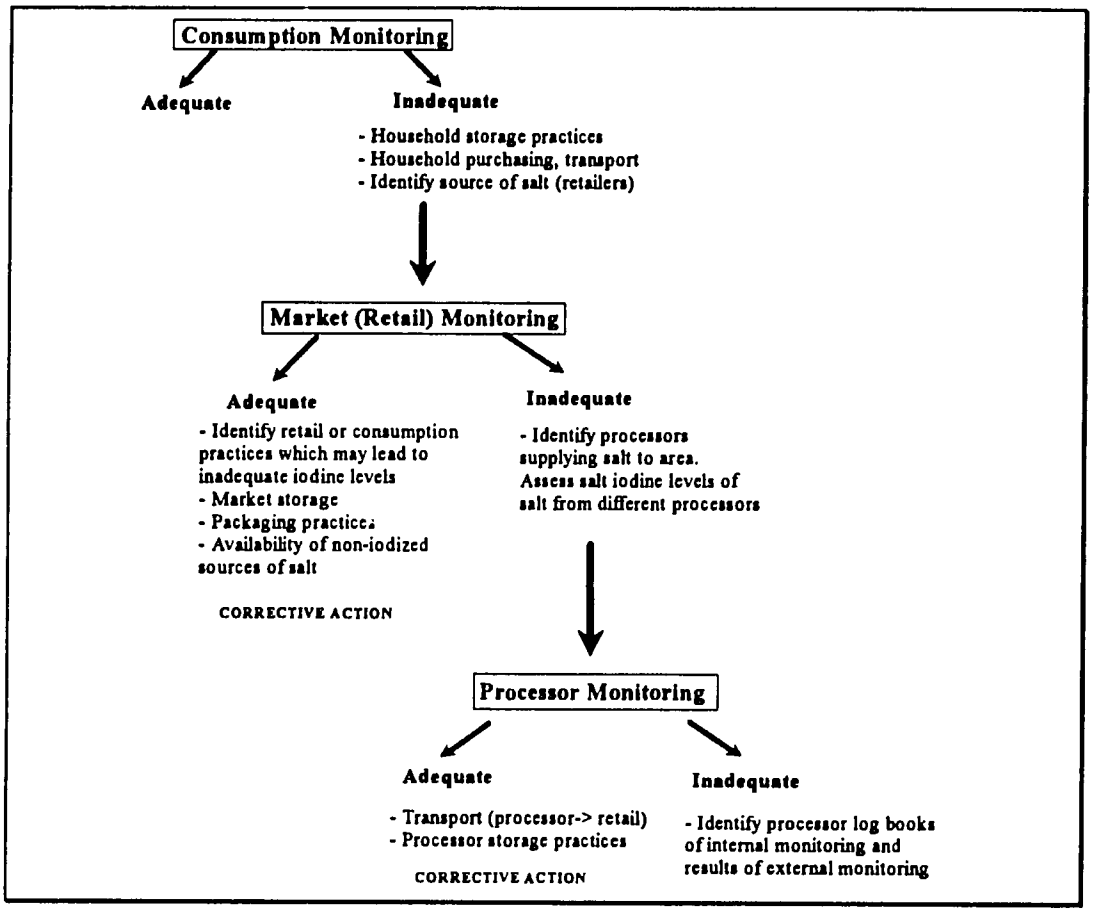
Overview

Monitoring of the availability of iodized salt and salt iodine levels and at the point of consumption provides the primary information for assessing the potential impact which may be realized as a consequence of salt iodization activities. The frequency of monitoring at the point of consumption will vary depending upon the coverage rates and the capabilities of the peripheral infrastructure. The information collected at this point should provide some impression of the status of progress towards achieving universal salt iodization (USI) in each District of NWFP. It is suggested that salt consumption salt monitoring be undertaken at the Union Council (U.C.) level. All schools in the U.C. will be listed, and schools will be randomly selected. If this approach is adopted, it will be important to change the designated school for each round of monitoring to gain reliable information over time. While retail level information will be collected at the Tehsil level, the monitoring of iodized salt consumption is done at the U.C. level to gain more specific information to target program activities. In those areas where there are low coverage levels, the source of the problem should be identified so that direct responses may be taken to improve the program delivery.

