

THE LEBANESE EXTERNAL QUALITY ASSESSMENT SCHEME FOR LABORATORIES WAS IT WORTH ESTABLISHING ?

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Hallak G. The Lebanese External Quality Assessment Scheme for laboratories : Was it worth establishing ? *Leb Med J* 2005 ; 53 (1) : 9-15.

ABSTRACT : The Lebanese External Quality Assessment Scheme (LEQAS) was established in 2000 with the aim of helping medical laboratories to improve the quality and comparability of their results. Participation in the scheme for hospital and private laboratories, from all over the country, was voluntary. Between the years 2000 and 2003, the participants took part in three series of surveys and were asked to analyze between 10 and 23 clinical chemistry analytes. Their results, revealed in the present study, were assessed using the Variance Index scoring system. At the start of the programme, the overall performance of the participants was unsatisfactory. But as the scheme progressed, and its educational aspects were also emphasized, interest in the scheme increased and overall as well as individual performance were significantly enhanced. The findings of this study, and particularly the improvement in laboratory performance observed during the study period, highlight the importance of establishing the Lebanese External Quality Assessment Scheme, and justify further efforts to expand and strengthen this scheme.

Hallak G. L'instauration d'un programme de contrôle de qualité externe pour les laboratoires libanais (LEQAS) fut-il un projet utile ? *J Méd Lib* 2005 ; 53 (1) : 9-15.

RÉSUMÉ : Le programme de contrôle de qualité externe (LEQAS) a été établi au Liban en l'an 2000 dans le but d'aider les laboratoires médicaux à améliorer la qualité de leurs résultats afin qu'ils soient comparables aux résultats d'autres laboratoires. La participation des laboratoires hospitaliers et privés était facultative. Entre les années 2000 et 2003, ils participèrent à trois séries d'études et ont analysé entre 10 et 23 examens biochimiques.

Les résultats de ces études ont été évalués selon le système du *Variance Index*. Au début de l'étude, la performance des participants n'était pas satisfaisante. Mais au fur et à mesure de l'évolution du programme et de son importance éducative, l'intérêt porté à ces études fut majoré et les performances des participants se sont améliorées de façon significative. Les résultats de cette étude, et surtout l'amélioration de la performance des participants, au cours de cette période, ont mis en évidence l'importance d'établir ce programme de contrôle de qualité externe, et justifient des efforts supplémentaires pour le développer et l'approfondir.

INTRODUCTION

In 1947, Belk & Sunderman in the U.S. performed what was probably the first external quality assessment (EQA) survey in clinical chemistry [1]. This was followed by increasing activity in the field of external quality assessment that led to the establishment of EQA schemes in many industrialized countries during the second half of the last century [2-5]. By the end of the 1990s many developing countries had followed suit [6-8]. The importance of EQA in improving the quality of laboratory services has been so well documented over the years that participation in an EQA scheme has become a prerequisite in many laboratory accreditation programmes in the developed countries [9-11]. The main aim of external quality assessment is to achieve interlaboratory

harmony (i.e. the comparability of results wheresoever the test is performed), and it attains this by helping laboratories to recognize systematic errors in their performance and, consequently, enhancing their internal quality control (IQC) and other quality systems [12].

In 1993, a report was compiled by the World Health Organization (WHO) entitled "Strengthening of Health Laboratory Service in Lebanon" (Ref:EM/LAB/252/E/R/8.93/30), which evaluated the condition of the health service in the country following the civil war. Among the points raised in that report was the urgent need for the establishment of an external quality assessment programme for laboratories (personal communication). Another WHO consultant compiled a similar report in 1999 entitled "Public Health Laboratory Services in Lebanon" (EM/LAB/330/E/R/02.00/15), which not only reiterated this, but also recommended a plan of action (personal communication). These reports, along with calls from different members of the profession, prompted the Laboratory Syndicate of Lebanon to sponsor steps taken for the establishment of the Lebanese External Quality Assessment Scheme (LEQAS) in the year 2000. The aim of the present study is to evaluate the

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impact of this scheme on the quality of performance of medical laboratories and on the concept of quality assurance among laboratory workers and students.

