WHY APLUSTBD?



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Current Status in Turkey

• There are several External Quality Assessment Schemes

• In 1980s there were only a few centers registered to an EQAS

 In 1990s the number of labs were increased and spreaded over Turkey

• Currently there are **18 different EQA programs**

Current Status

- Since 2010 EQA is mandatory for some chemistry assays
 - At first 15 tests
 - In 2014 HbA1c
 - In 2017 + 8 analytes
- The results of these assays should be entered to the EQA IT system (EQA monitoring system)
 - Program
 - Period or cycle
 - Method and instrument
 - SDI, unconformity, and possible cause of unconformity

Current Status

Research Article

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National External Quality Assessment follow-up: 2010–2017 Turkish experience Ulusal Dış Kalite Değerlendirme İzlemi: 2010–2017 arası Türkiye Deneyimleri

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Abstract

from 24 different clinical chemical tests were used to conduct a process assessment.

Results: There is a significant discrepancy in unsatisfactory performance ratio among different EAQ-programs



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- 1941 labs
- 24 chemistry assays
- 18 different EQA programs
- 801 028 entries
- Unconformity ratios were determined
- Causes of unconformity were evaluated

Current Status

Table 4: Distribution of reasons for unconformity by years.

The reason for unconformity	2015 (%)	2016 (%)	2017 (%)
Data entry errors (target or own results of the laboratory values)	22.2	18.04	8.27
Erroneous definition of methods	1.7	0.97	2.22
Erroneous definition of units	0.2	0.69	1.06
Erroneous preparation of samples (especially dilution)	5	6.37	11.4
EQA sample problems (inappropriate transfer or storage conditions)	2.7	0.97	0.15
Technical errors (probe, lamp, electrode, etc.)	7.9	4.58	3.76
Error concerning the reagent (past expiry date, waited too long on the device, insufficient collection by probe due to small amount)	4.6	4.09	3.07
Problems concerning the deionised water system	1.8	1.02	1.61
No problem detected. Patient and IQC practices checked and found to be conformant. Subsequently control observed to be conformant	44.9	53.8	59.5
Other reasons	9.0	9.47	8.96

Inability to identfy the problem is much higher than those of the given in the literature (19-24%)

Why TBS Started this EQA Program?

j) İlgili kurum ve kuruluşlarla işbirliği yaparak ilgili laboratuvarlarda eksternal kalite kontrol programları uygulayabilir ve laboratuvar akreditasyonu yapabilir.

 «J) (The society) may perform external quality assessment programs and laboratory accreditation in collaboration with related institutions and organisations»

Historical Truths

- TBS was founded in 1975
- In 1990s two pilot EQA studies (interlaboratory comparison) were performed by Istanbul branch of TBS
- The results of those studies were presented in two national congresses
- In these years, TBS was splitted and emerged two other associations in 1996 (Izmir) and 1999 (Istanbul)
- Also TBS EB was radically changed in 2000 and the period of 2000-2002 was a big trauma for TBS
- In conclusion, the EQAS knowledge and connections of TBS were wasted

What are the Main Criteria for an EQAS?

The following questions have to be addressed:

- How closely does the EQA material match typical patient samples?
- Is the EQA material commutable?
- How many replicates are measured?
- How is the target value established?
- What is the number of participants in the scheme and in a particular method group?
- How are the performance specifications set?

Miller G, Sandberg S. Quality control of the analytical examination process. In: Tietz Textbook of Clinical Chemistry and Molecular Diagnosis (2018)

Why Commutable Materyal?



Miller G, Sandberg S. Quality control of the analytical examination process. In: Tietz Textbook of Clinical Chemistry and Molecular Diagnosis (2018)

Commutable vs Noncommutable

- If noncommutable material is used, a laboratory can only compare its own results with results from participants using a similar measurement procedure
 - Even reagent or calibrator lot changes may affect the results
 - In theory, «each reagent lot could have its target value»

Commutable vs Noncommutable

- When commutable, "patient-like," material is used, a laboratory can compare its own results with results from all other measurement procedures
 - For any method the result should be the same

Commutable vs Noncommutable

- For noncommutable materials the «peer group» is essential
 - The target value is determined by peer group mean or median
 - The measurement techniques should be the same
 - Assessment of mean results among different peer groups or to a reference measurement procedure is impossible
- The report reveals that the results of lab for any test for patients are in agreement or not with those of other laboratories in the peer group

Liquide vs Lyophilised

- There are two distinct types of control materials available: Lyophilised and liquide
- Lyophilisation (freze drying) or other processes change the matrix of plasma/serum
 - But stable and easy to implement
- Ideally, the control material should be fresh
- Therefore the liquide material is adventageous
 - But difficult to transport and preserve



We aim to manufacture commutable EQA materials and a user friendly software