Figure 3 presents some of the possible factors why the salt iodine concentration may not be adequate by the time that it reaches consumers. These factors provide the decision framework through which District Health Officers and others involved in the salt iodization program may take corrective action.

Figure 3

Possible Constraints in Iodized Salt Supply to Consumers



It is recommended that monitoring of salt consumption take place at least four times a year (every three months) so that trends in coverage may be seen over time. As programme performance improves and higher rates of coverage are achieved and maintained (criteria should be clearly specified), it will be possible to collect data only once or twice a year.

As with the retail market monitoring, the monitoring of salt at the point of consumption will be done using LQAS approaches. It is proposed that data be collected from selected schools using rapid test kits, as these provide qualitative information about the adequacy of salt supplies. It is important that the schoolteachers are convinced of the importance of this activity and that their involvement is integral to the success of the salt iodization program, through support of both education and monitoring functions. It may be necessary to gain a policy statement from the Ministry of Education, at the Province level which will provide the mandate for the health sector to request the support and assistance of educators (see note to this effect in Consultant Report).

Data collection

The following guidelines have been drafted based on a total sample of 42 children as above.

For each village, a single primary school will be selected at random from all schools. For each round of monitoring, the selection of schools should change, so that random data may be assured. The selection of schools should take place as follows:

1. A listing of all primary schools in each village should be constructed from information provided by the Ministry of Education. The total number of primary schools should be counted and taken as the sampling interval (*r*).

3. A random number needs to be selected between 1 and r to select the school. In this way, it is possible to ensure that all schools have an equal probability for selection in the sample.

4. It is important to note that if there is concern about whether the selected school is representative of the U.C., it may be best to focus on schools in more remote villages or other areas where access to adequately iodized salt may be lower. In this way, the monitoring can provide the information necessary about whether the more vulnerable groups in the U.C. are covered by the program. If they are covered, it may be assumed that other areas will also be covered. If they are not covered, then the whole U.C. may be exposed to further programmatic inputs.

Children in each school will be selected in a way similar to that which was used for the selection of the schools themselves. The total number children in the school will be divided by 42 (the sample size for the school) to calculate the sampling interval (r). The first child will be chosen by selecting a random number between 1 and the value of the sampling interval (r) on a roster. The next 41 children should then be selected.

Each schoolteacher included in the sample will be provided with rapid test kits and asked to construct the list of eligible children and do the sample selection one day prior to the data collection so that the selected children can be asked to bring salt samples to the school. If a child is not present when the selection is made, efforts should be taken to involve them. The following day, the teacher will get the salt samples and analyze them with a test kit.

The teacher should use the opportunity of the monitoring to educate the students about iodized salt and its importance in learning and education. The teacher will record the number of inadequate samples and send them back to the District health officer. If more than 5 samples (of the 42) are found to not turn blue, then the village will be designated as consuming less than 75% of its salt as iodated, where the expected level of iodized salt consumption is at least 90%. In turn, by aggregating the results at the District level, it will be possible to estimate the sixth program performance indicator, and to focus action on those areas where the consumption of iodized salt is less than 75%.

INDICATOR P6 **PERCENT OF POPULATION WHERE > 90% OF SALT CONSUMED IS ADEQUATELY IODIZED**

2. Program Evaluation

In addition to the ongoing monitoring of the performance of the salt iodization program, it will also be important to undertake program evaluations less frequently to assess the impact of the activities on the iodine status of the populations. It is recommended that a market-based survey be done in conjunction with a school-based survey employing three basic indicators, including; goitre measured by palpation, urinary iodine and salt consumption patterns. It is important to determine if the evaluation will be representative of the Province as a whole, of each Division or of each District. In either case, these should be undertaken no more than once every two years.