The Lebanese External Quality Assessment Scheme (LEQAS)

The main aim of creating LEQAS is to establish a system that will help improve the quality and comparability of laboratory results in Lebanon. Other aims include providing support for laboratories that perform poorly, while guaranteeing the confidentiality of performance, and promoting a quality assurance philosophy among laboratory workers and in the educational institutions. Hopefully, with time, the scheme may also contribute potentially to improving the system of laboratory (or hospital) licensing or accreditation and thus help isolate unacceptable laboratories.

The first step taken in establishing LEQAS was the setting up of a Steering Committee to take an overview of the programme and support the directors of the EQA schemes of the different laboratory disciplines. The committee was initially seven members; three from the board of the Laboratory Syndicate of Lebanon, three representing the universities, and the director of the clinical chemistry EQA scheme. Afterward, in 2003 a representative from a fourth university was invited to join the committee. However, provisions were made to enlarge the size of the committee in due course by nominating more directors to run EQA schemes in other disciplines and inviting the appointment of a representative of the Ministry of Public Health to enhance the status of the programme. The LEQAS charter also stipulated that once there was more than one director, the directors would form a directors' subcommittee, which would be charged with the day-to-day running and promotion of the EQA schemes.

The role of the Steering Committee is to establish the conditions for joining the scheme, policies for financing it, and ways for promoting the educational aspects of EQA. It also reviews suggestions made by the directors for encouraging and helping laboratories with out-of-consensus performance and ways for dealing with "*per-sistence of such performance.*" The Directors' Committee, on the other hand, has the task of handling issues on organization and logistics, dealing with inappropriate participant behavior and organizing comprehensive educational events. It is also the duty of the directors to preserve the confidentiality of performance, without which the scheme would lose all credibility.

The first EQA scheme to be launched by LEQAS was the clinical chemistry scheme, which started in the year 2000 with a six-month trial period to test the feasibility of the programme and examine the logistical problems that would be faced by the scheme design. This was followed by two twelve-month periods between August 2001 and October 2003.

MATERIALS AND METHODS

The participants

The scheme was open to all legal private or governmental laboratories anywhere on the Lebanese territory. Participation was voluntary and, in the first series, it was also free. Initially there was a problem trying to convince laboratories to join the scheme. There was a lot of suspicion about the motives of the EQA scheme and mistrust in its ability to guarantee the confidentiality of performance. But Lebanon is a small country, which allowed for close personal contacts between members of the syndicate, individual laboratories and the scheme director. This, plus the emergence of a hospital accreditation programme, which was started by the Ministry of Public Health in 2002 and that required laboratories to be enrolled in an external quality assessment scheme, resulted in a significant increase in interest to join LEQAS by the end of 2003.

In the first series there were 28 participants: 15 hospital laboratories and 13 private laboratories. In the second series, when laboratories were asked to pay a fee, the number of participants dropped to 24: 13 hospital laboratories and 11 private laboratories. In the third series there were 14 hospital laboratories and 15 private laboratories, making a total of 29 participants. But the current series, which started in November 2003 and is not included in the study presented here, consists of a total of 43 laboratories, which is a 48% increase on the number of participants in the previous series.

It is worth mentioning at this point that there are an estimated 250 laboratories in Lebanon, 80% of which are enrolled in the Laboratory Syndicate. This means that about 20% of laboratories have so far joined LEQAS. This is not a bad accomplishment for a scheme that is still in its early days of development. But there is certainly room for further expansion. The author hopes that with time, and as more people become aware of the importance of EQA, the demand for participation will increase.

Control material

Enough control material of human origin was obtained to perform three different series of surveys over a period of about three years. At the start of each series, the sera were sent to the participants who were asked to reconstitute one specimen per month, analyze it and return results to the LEQAS center by pre-specified closing dates. A set of lyophilized sera was kindly donated by the United Kingdom's National External Quality Assessment Scheme (UK NEQAS) to help launch the first series. It was made of six lots of assayed sera that had already been used in the UK scheme. These sera were used in six distributions over a period of six months (1 sample/month). The second set of control sera was obtained from Belgium. This too was assayed material that had previously been used in the Belgian national scheme. It contained enough sera to provide samples for

12 distributions to be analyzed by participants, also at the rate of one specimen per month. The third set of lyophilized sera was obtained as unassayed specimens from a commercial source and was used in the third series over a period of 12 months at the same frequency as the previous ones.

