Meeting the needs of Mediterranean nations: improving efficiency in laboratory medicine

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Inter-laboratory comparisons and EQA in the Mediterranean area

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ABSTRACT

The role of Proficiency Testing schemes (PT) or External Quality Control programs (EQA), involves the use of inter-laboratory comparisons for the determination of laboratory performance. EQA-PT schemes are of primordial importance to the analytical quality, standardization of methods and harmonization of the results. Laboratories are familiar with EQA-PT schemes as they are a prerequisite for their accreditation according to the ISO/IEC 15189 standard.

The IFCC Committee on Proficiency Testing (C-PT) conducted a survey among the colleagues of the Mediterranean countries in order to evaluate the status of the EQA-PT providers in the region, their acceptance among laboratories, and possible issues in their implementation. The survey was organized electronically and we received 59 replies from colleagues (IFCC National Representatives and affiliated EQA-PT providers), from 17 of the 23 countries (74%) of the Mediterranean area.

We concluded that there is a broad difference in the application of the rules of External Quality Control programs or Proficiency Testing schemes, among the Laboratories in the Mediterranean countries. Moreover, as the Accreditation of the Laboratories is

not mandatory in the majority of these countries, there is no valid reason for participation in EQA-PT schemes.

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The role of Proficiency Testing schemes (PT) or External Quality Control programs (EQA), involves the use of Inter-Laboratory comparisons for the determination of Laboratory Performance (1). The application of comparative analysis adds value to the competency of the laboratories and provides room for improvement (2). Laboratories are familiar with EQA-PT schemes as they are a prerequisite for the accreditation according to the ISO/IEC 15189 standard (3).

EQAs-PT schemes are of primordial importance to the analytical quality, standardization of methods and harmonization of results (4-6).

IFCC has been recognized for its leading role and efforts towards the standardization of Clinical Laboratory methods. Many commercially available IVD tests acknowledge, in their inserts, the use of IFCC methods. The work of the federation also led to novel analytical approaches, which, although recognized by the different regulating bodies are not, yet, unanimously accepted worldwide as in the case of HbA1c.

Meanwhile, the IFCC possesses the resources and knowledge via the involvement of member societies running Proficiency Testing schemes as non-profit organizations, and also the expertise provided by distinguished scientists who have the know-how to design and produce the necessary novel control materials for specialized External Quality Control programs.

The IFCC Committee on Proficiency Testing (C-PT), ex Task Force on Proficiency Testing (TF-PT), helps publicize the existence of specialized and of general-purpose EQA-PT schemes in the field of clinical Chemistry - Laboratory Medicine. The main project of the committee is the creation of an online database - web application (PTDB) accessible via web browsers and via specific client applications, for the major mobile platforms, offering broader functionality and ease of use. The foundation of this database are the analytes (tests, measurands) and the corresponding analytical methods (assays, instruments, reagents, etc.).

The second part of the database is the PT providers section containing all their contact information, and their programs, their accreditation or certification status, etc. The providers part of the database was completed in mid-February 2017 and June 2018, the PTDB includes 68 providers from all around the globe. The PTDB can be consulted directly at http://ptdb.ifcc.org/providers.

On the occasion of the First IFCC, EFLM, AFCB Conference, “Laboratory Medicine: Meeting the needs of Mediterranean Nations”, held between 2-4 July 2018 in Rome, Italy, the C-PT conducted a survey among the colleagues from the Mediterranean countries in order to access the status of the EQA-PT schemes in the region, their acceptance, as well as possible issues in their implementation.