In addition, it may be of interest to incorporate more sophisticated biochemical evaluations of iodine status, including the measurement of urinary iodine excretion levels in the future. These tests become increasingly important as the rate of palpable goitre decreases, and the levels of clinical IDD in the community decline, thereby necessitating the use of indices of marginal, or sub-clinical manifestations of IDD. The actual transition from clinical to sub-clinical indicators of IDD should be based on a combination of threshold levels of the prevalence of clinical IDD, say, when the total TGR in schoolchildren falls below 5%, and the resources available for carrying out the more elaborate measurements.

2.1. Retail Market Salt Survey

The market survey would use a standardized format as presented as Form 4.

FORM 4

MARKET SURVEY OF IODIZED SALT

District _____

Sub-division _____

Village _____

Total salt sold (monthly average):

	Rock	Crushed (iodized)	Crushed (uniodized)
Percent of salt sold (%)	____	____	____
Average price (Rs.)	____	____	____

Is iodized salt important for health (Y/N) ?

Is there consumer demand for iodized salt (Y/N) ?

Is the supply adequate to meet demand (Y/N) ?

Sample Size (Number of Market stalls to be visited)

In order to determine the sample size necessary for the market survey, there are a few parameters which need to be specified, including the expected proportion of an indicator, its precision and confidence level. For example, to estimate that the proportion of markets selling iodized salt is 75% with absolute precision of 5% and 95 % confidence, a sample of 288 market stalls would be required for the Province (see Annex 3). However, due to the fact that a multi-stage cluster design is to be used it is important to specify the effect that the design may have on the prevalence estimate, or more specifically, on the variance of the estimate. The ratio between the variance of a cluster survey design and that of a simple random sample is known as the 'design effect' and is a function of how homogeneously distributed an indicator is in a geographic area. The less homogeneous that an indicator is distributed, the greater the design effect.

While there is little information on the homogeneity of salt market data, an design effect of 2 is designated. Consequently, the original sample size of 288 will need to be inflated by a factor of 2 to 576, which can be further rounded up to 600. Annex 3 details the sample sizes necessary for different expected levels of iodized salt availability (taking into account desired precision and design effect).

For a sample size of 600, 30 villages will be chosen for each Province and within these, 20 market stalls randomly selected for visit by the field teams to collect the information included in Form 4. The following section details the process through which the villages and markets may be identified.

Sample Selection of Markets

There should be a random selection of villages in each division at the first stage of the survey design, and then a random selection of a corresponding number of households within each selected village at the second stage. The selection of villages could be executed either through a population proportional to size (PPS) sampling approach, or by simple random sampling (SRS). However, while SRS may be operationally more attractive, it will possibly lead to biased estimates by not allowing for villages to be included in the sample in the same proportion that they are represented in the population as a whole. PPS, by definition will select villages by taking into account their population size, and in turn, leads to a 'self-weighting' selection process. For each market survey, a different selection of villages, and in turn, different sub-set of markets should be selected to ensure randomness and representative, unbiased information.

The procedures for the sample design are outlined below.

1. Prepare a listing of all villages in the Province, detailing the approximate population size and include the cumulative population totals.

2. For a PPS selection of villages, determine the total population in the Province and the population size of all villages. The total population figure is then divided by the total number of villages required in the sample, in this case, 30. The resulting value is the sampling interval, r.

3. The selection proceeds by picking a random number between 1 and r. Next, identify the village whose cumulative population includes the random number (taken as the random start). By adding the sampling interval,r, to the first random start, it is possible to identify the second village. This procedure continues until all thirty villages have been selected.

To illustrate the PPS selection process, we will select a sample for a Province with a total population of 1,200,000 from where we want to select 30 villages.