Design of the series

Before each series the laboratories were asked to complete a method questionnaire detailing the methods and instruments used by them to perform the requested tests. They were then sent the serum specimens along with written instructions on how to store, reconstitute and test each sample. They were specifically asked to treat the sera in the same way that they would treat patients' samples. Each specimen was given a distribution number and the results of each distribution had to be returned to the LEQAS centre before a specified date. Sera were distributed to participants by express courier service and normally reached the laboratories within 3 working days. Participants were asked to return results by fax.

In the first assessment series participants were asked to examine 10 analytes : sodium, potassium, chloride, urea, glucose, creatinine, cholesterol, calcium, iron, and AST (SGOT). In the second series uric acid, magnesium, triglyceride, total proteins, albumin, LDH, amylase and gamma-GT were added and AST was replaced by ALT (SGPT) to make a total of 18 analytes. In the third series the number of parameters tested was increased to 23 by the further addition of phosphate, total bilirubin, alkaline phosphatase, AST and CPK.

The processing of results and the issuing of report documents and charts was normally completed and posted to participants in less than one week after each closing date. Reports were distributed via the county's postal service and normally took about 3-7 days to reach the participants. This meant that laboratories normally received their performance reports less than two weeks after the closing dates, which meant that they had sufficient time to examine their performance in each specimen before analyzing the next one. Results reaching the LEQAS centre after the closing dates were processed with the other results but reports for these laboratories were not posted to them until the next distribution.

Financing the scheme

In the initial stage of the scheme the Laboratory Syndicate of Lebanon kindly provided funds to pay for all expenses incurred in the first period. After that, laboratories were asked to pay a participation fee to cover the expenses of the subsequent periods.

Educational activities

Since quality assurance (QA) is not merely an exercise in analytical performance but rather an integral aspect of professional standards in the laboratory, it was essential that the concepts concerned with this philoso-

phy be adequately conveyed to people studying or working in the field of laboratory medicine. To do this it was necessary to,

- Introduce and/or strengthen the teaching of QA philosophy in the technologist training schools.
- Organize continuous educational programmes whilst the EQA schemes were developing. These programmes would be aimed at, and involve, clinical pathologists, biologists, and technologists simultaneously.

With these objectives in mind, the Steering Committee set upon ensuring the adequate incorporation of quality philosophy into the curricula of some of the universities teaching medical technology. It also organized conferences and meetings that highlighted the importance of QA, internal quality control and external quality assessment in the laboratory. Five such meetings were held over a period of three years and involved international as well as local consultants.

STATISTICAL ANALYSIS

The Variance Index Score (VIS) system

This is the system used to statistically analyze and score participants' results. It is a system devised in the United Kingdom [13] and used by their National External Quality Assessment Scheme (UK NEQAS) for more than 30 years. Its basic scoring unit is the BIS (Bias Index Score), which is a measure of how far a result is from the target value. It is calculated from the difference between the result (X) obtained by the laboratory and the designated target value (TV), expressed as a percentage of the target value, divided by the Chosen Coefficient of Variation (CCV) for the analyte, and again expressed as a percentage :

$$\text{BIS} = (X - \text{TV})/\text{TV} \times 100/\text{CCV} \times 100$$

The BIS may, therefore, have a negative or a positive value, depending on whether the laboratory's result is below or above the target value. In either case, the smaller the BIS (i.e. the closer it is to zero) the better is the performance.

The CCV is a scaling factor for each analyte, against which all results can be scored irrespective of differences in the state of the art between them. CCVs for the different analytes are the best interlaboratory coefficient of variation achieved in the UK NEQAS in 1972, and are still representative of the relative performance.