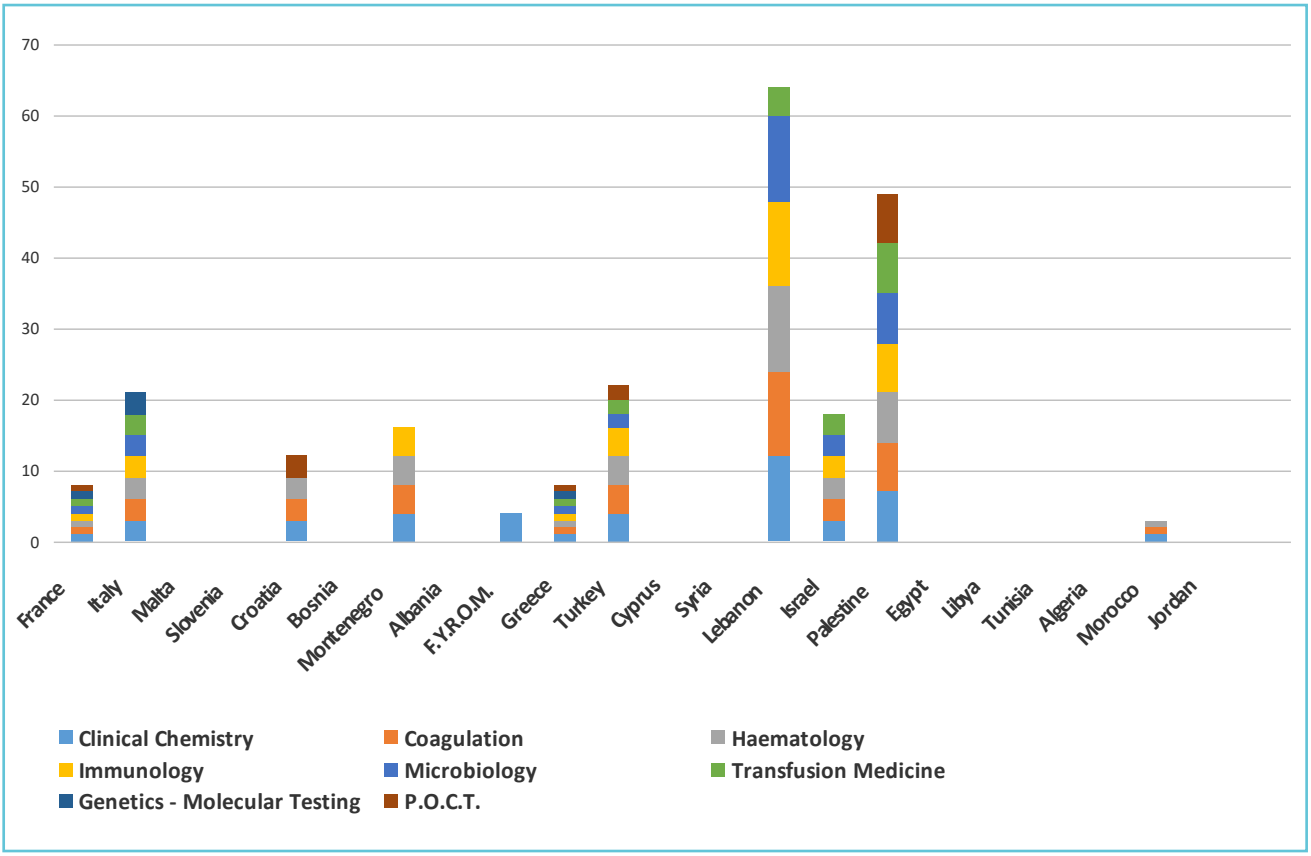
The survey was organized electronically, and ***59 colleagues replied***, mostly IFCC National Representatives and affiliated EQA-PT providers, from ***17 of the 23 countries*** of the Mediterranean area (***74%*** of the Mediterranean countries).

For the first question
“Is the participation of medical laboratories in External Quality Control - Proficiency Testing schemes in your country mandatory, by:”

53% of the countries replied by ***law***, ***29***% of the countries replied by ***Scientific Society guidelines***, **6**% of the countries replied by ***Social Security*** organization in order ***to reimburse the tests*** and finally ***47%*** of the countries replied

Figure 1 Reasons for participation of medical laboratories in EQA-PT schemes in Mediterranean countries

Figure 2 Frequency of participation by discipline of medical laboratories in EQA-PT schemes in Mediterranean countries



that the participation of Medical Laboratories in EQA-PT schemes ***is non mandatory at all*** (Figure 1).