1) Calculate the sampling interval: 1,200,000/30 = 40,000

2) Select a random number between 1 and 40,000 by consulting a table of random numbers. Lets say we select the value 10,500. Looking at the cumulative population totals for the District, we note the village which contains the value 10,500 (for example, this village may include the population interval numbering between 10,200 and 10,600). Therefore, this is the first village selected.

3) Add the sampling interval to the random start: 10,500 + 40,000 = 50,500. Again, by consulting the population listing, observe the village whose cumulative population interval includes this value, and consequently this is the second village selected. Repeat this process until all 30 villages are selected.

Data Collection and Analysis

The Director of Health Services (or Industry ??) will supervise the Market survey, and utilize health personnel from local BHU's of selected villages, as well as CHV's and VHW's. The selection of markets should be done in each selected village similar to the procedure followed in the ongoing monitoring sample selection. The data forms for the 600 stalls visited will be gathered and then brought to a central point for processing. It is assumed that this may have to take place at the Province level, where computer facilities are available. The data should be entered using user-friendly computer software, which should also be programmed to prepare general summary analysis. It is important to take into account the complex survey design when analyzing the data, especially when Provinces are compared to one another, as measures of association will be affected by the increased variance associated with complex design.

2.2. School-Based IDD Prevalence Survey

The primary impact indicators for the IDD Control program will be the Total Goiter rate and the median urinary iodine concentration in schoolaged children. The sampling procedures are very similar to those followed for the Market Survey, except that where villages (and markets) were used for that purpose, schools (and schoolchildren) will be the unit for the sample. A proposed format for the survey could be similar to that presented in Form 5.

Form 5

Questionnaire for IDD Prevalence Survey

District _____ Tehsil _____

Union Council _____ Village _____

School _____

Child I.D.	Name	Age (Yrs)	Sex (M/F)	Type of Salt (Rock,Crush)	If salt Crushed Salt Iodine level	Goitre Grade	Urine Sample
1							
2							
3							
4							
etc.							

A total sample size of 780 school-aged children, aged 8-10 years will be included for goitre assessment by palpation, and a 20% sub-sample (1 out of every 5 children) will have urine samples taken to measure urinary iodine excretion. The sample size for palpation is based a simple sampling formula to estimate a population proportion with specified relative precision with the following parameters:

Estimated goitre prevalence in each district = 50 %

Absolute precision of the goitre prevalence estimate = 5 %

The prevalence of 50% has been estimated as this leads to the largest sample size. With these parameters, a sample of 384 children would have to be measured. However, again since a multi-stage cluster design is used, the design effect needs to be accounted for. A design effect of 2 has

been designated for the prevalence survey. Consequently, the original sample size of 384 has been inflated by a factor of 2 to 768, which has been further rounded up to 780.

For each of the District, 30 schools (clusters) will be chosen randomly from a list of all schools and for palpation, 26 children within each cluster will be measured to ensure that the sample requirement is met (30 * 26 = 780). For urine collection, a total of 5 children per cluster will be selected systematically, for a total of 150 samples for each area.

Selection of Schools

The selection of clusters (schools) for each District will be similar to the selection of villages for the Market survey.

1. In the first stage, a listing of all schools in each district where school-aged children, between the ages of 8 and 10 years, would be attending is constructed. Primary grade classes in which children of this age range may be attending are offered in three different types of schools, including: 1) high schools, 2) middle schools, 3) primary (also mosque) schools. Each of these schools need to be included in the listing.

2. The total number of schools in each district is divided by the number 30 (the number of schools selected) to produce a sampling interval (r).

3. A random number is selected between 1 and r to select the first school (random start). This is then followed by adding the value of the random start to the sampling interval (r) to identify the second school. This process will be repeated until all thirty schools were identified. In this way, it is possible to ensure that all schools had an equal probability for selection in the sample.

4. It is important to note that many schools have only a single gender, but are associated with a second school for the other gender. Thus, if a boys school is selected, then an associated girls school would be linked to it, so that the sample cluster will include both sexes.