Other parameters in the scoring system are the Variance Index Score (VIS), which is the absolute value of the BIS (i.e. ignoring its sign), the Average Variance Index Score (AVIS), which is the mean of all a participant's VISs, and the Mean Average Variance Index Score (MAVIS), which is the mean of all the participants' AVISs.

Processing of results

Before processing the results, they were examined for the presence of any gross discrepancies such as errors due to "copying" mistakes, results reported in the wrong

units and results falling widely outside the limits of the other results. These results were excluded from further processing. The remaining results for each determination were used to calculate "All Methods Means" and standard deviation (SD) in the first series, and "All Methods Means" plus "Method-related Means" and SD in the second and third series. For the "All Methods Means", results that fell outside the $\pm 3SD$ limits were removed and a "trimmed" mean, SD and coefficient of variation (CV) were recalculated. For the "Method-related Means", results that fell outside the $\pm 2SD$ limits were removed before recalculating the "trimmed" mean, SD and CV. This is because method-related means were often derived from a small number of participants, and 3SD limits on either side of the mean would have excluded only the most extreme of outliers.

The results were then statistically analyzed and scored by the Variance Index scoring system using a basic data processing software made available to the scheme by Dr. David Bullock, director of the clinical chemistry UK NEQAS and WHO Collaborating Centre. The software was later upgraded by the author to provide participants with their BIS and VIS, for each analyte, as well as their AVIS and the overall MAVIS of participants. The software also presents laboratories with running charts of the AVIS and of each analyte's VIS results. Reference values for AVIS were set as follows: desirable 60, good 100, acceptable 120.

To score the participants' results and give participants confidence in the scheme's data, the choice of accurate target values (TV) for the analytes tested was crucial. Ideally, target values should be derived from reference methods and reference material that has been validated fully. But since this is not always possible, participants' "consensus means" have frequently been used, and these have been shown to be comparable to reference methods [14]. For our scheme, and since the sera provided to us for the first and second series had already been assayed by a large number of laboratories in the British scheme (> 500) and the Belgian scheme (> 300) respectively, it was decided to use their "All Methods Means" and "Method-Related Means" as target values for scoring our participants' results.

In the third series "Method-Related Consensus Means" obtained from the results of the participants were used as target values for scoring results.

RESULTS

Results of the EQA series

In the beginning of the first series the overall performance of the participants was unsatisfactory. This was indicated by a wide scatter of AVISs ranging from 35 to 170, with an average MAVIS of 101 for the first specimen. Though this may have been expected in a country that had never experienced such an assessment scheme, some of the participants suggested that the poor performance might have been due to changes in the quality of

the specimens caused by the three days that they had spent in transit during distribution. This was, of course, a possible cause especially as the express courier service that undertook the distribution of specimens did not use refrigerated containers in their delivery service. To examine such a possibility, we took three specimens from the same lot and exposed them to three different weather conditions. The first (reference) specimen was kept at between 4°C and 8°C. The second specimen was kept on the bench in the laboratory, where the temperature is maintained at between 22°C and 25°C, for four days. The third specimen was kept for four days outside the window of the laboratory, where it was exposed to indirect sunlight and temperatures that varied between 6°C at night and 33°C at midday. On the fifth day, all three samples were reconstituted and analyzed using the same reagents and instruments. The results, shown in table I, indicate that the specimens used were quite robust and the analytes tested in them were not significantly affected by the four days of different storage conditions.

To see whether the EQA scheme was having any effect on the overall performance of participants, we compared the mean of the participants' MAVIS in the first three specimens with the mean of their MAVIS in the last three specimens of each series. Only a difference of more than 10% between the two MAVIS means was considered as indicative of any significant improvement or deterioration in performance. The results, presented in table II, show significant increasing improvement in participants' scores in all three series. In addition we compared the mean of the first three AVISs of each individual laboratory with the mean of their last three AVISs in each series in order to monitor the performance of each individual laboratory in the series. In this case, however, a difference of more than 15% between the two mean AVISs was required to indicate a significant improvement or deterioration in performance. One laboratory in each series was excluded from the statistics for not taking part in the whole series. Also, one laboratory in the

