Micronutrient laboratory proficiency testing to achieve sustainability of the quality of monitoring data: the Andean countries experience.

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Abstract:
The success of food fortification, and other public health programmes, critically depends on the reliability of monitoring data generated in chemical laboratories. In 1997 the Subregional Andean Micronutrient Deficiency Control Programme (UNICEF) started a proficiency testing programme for iodine in salt aimed at private and public laboratories in the Bolivia, Colombia, Ecuador, Paraguay, Peru and Venezuela. The results allowed us to recognize 4 types of laboratories, each of which is associated with specific interventions to achieve sustainability of the reliability of their results. A type 1 laboratory is highly reliable. Type 2 shows sporadic weak proficiency related to the absence of a formal quality assurance system. Type 3 is a weak performer susceptible to improvement. Type 4 is not able to improve its weak proficiency and drastic change in management policy is needed. The model has proved its usefulness to identify and resolve major laboratory problems that jeopardized adequate salt iodization, to achieve progress in the standardization of analytical methods and to optimize our resources for laboratory support. Long-term impact is found in the demystification of quality management among laboratory staff that started implementing formal quality assurance programmes that conform to the requirements of ISO Guide 25. The sustainability of the proficiency-testing programme is enhanced by its decentralization to a type 1 laboratory in each Andean country.

1. Introduction

The success of food fortification, and other public health programmes, critically depends on the reliability of monitoring data generated in chemical laboratories (1,2,3). Although the Andean countries (Venezuela, Colombia, Ecuador, Peru, Bolivia) and Paraguay make great progress towards the virtual elimination of Iodine Deficiency Disorders (IDD) and the control of anemia and Vitamin A deficiency, monitoring, epidemiological surveillance and quality control are still considered as a bottleneck (4,5,6,7). The use of well established, simple analytical techniques and de introduction of highly automated equipment improve the confidence of the users of laboratory data. In the Andean subregion, micronutrient analysis laboratories did not have a referential body that assesses them on how to perform their analysis, maintain their methods of analysis or assess the adequacy of their performance. The hypothesis that the implementation of a proficiency testing program could create sustainable awareness in laboratory staff about laboratory and method performance, and show the need of implementation of a Quality Management System. The PT program for iodine in salt led to a unique experience of laboratory-based capacity building in the Andean subregion.

2. Materials and Methods

In interlaboratory studies, participating laboratories analyze identical test materials, which have been prepared from a homogeneous stock. The results are presented in a single report, showing the results of each participating laboratory clearly in relation to those of the others (8). Interlaboratory studies can have various objectives, but when the results are used to assess the technical competence of the participating laboratories, they are referred to as Proficiency Testing (PT).

The analysis of iodine in salt is generally considered as simple, without presence of major technical problems. In view of the achievement in the Andean countries of the year 2000 goal of virtual elimination of IDD, and the related evaluation of IDD control programs, there exists a need to assess the performance of salt analysis laboratories. Therefore, the first PT program to be started was for iodine in salt. The first step was to make an inventory of the laboratories in each country and their working conditions (table 1).

	[I] (mgI/kg)	Compound	# labs		Analytical method	
		Added	Public	private	Central Laboratory	periferic laboratories
Bolivia	40-80	KIO_3	5	0	Colorimetric	Volummetri c*
Colombia	50-100	KI	18	4	Potentiomet ric	Potentiometr ic Volumetric*
Ecuador	50-100	KI / KIO_3	7	2	AOAC 925.56	-
Paraguay	67-100	KI	1	1	AOAC 925.56	-
Peru	30-40	KIO_3	16	2	Volumetric*	Volumetric*
Venezuela	40-70	KI/KIO_3	5	8	Potentiometi c AOAC 925.56	-

Table 1: Situation of iodine in salt analysis laboratories in the Andean subregion, 1996 (9)
*) modification of AOAC 925.56, omitting the use of bromine and thus only determining KIO_3

Only the standard volumetric method AOAC 925.56 measures iodine as iodide and iodate. Potentiometry selectively detects iodide, whereas colorimetry and a modification of the standard AOAC method only detect iodate. The latter has been formally validated (10).

The acceptance in all Andean countries of ISO standards (8,14) facilitated a fast consensus among the laboratories about the fundamentals of the methodology to be used. Participation in PT programs or other interlaboratory test comparisons is a requirement of Guide ISO/IEC 25. Reference samples were prepared by adding a known amount of potassium iodide or iodate to a matrix of analytically pure sodium chloride. Concentration levels were established at 20, 50 and 70 mg I/kg, 20 mg I/kg at the time of the study being considered as the lowest level of iodine that protects the population at risk of IDD (11). The intersample variation was 2.5%. A preestablished group of participants received six replicates of each of three concentration levels, accompanied by instructions and reply forms, and were given three to four weeks to send their results to the coordinator. To assure that the PT program would keep complementary to internal quality control, the frequency was established at twice per year. The use of code numbers to identify the laboratories guaranteed their anonymity throughout the process. The PT program was well accepted in all countries and the number of participating laboratories always assured statistical significance of the generated data. For the interpretation of the results a computer spreadsheet was developed. Since iodine compounds are highly pure and stable (potassium iodate is a primary standard), the theoretical values of added iodine were taken as reference values.