Data Collection and Analysis

Data should again be collected at schools, but unlike the ongoing monitoring which used schoolteachers, it is recommended that doctors with some experience in palpation be used. IDD mobile teams, such as those in AJK would be useful for this purpose. Alternatively, DHO's and

District Nutrition staff could be mobilized for the evaluation survey, but the time required for this activity will need to be considered.

The feasibility of a school-based survey will depend upon the availability of resources and expertise. If it is deemed not possible to do a separate school-based survey which uses palpable goitre as an indicator, an alternative would be to structure the World Bank Project Evaluations in such a way so that Province-level epidemiological data on IDD prevalence may be obtained. As the virtual elimination of IDD is one of the key targets set for the World Bank Project, it will be necessary to incorporate mechanisms to ensure that the program activities, of which salt iodization is integral, has its anticipated impact. The World Bank Project Proposal presents an outline for two National Surveys, each which will provide representative data at the Province level in which several indicators will be collected on IDD, as well as Iron Deficiency Anemia and Protein-Energy Malnutrition (e.g., wasting, stunting and underweight). The groups focused upon in these surveys will be preschool children and women of reproductive age, and the sample frame will most likely not provide a way to collect data on schoolchildren. Thus, while this age group may be considered optimal for assessing the prevalence of IDD, other age groups, because of their access, will be used to provide an overall estimate of the status of IDD in the population.

ANNEX 1

SAMPLE SIZE FOR MARKET MONITORING

LQAS Sample size requirements

P_0	Threshold Limit - point used to determine where need to respond
P_a	Expected level of performance (anticipated level of adequate samples)
n	Total number of samples to be collected in an administrative area
d	Total number of samples to be detected in order to identify an administrative area as exceeding the threshold limit

		Level of significance = 5 %	
		Power = 80%	
P_a	P_0	n	d
50 %	20 %	13	8
	25 %	21	12
	30 %	35	20
75 %	50 %	23	7
	60 %	61	18
	65 %	133	37
90 %	70 %	26	3
	75 %	42	5
	80 %	83	10
95 %	75 %	21	1
	80 %	32	2
	85 %	60	4

ANNEX 2

TIME FRAME FOR DIFFERENT INDICATORS AND THRESHOLD LIMITS IN MARKET MONITORING OF IODIZED SALT PROGRAM

Indicator	Expected level (P_a)	Threshold level (P_o)
Phase I - Program initiation (low levels of iodized salt on market)		
I.1 Proportion of markets with < 25 % of salt sold as rock form	75 %	50 %
	90 %	75 %
Phase II - Program continuation (iodized salt is introduced to market)		
II.1. Proportion of markets with no salt sold as rock form	75 %	50 %
	95 %	80 %
II.2. Proportion of markets with > 50 % salt sold is iodized	75 %	50 %
(packaged in bags claimed to be iodized)	90 %	75 %
Phase III - Program maintenance (iodized salt widely available in market)		
III.1. Proportion of markets with > 75 % salt sold is iodized	75 %	50 %
(packaged in bags claimed to be iodized)	90 %	75 %
III.2. Proportion of markets with all iodized salt adequately iodized	75 %	50 %
(measured using rapid test kits)	90 %	75 %

ANNEX 3

SAMPLE SIZE REQUIREMENTS FOR SCHOOL-BASED GOITER PREVALENCE SURVEYS AND RETAIL MARKET SURVEYS

Data to be collected in 30 villages (for market survey) or 30 schools (for goitre) in each District
Confidence level = 95 %

Indicator: Availability of iodized salt, Goitre prevalence
Design Effect: 2

Absolute precision	Availability of Iodized Salt (%)	Sample Size	Adjusted Sample (deff)[a]	# Units in Each Cluster [b]
5 %	50%	384	780	26
	25% or 75%	288	600	20
	20% or 80%	246	510	17
	10% or 90%	138	300	10

[a] Adjusted sample size adjusted for design effect = 2, and rounded to have equal cluster sizes

[b] Assumes 30 clusters in each District