Opinion Paper

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Evaluation of the first Turkish in vitro diagnostic symposium

1.Türkiye in vitro diyagnostik sempozyumu'nun değerlendirilmesi

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Abstract: In vitro diagnostic (IVD) medical laboratory devices, tests and equipment are closely related with public health, patient safety and the safety of all who utilize these tools in laboratories. The close monitoring of the process from the production line to the end-point user is crucial so that IVD devices and tests do not pose a risk to individuals and society. Based on this background, the "First Turkish in vitro Diagnostic Symposium: Medical Laboratory Tests" was held in February, 2016. The symposium was organized by the cooperation of Turkish Biochemical Society, Izmir Branch and Dokuz Eylul University Health Sciences Institute along with the contributions of TurkLab Calibration Association. It was intended that the meeting would shed light on questions such as, 'What is the place and importance of IVD in Turkey?', 'What are the responsibilities of educational institutions?', 'What is the role of Ministry of Health?', with the aim that the answers would help to determine the infrastructure needed for successful production of IVD medical devices in Turkey. At the end of the symposium, feedback from participants were collected via a questionnaire. This article presents the general evaluation of the symposium based on the results of this survey.

Keywords: In vitro diagnostic medical devices; Innovation; Manufacture; Informatics; Education; Patient safety; Laboratory tests.

Özet: In vitro diyagnostik (IVD) tıbbi cihaz (TC), tıbbi laboratuvar testleri ve ekipmanları, halk sağlığı, hasta güvenliği ve testleri laboratuvarda kullananların güvenliği ile yakından ilişkilidir. Bu materyallerin birey ve toplum sağlığı için herhangi bir risk oluşturmaması, üretimlerinden tüketilmelerine kadar geçen sürecin iyi kontrol edilmesi ve değerlendirilmesine bağlıdır. Bu temel gereksinimden yola çıkılarak; 2016 yılı Şubat ayında Dokuz Eylül Üniversitesi Sağlık Bilimleri Enstitüsü ve Türk Biyokimya Derneği İzmir Şubesi ortaklığına ek TürkLab Kalibrasyon ve Deney Laboratuvarları Derneği'nin katılım desteğiyle, "1. Türkiye in vitro Diyagnostik Sempozyumu: Tıbbi Laboratuvar Testleri: Eğitim-Öğretim, Araştırma, Üretim, Hizmet, İnovasyon, Bilişim" başlığı ile bir sempozyum gerçekleştirilmiştir. Sempozyum kapsamında; 'Türkiye'de IVD'nin yeri nedir?', 'Eğitim kurumlarının sorumlulukları nelerdir?', 'Yasal uygulayıcı olan Sağlık Bakanlığı'nın rolü nedir?' gibi temel sorulara açıklık kazandırılması ve ülkemizde IVD-TC üretiminde başarılı olmak için gereken alt yapının belirlenmesi, sorunlarının tartışılması amaçlanmıştır. Sempozyum sonunda, anket uygulaması ile katılımcılardan sempozyuma yönelik geri bildirimler alınmıştır. Bu yayında, anket çalışması sonuçları sunularak sempozyuma yönelik genel bir değerlendirilme yapılmıştır.

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Anahtar Kelimeler: In vitro diyagnostik tıbbi cihazlar; Inovasyon; Üretim; Bilişim; Eğitim; Hasta güvenliği; Laboratuvar testleri.

Introduction

In vitro diagnostic products (IVD) are defined as all reagents, instruments, and systems used for the collection, preparation, and examination of biological specimens, to diagnose, treat or prevent diseases as well as to determine the health status of an individual [1]. Turkish regulation concerning medical equipment used in vitro (published in the Official Gazette in 2007) defines IVD as all reagents, calibrator and control materials, kits, tools, instruments, equipment or systems that have been designed by the manufacturer to obtain information mainly about (a) physiological or pathological conditions or (b) congenital