LabCode	Round 1		Round 2		Round 3		Type
	CV	Z	CV	Z	CV	Z	
1	1.15	*5.64*	2.47	*> 10*	*7.88*	*> 10*	*4*
2	1.3	*3.08*	2.29	1.7	2.83	4.21	2
3	0.27	*> 10*	1.07	2.43	2.10	2.24	1
4	0.00	*> 10*	3.13	*> 10*	2.38	1.56	3
5	0.00	*> 10*	0.00	*> 10*	2.11	*6.38*	4
6	0.23	*3.08*	2.31	0.02	1.70	1.19	1
7	*15.85*	*> 10*	4.57	*8.97*	*ND*	*ND*	*4*
8	0.98	*3.03*	1.61	2.51	2.79	0.45	1

Table 2: Coefficients of variation (CV) and Z-scores of a group of 8 laboratories for concentration level 20 mgI/kg in three PT rounds.

Feedback to the laboratories was assured through the reports of the PT program, and the possibility to obtain technical assistance

The overall cost is estimated in 38 US$ per participating laboratory per round, of which 80% represents the shipping of the samples.

3. Results and discussion

For the interpretation of the results, repeatability (precision) and approach to the reference value (accuracy) were evaluated in terms of coefficient of variation (CV) and Z-score respectively (13). The expected values for CV is < 5% and for |Z-score| <3 with a chosen coefficient of variation of 0,8-1%.

The results of the first round (table 2) revealed weak performance in most laboratories with a rejection rate of >70 % (Grubbs test). The zero values for CV in laboratories 4 and 5 are highly unlikely.

Results of the second round show that some laboratories managed to improve their performance, which indicates that they were able to identify and correct the causes of CV>5% and |Z-score| > 3, but only some of them were able to maintain this progress in the third round. It is obvious that laboratories can not be divided in strong and weak performers only based on PT, however the results suggest that in salt analysis laboratories may exist unawareness performance problems, that in some cases may seriously jeopardize adequate salt iodination.

The PT results combined with field visits allowed to recognize four types of laboratories. The laboratories No. 3, 6 and 8 (table 2), after initial adjustment, consistently produce results within expectations. These laboratories have a Quality Management System (QMS) adjusted to adequate standards or benchmarks. They are classified as type 1 and are considered highly reliable support centers for iodine analysis. They are prepared for periodic assessments (audits) of their quality system against