For the second question
"If it is mandatory in which sectors and which is the minimum frequency of participation per year"

71% of the countries replied in ***Clinical Chemistry*** with minimum frequency of participation per year 1 and maximum 12, *(median 3),* ***59***% of the countries replied in ***Coagulation*** with minimum frequency of participation per year 1 and maximum 12, *(median 3),* ***59***% of the countries replied in ***Hematology*** with minimum frequency of participation per year 1 and maximum 12*, (median 3),* ***47***% of the countries replied in ***Immunology*** with minimum frequency of participation per year 1 and maximum 12*, (median 3),* ***41***% of the countries replied in ***Microbiology*** with minimum frequency of participation per year 1 and maximum 12, *(median 2,5),* ***41***% of the countries replied in ***Transfusion Medicine*** with minimum frequency of participation per year 1 and maximum 7, *(median 2,5),* ***18***% of the countries replied in ***Genetics - Molecular Testing*** with minimum frequency of participation per year 1 and maximum 3, *(median 1),* and ***29***% of the countries replied in ***Point Of Care Testing (POCT)*** with minimum frequency of participation per year 1 and maximum 7, *(median 2),* (Figure 2).

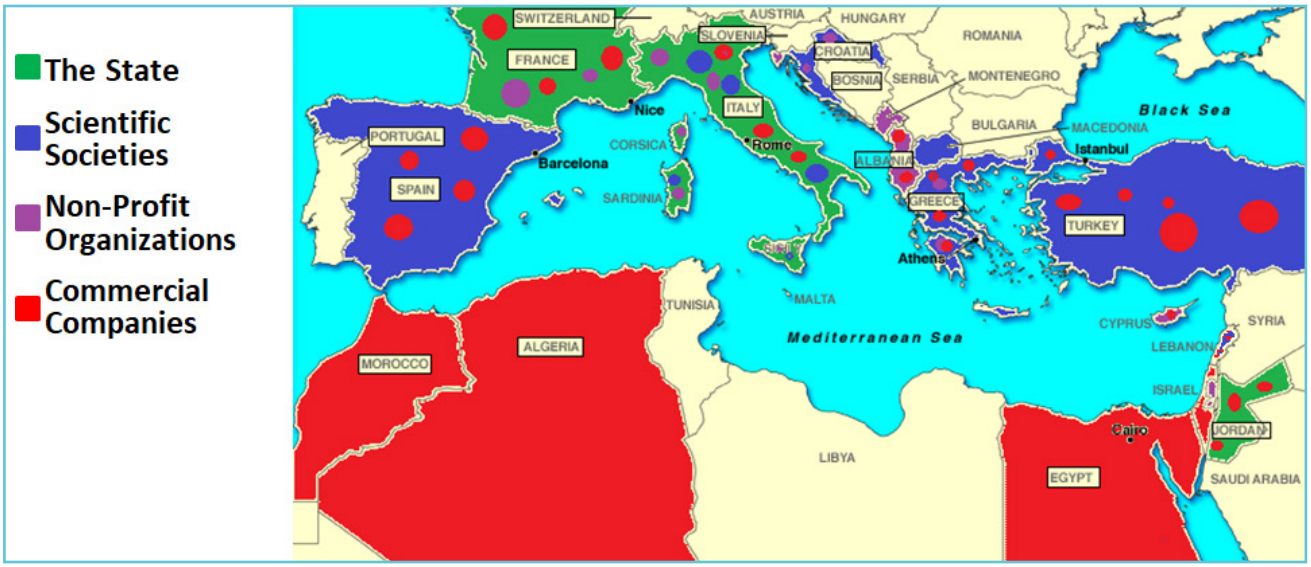
For the third question
"The External Quality Control - Proficiency Testing schemes are organized by the:"

18% of the countries replied by the ***State***, ***41***% of the countries replied by ***a Scientific Society***, ***47***% of the countries replied by a ***non-profit organization*** and ***76***% of the countries replied by ***commercial companies*** (Figure 3).

For the fourth and last question
"Is the accreditation of the laboratories mandatory by:"

30% of the countries replied by ***law***, **12**% of the countries replied by ***Social Security*** organization in order ***to reimburse the tests*** and finally ***58%*** of the countries replied that the accreditation of Medical Laboratories ***is non mandatory at all*** (Figure 4).

Figure 3 Organizers of EQA-PT schemes for medical laboratories in Mediterranean countries



Moreover, we received as remarks that:

In Italy

- The accreditation is mandatory based on Regional requirements.
- Some laboratories are accredited, on voluntary basis, according to ISO 15189:2012.
- The frequency of EQA Schemes participation is not specified in the requirements and depends on test typology. Generally fluctuates, from two surveys (4 control materials) to six surveys (12 control materials) per year.