TABLE II
DIFFERENCES BETWEEN
THE MEAN MAVIS OF THE FIRST 3 SPECIMENS
& THE MEAN MAVIS OF THE LAST 3 SPECIMENS
OF EACH SERIES

	Mean MAVIS of		% difference
	the first 3 specimens	the last 3 specimens	
FIRST SERIES (2000)	101	90	- 11%
SECOND SERIES (2001-2002)	93	83	- 11%
THIRD SERIES (2002-2003)	84	73	- 13%

TABLE I
RESULTS OF 3 SPECIMENS FROM THE SAME LOT EXPOSED TO DIFFERENT STORAGE CONDITIONS FOR 4 DAYS AND THEN ANALYZED ON THE 5TH DAY USING THE SAME REAGENTS AND INSTRUMENT

ANALYTE	Units	Specimen 1	Specimen 2	Specimen 3
		2-8 °C	22-25 °C (% change from Specimen 1)	6-33 °C (% change from Specimen 1)
SODIUM	mmol/L	135.6	136.1 (+ 0.4%)	135.4 (- 0.1%)
POTASSIUM	mmol/L	3.82	3.85 (+ 0.8%)	3.83 (+ 0.3%)
CHLORIDE	mmol/L	95.4	95.0 (- 0.4%)	94.8 (- 0.6%)
UREA	mg/dL	47	49 (+ 4%)	49 (+ 4%)
GLUCOSE	mg/dL	103	103 (0%)	103 (0%)
CREATININE	mg/dL	1.47	1.51 (+ 2.6%)	1.48 (+ 0.7%)
URIC ACID	mg/dL	5.2	5.2 (0%)	5.2 (0%)
CHOLESTEROL	mg/dL	144	147 (+ 2.1%)	148 (+ 2.8%)
TRIGLYCERIDE	mg/dL	93	93 (0%)	92 (- 1.1%)
CALCIUM	mg/dL	8.2	8.06 (-1.7%)	8.16 (- 1.2%)
SERUM IRON	mg/dL	103	103 (0%)	103.6 (+ 0.6%)
MAGNESIUM	mg/dL	2.18	2.15 (- 1.4%)	2.14 (- 1.9%)
TOTAL PROTEINS	mg/dL	5.7	5.67 (- 0.5%)	5.64 (- 1.1%)
ALBUMIN	mg/dL	4.0	4.0 (0%)	3.9 (- 2.5%)
ALT/SGPT	mg/dL	45	44 (- 2.2%)	47 (+ 4.4%)
LDH	mg/dL	342	334 (- 2.3%)	335 (- 2.0%)
AMYLASE	mg/dL	95	97 (+ 2.1%)	96 (+ 1.1%)
GGT	mg/dL	55	56 (+ 1.8%)	55 (0%)

first, one in the second and three in the third were excluded from the calculations because they were scoring AVISs of less than 60 throughout each survey, and their performance therefore was not in need of much improvement. The results are presented in Chart A. The majority of participants in each of the three assessment series had significantly improved their performance by the end of the series. The chart also shows that by the end of the third series there was a considerable drop in the participants showing significant deterioration in performance.

We also monitored improvement in performance by comparing the number of participants scoring a mean AVIS of < 60 (good performers) at the start and end of each survey. Not only were there significant increases in good performers by the end of every series, but their numbers (in percentage of total) at the end of the third series had shown a remarkable eight-fold increase compared to the start of the first series (Chart B).

Interestingly, the surveys revealed that those who had worked on improving their results during the first two series, and had managed to reach a satisfactory standard of performance, were able to maintain this performance throughout the third series. This explains why the percentage of laboratories in chart A, showing "no significant improvement" in performance in the third series was more than double that in the first series. It also explains why the percentage of good performers in the beginning of the third survey, in chart B, was so much higher than that in the beginning of the first two surveys.