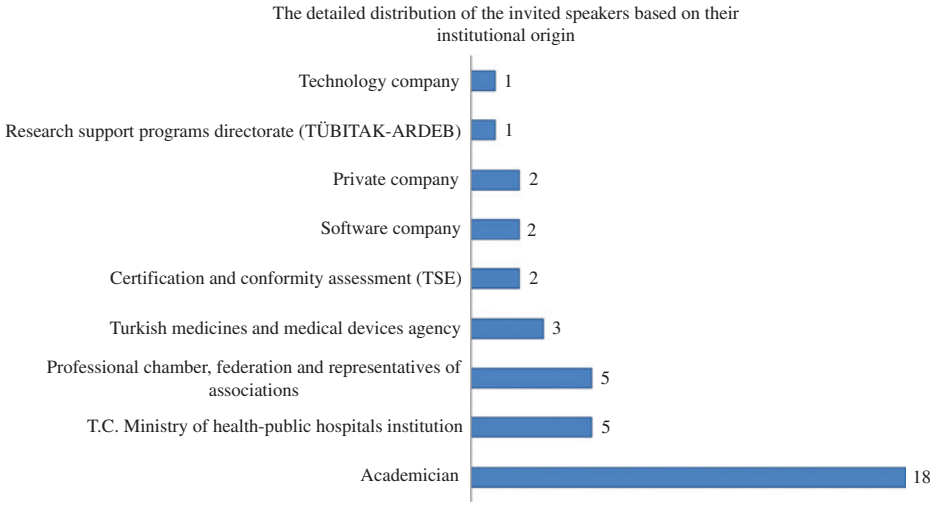

Figure 1: The detailed distribution of the invited speakers based on their institutional origin.

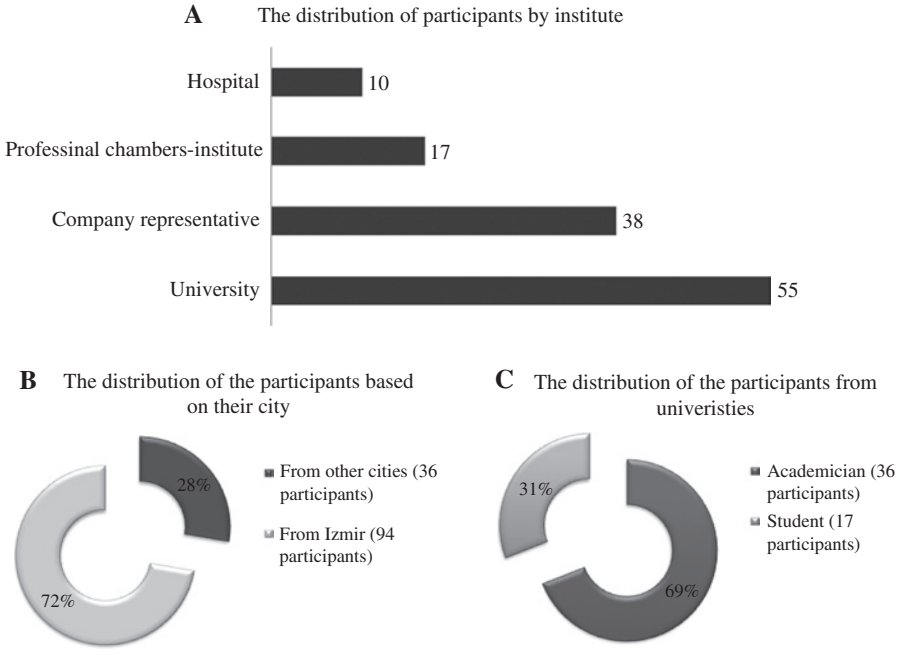

Figure 2: The detailed profiles of the symposium participants.
(A) The distribution of participants by institute. (B) The distribution of the participants based on their city. (C) The distribution of the participants from universities.

abnormalities or determining (c) appropriateness and reliability for potential recipients or (d) in vitro examination of the samples taken from the human body, including blood/tissue donations, whether they are used alone or with other instruments for monitoring treatment; and the sample dishes with/without vacuum characteristics, which are used by the manufacturer for the storage and preservation of samples derived from human body specifically for in vitro medical diagnostic examinations [2]. Products within the scope of IVD are used in obtaining, storing, preparing and analyzing the sample materials from the individuals. It is considered, more than 50% of the medical decisions worldwide are taken through results of IVD medical devices/tests.

As the USA is the pioneer and director of the developments in the IVD field, the greatest contribution to legislation and regulations related to IVD were provided by the American FDA, the legislations and regulations prepared by the European Union (EU) (98/79/CE IVD-TC directive), United Kingdom (UK) and Australia also contributed to the progresses and developments in the field [1, 3–6]. Today, the world medical device market has 60.5 billion dollars share in economy thus its existence will also be important in coming years [7]. This share is predicted to reach 75 billion dollars in 2020 [8].

In the EU harmonization process of Turkey, significant steps have been taken regarding IVD products within the scope of legislative arrangements, as of 2007, the '98/379 EEC Directive' of the EU has entered into force. "Regulation Concerning Medical Equipment Used in vitro" was amended and published in the Official Gazette (07.06.2011, No.27957). IVD field in Turkey is in continuous development from production to use of these products. Taking into consideration that a meeting assembling all stakeholders, inevitably and significantly would contribute to this process, "first Turkish in vitro Diagnostic Symposium: Medical Laboratory Tests: Education-Training, Research, Production, Service, Innovation, Informatics" was held between 18 and 20 February 2016, with contributions of Turkish Biochemistry Society İzmir Branch, Dokuz Eylül University Health Sciences Institute and support of TurkLab Calibration and Experimental Laboratories Association.