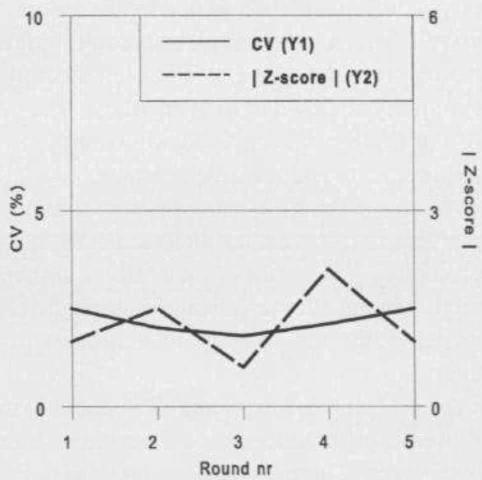

Fig. 1: Type 1 laboratory profile

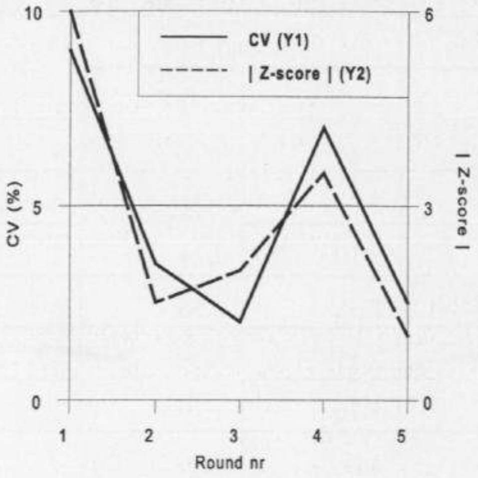

Fig. 2: Type 2 laboratory profile

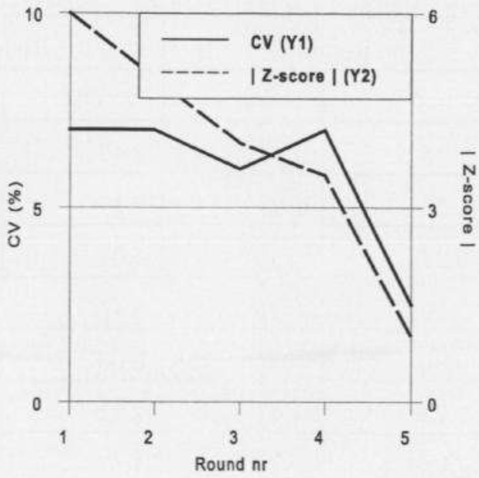

Fig. 3: Type 3 laboratory profile

suitable standards or benchmarks, which could result in a comprehensive report on the performance of the system which can be used to provide confidence or a baseline for improvement.

Type 2 laboratories (table 2, No.2 and 4) show inconsistent results. Usually they are well-equipped and have experienced operators, but they have no QMS adjusted to adequate standards or benchmarks, and are therefore vulnerable to periodic drawbacks in their results.

They have to be stimulated to apply the standard and involve all employees in the development of the QMS, to ensure it reflects their knowledge and expertise, earns their commitment and is relevant and achievable in practice. Guidance is needed to assure that well-established and proven successful practices are maintained, the QMS is not over documented and simplicity is aimed at in every stage. The preparation of the QMS might include adjustment to regulatory requirements and risk management.

Type 3 (Table 2, no. 4) are continuous weak performers that are not able to detect the origin of their problems, but are generally susceptible to improvement after technical assistance that helps them to determine the strategy to identify end eliminate them.

Type 4 (Table 2, nos. 1 and 7) is not able to improve its weak performance although technical assistance has been given. There are indications of serious problems with management, personnel and/or equipment. Lab no. 7 is an extreme case, quitting with its participation in the PT program. Typically there is a strong resistance towards technical assistance and questioning of the technical need and reliability of the use of any form of quality tools.

Intervention is aimed at motivating laboratory management and operators to start a quality management program, to make them understand the importance of the laboratory and the requirements of the program. They are informed about use of standards, for example ISO/IEC Guide 25. Operators are invited to identify the critical steps in their processes, and to try to determine where the laboratory is in relation to the standard's requirements, so they can identify the areas which need improvement. A self evaluation questionnaire might be useful in this step.

This classification allowed us to optimize our resources for technical assistance and follow up of laboratories after assistance.

The delay in the implementation of a QMS is often justified by the lack of sufficient human and economic resources or support by laboratory management or health program directors, whom sometimes are not fully aware of the potential the laboratory offers.

Therefore technical assistance focused on four fundamental and achievable quality tools : training, manuals, statistical process control and participation in the PT programs. This simplified approach convinced and motivated operators to start adjusting their working environment to the appropriate standard. The implementation of quality tools brought an immediate improvement of performance

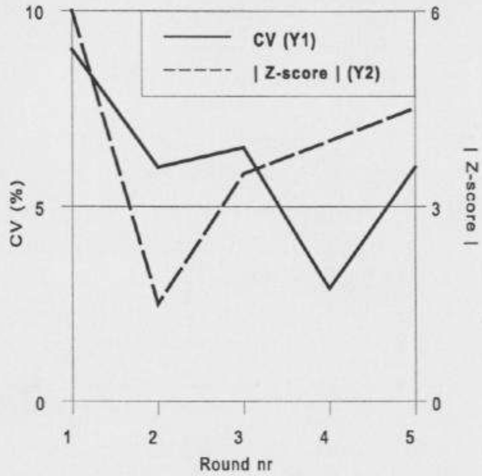

Fig. 4: Type 4 laboratory profile

in many laboratories.

The increased awareness from this approach contributed to identifying and resolving major laboratory problems and thus improving reliability. It also helped to make progress in the unification of analytical methods at subregional Andean level.

To assure the sustainability of the PT program, the national coordination was transferred to type 1 laboratories in each of the Andean countries, taking care to maintain the developed methodology. This contributed to support national institutions and promoting quality culture based on internationally recognized standards, helping to increase their self confidence, showing they can themselves develop initiatives to improve quality, without relying on expensive programs or technical support from outside the country or Andean subregion.

The whole of the model was annually reviewed during an Andean Subregional Workshop on quality and standardization, attended by delegations of laboratory technicians and micronutrient experts of each of the six countries.

The most important achievement of this experience is the sensibilization of laboratory staff, representatives of governments and aid agencies, and many others for the need, benefits and practical possibility of implementing a QMS in private as well as in public health laboratories. Due to the success of PT for guiding laboratories towards sustainable improvement of the quality of their work, the developed method was extended to PT programs for iodine in urine, iron in wheat flour and retinol in serum.

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Salt and History