Results in the educational aspects of the scheme

The three members of the Steering Committee, who represent the largest and longest-established universities in the country, were given charge of strengthening the teaching of quality in their respective institutions. As a result of their efforts the subject of quality assurance has been given due emphasis in the curricula of all the three universities. In the first university, the number of hours devoted to quality assurance was increased from 2 hours to 6 hours per year. In the second university, quality assurance did not feature in their teaching syllabus, but has been assigned 5 teaching hours per year since 2002. In the third university, quality assurance was given only little attention before 2000, but now features as a main subject in its curriculum. A fourth university, that was not represented in the LEQAS committee before 2003, also took steps to boost the teaching of quality assurance to its technologists by inviting the author to give them 8 hours of lectures a year on the subject.

DISCUSSION

If we assume that good results in EQA reflect good laboratory performance, then the results of the present study have shown that the quality of performance of laboratories in Lebanon in the field of clinical chemistry has certainly benefited from the establishment of LEQAS. The results reviewed above show a significant improvement in performance of the majority of laboratories

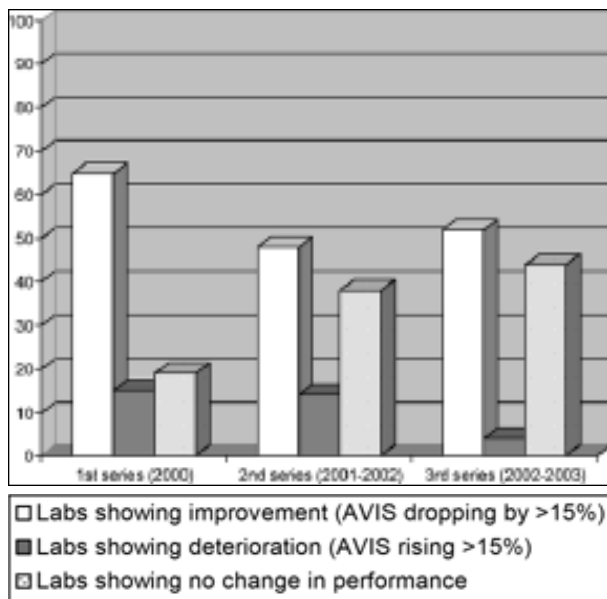


CHART A. Changes in the performance of participating laboratories during the three series (indicated by differences between the mean AVIS of the first three samples and the mean AVIS of the last three samples in each series).

taking part in the assessment series.

These improvements were attributed to a multitude of reasons. Some laboratories taking part in the EQA scheme achieved better results by introducing automation into their routine work, others changed the reagents they had been using in favor of more reliable (though sometimes more expensive) manufacturers, and others simply applied more stringent QA and IQC measures to their work.

Another factor that appeared to contribute to the improvement of performance is the involvement of the technical staff in the “competitive” nature of the surveys. Most participants reported that technologists in their laboratories became so excited about trying to improve their results in the EQA surveys that they were more willing to apply rigorous internal quality control measures to improve their performance. Whilst this is very gratifying and indicates increased awareness in quality, the author is not sure that the consequences of such “excitement” was necessarily beneficial to the main aim of quality assurance, namely that of producing dependable patient results, especially if it meant that control specimens were given more attention than patient specimens in an effort to improve EQA performance. However, increased “staff interest” in their laboratory’s performance can only be looked upon as a positive contribution to good laboratory practice.

One must not relish the positive results of establishing an EQA scheme in Lebanon without examining its weaknesses. For example, although there was considerable improvement in the performance of most participants, there were a few laboratories that made little effort to improve the quality of their results. Maybe these laboratories did not trust the validity of the assess-