The symposium aimed to raise awareness on recognition of IVDs in Turkey, and to create an infrastructure that would foster the production and innovations in this sector, to facilitate the understanding of the necessary issues underlining the legislations as well as to serve as a platform that would help to improve the areas requiring development. This article aims to share the details of the symposium and results of the feedback gathered from the participants through the questionnaire carried out at the end of the symposium. We believe such data will be interesting to the biochemistry community, which uses IVD medical devices and tests in all fields of their professional lives.

Table 1: The results of the questionnaire.

Questions	Options	Results (%)
How did you learn about this symposium?	E-mail	53.57
	Banner	7.14
	WEB	10.71
	From a colleague	32.14
How would you rate the effectiveness of the announcements of the symposium?	Sufficient	50.00
	Not sure	25.00
	Insufficient	25.00
What is your overall impression about symposium?	Successful	86.21
	Not sure	10.34
	Unsuccessful	3.45
Did you encounter any problems during registration?	No	100.00
	Yes	0.00
What are your thoughts about the length of the symposium?	Too long	10.71
	Sufficient	82.14
	Too short	3.57
Were the allocated times for the session was appropriate?	Too long	3.57
	Sufficient	92.86
	Too short	3.57
What is your opinion on the number of topics discussed within the scope of the symposium?	Excessive	7.14
	Sufficient	57.14
	Insufficient	32.14
Did the symposium fulfill your expectations, please rate (1-not at all, 5-fully)	**1**	3.45
	2	6.90
	3	20.69
	4	41.38
	5	24.14
What is your opinion about invited speakers?	Excessive	10.71
	Sufficient	60.71
	Insufficient	25
What is your impression of the symposium venue?	Positive	71.43
	Neutral	0
	Negative	3.57
What is your belief about the contribution of the symposium to the situation assessment in IVD in Turkey?	Positive	55.17
	Neutral	44.83
	Negative	0
Are you planning to attend next IVD symposium?	Yes	44.83
	Undecided	48.28
	No	6.90

Discussion

IVD constitutes an important and valuable segment of the global healthcare industry [7]. In this sector, day by day,

better diagnostic tools, advanced treatment monitoring techniques, advanced rapid diagnosis/response tests are on the stage, thanks to the technological developments. This symposium aimed to bring all related stakeholders together in order to contribute to the recognition and development of IVD products in Turkey [9].

All institutions, organizations, and individuals associated with IVD in Turkey were informed and invited to the symposium via e-mail, web sources, posters or individual communications. Within the scope of the symposium, especially the representatives of the Ministry of Health, as the legal authority in our country, the Turkish Standards Institute as the conformity assessment organization, representatives of important global IVD producers and worldwide known companies which have a production line in Turkey, scientists engaged in health technology related researchers in engineering fields; students; representatives of other non-governmental organizations participated at this event. A total of 39 speakers gave presentations on different aspects of IVD related issues. The detailed distribution of the invited speakers based on their institutional origin is presented in Figure 1. A total of 120 participants including 55 university-personnel, 38 company representatives, 17 representatives from trade associations-institutes and 10 clinician physicians working at hospitals attended this 3 day event (Figure 2).

The fact that the participants of the symposium were involved with different stages of IVD products, suggests that the main purpose of the symposium which was 'to bring together all the stakeholders' has been fulfilled. Although the majority of the participants (94/120) to this symposium organized for the first time were from Izmir, there was also significant contribution (36/120) from other cities as a sign of interest to IVD in Turkey.

To evaluate the impact of the symposium, we conducted a questionnaire consisting of 12 questions on the last day of the event (Table 1). One-third of the participants answered the questionnaire. 86.2% of the participants rated the symposium as successful and 75.6% of them found the scientific content successful. While 60.1% of the participants stated that the number of speakers was sufficient, 25% stated there should have been more. Finally, 55.2% of the participants stated that the symposium contributed positively to evaluation of IVD in Turkey and 44.8% reported that they would participate if the IVD symposium was held again in the coming years.

Conclusions

IVD products were the focus of this symposium organized by the participation of academicians, medical laboratory supervisors and specialists, research physicians and other representatives from universities, legal authority, and industry. During the symposium, significant gaps-problems in IVD field in our country were discussed and suggestions for development were voiced. The results of questionnaire conducted to evaluate the symposium show that the main purposes of the symposium were fulfilled. As great majority of participants rated the symposium as beneficial and successful, it is clear that similar activities are required to overcome the barriers observed in IVD field in Turkey.

Conflict of interest statement: Authors have no conflict of interest.

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