In Spain

- The establishment of the conditions and technical requirements for clinical laboratories corresponds to the respective Spanish Autonomous Region where the laboratory is located.
- In the Autonomous Regions in which this matter is regulated, the respective regulations require the participation of laboratories in external quality assurance programs, organized by official bodies or by scientific societies of recognized prestige and authority.
- The frequency of participation depends on regional regulation also and, in some of them, it is stated that the frequency should be at least once per month for common tests.

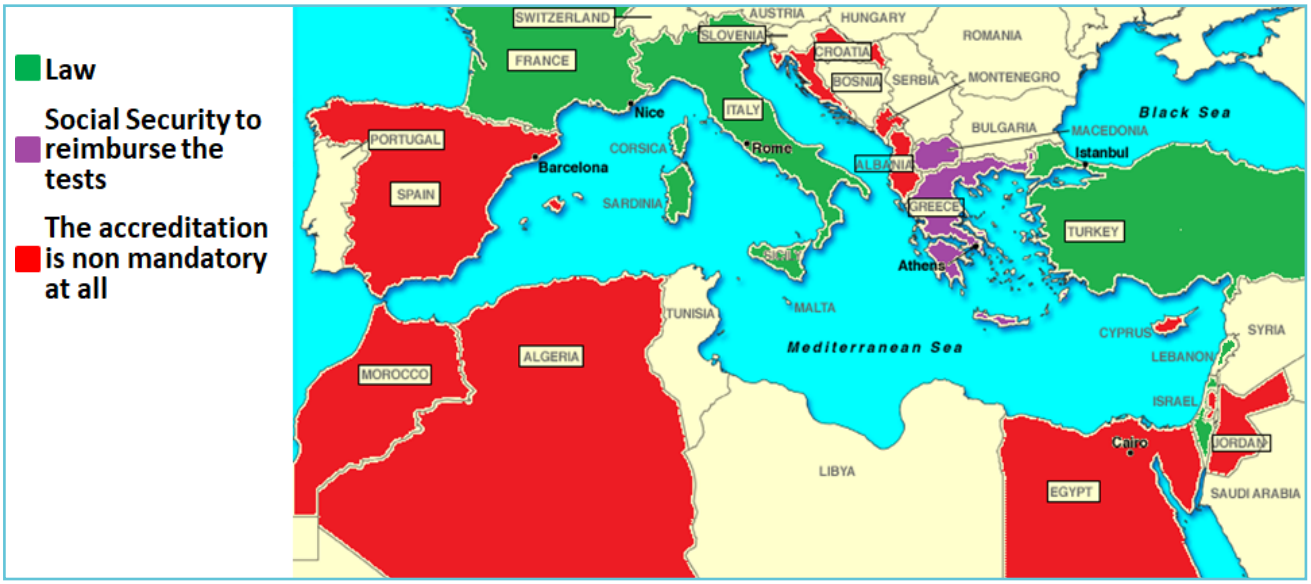
The External Quality Control in Jordan

- Is not mandatory.
- Ministry of Health Law and guidelines encourage the participation in External Quality Assurance programs.
- In fact, the Laboratory Directorate of the Ministry of Health had established an external quality control scheme for HBsAg, HCV, and HIV tests, where they provide two samples twice a year for each of these tests free of charge, and it will be mandatory soon for all laboratories performing these tests to participate in this program.

In Croatia

- The accreditation is not mandatory now, but it will be in the near future.
- The CROQALM is a non-profit organization, one of the CSMBLM activities, where, according to the Croatian Chamber for Medical

Figure 4 Accreditation status of medical laboratories in Mediterranean countries



Biochemistry, each laboratory in Croatia must participate. Laboratories also participate in other type of external quality control according to their practice, accreditation etc.

In conclusion, we can remark that ***there is a broad difference in the application of the rules of External Quality Control programs - Proficiency Testing schemes among the Laboratories in the Mediterranean countries***. Moreover, as the ***Accreditation of the Laboratories is not mandatory*** in the majority of Mediterranean countries, there is not any trend for increased participation in the EQA-PT schemes that helps the harmonization of the quality specifications in Laboratory Medicine.

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