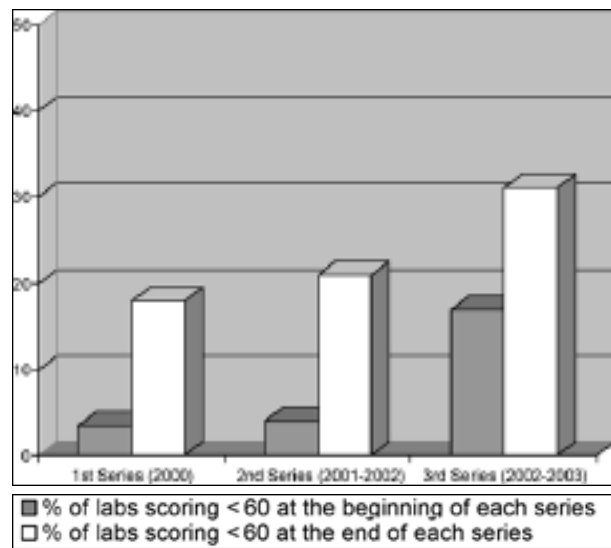


CHART B. Laboratories scoring a mean AVIS of < 60 in the first three samples of each series compared to the number scoring a mean AVIS of < 60 in the last three samples of each series.

ment process. Alternatively, they might have been more interested in joining the EQA scheme to advertise their participation in it than to improve their performance especially that the confidentiality of their results was guaranteed, and they did not have to fear any consequences from their poor performance. In either case, this raises the question about whether there should be “consequences” to persistent poor performance, or simply greater emphasis on educating the poor performer. The author favors the latter option.

Another point of weakness in the present scheme, and which constantly came up in discussions with participants, is the delay in launching similar schemes in other laboratory disciplines during the last four years. A possible reason for this is the availability of trained professionals to run such schemes, or skepticism among some members of the profession about the intentions or abilities of individuals willing to manage such schemes. Such thoughts, together with the key knowledge that QA is a fundamental feature of educational standards, encourage the author and several ranking members of the Syndicate, to support suggestions to hand over management of the schemes to the educational establishments, while keeping the executive responsibilities in the hands of the Syndicate. In any case, the present scheme, whilst valuable to the profession, will always be deficient and may lose credibility unless other schemes are launched very soon. The author, therefore, urges the sponsors of the scheme, the Laboratory Syndicate of Lebanon, to urgently tackle this problem and take the necessary steps to launch EQA schemes in other disciplines. For without this, LEQAS cannot fulfill its principal aim ; namely that of improving the quality and comparability of results in all laboratory disciplines in the interest of patient care.

ACKNOWLEDGEMENTS

I thank the Laboratory Syndicate of Lebanon for financial support of the first series. I thank the WHO Collaborating Centre in Birmingham, UK (Dr David Bullock) for provision of UK NEQAS sera and the basic data processing. I thank Dr Jean-Claude Libeer from the Institute of Public Health in Brussels, Belgium, for kindly providing sera in the scope of the serum donation program of the IFCC. I thank the administration of "Centre Hospitalier de Bhannès" for allowing the scheme to run from their laboratory department during the years 2000 to 2004, and providing the office facilities for its operation. Last, but not least, I thank Miss Rita Lattouf for her invaluable help in the data processing procedures.

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بيان تقييمي لبرنامج للجودة في مختبرات الطب في لبنان. هل هي جديرة بتبنيها؟

موجز: إنَّ منهج المراقبة النوعية الخارجية توطّدت في لبنان سنة ٢٠٠٠ بهدف مساعدة المختبرات الطبية لتحسين نوعية النتائج بصورة تكون مشابهة لنتائج مختبرات أخرى. ان مشاركة مختبرات المستشفيات أو الخاصة كانت اختيارية. بين سنتي ٢٠٠٠ و ٢٠٠٣ شاركت المختبرات بثلاث دراسات وتمّت دراسة ما بين ١٠ و ٢٣ فحصاً كيميائياً حيوياً ، قُيِّمت نتائج الدراسات استناداً إلى منظومة «اختلاف المشعر». في بدء الدراسة لم تكن إنجازات المشاركين مقبولة، ولكن شيئاً فشيئاً تطوّر المنهج ومظهره التعليمي، فمصلحة هذه الدراسات قد ازدادت وكذا نتائج المشاركين تحسّنت بشكل واضح. نتيجة هذه الدراسة وخاصة تحسين تقييم المشاركين في هذه المرحلة قد أبدت أهمية وضع منهج مراقبة نوعية خارجية ومتابعة الجهود لوضع منهج مراقبة النوعية الخارجية وتؤيّد الجهود التكميلي للتعمّق في هذا المنهج.