



Montenegrin experience with the EDQM B-PTS & B-QM Programmes

Keeping up with Reality and Quality: A challenge for European Blood Establishments

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Gordana Rasovic

Institute for Blood Transfusion of Montenegro

Background - WHO WE ARE?

- **Montenegro** is a small country belonging to the countries of Southeastern Europe
- By 2006, when Montenegro became an **independent** State, it was one of the six (6) republics of the former state of Yugoslavia



DEMOGRAPHIC (2018)

Land area → 13 812 km²

Population → 622 227 inhabitants

Population → **18-65 years – 66,9% (targeted blood donors population)**

Gender structure

→ Women – 50,2%

→ Men - 49,8%

Rural population → 34%

Urban population → 66%



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Institute for Blood Transfusion of Montenegro (IBTMN)- ROLE

- The main **role** of the Institute is the provision of **sufficient** quantities of safe blood, for the needs of the citizens in Montenegro for:
 - Regular treatments
 - Emergency care
 - Emergency circumstances
- This task includes **blood collection, testing (ABO / Rh / K; TTI), processing, storage, distribution and use of blood.**
- The Institute also provides diagnostics for hospitalized and ambulatory patients, including pregnant women.

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Institute for Blood Transfusion of Montenegro (IBTMN)- ROLE

- **IBTMN** – Public Health Institution organized at the national level, under the jurisdiction of the **Ministry of Health (MoH)**
- It was founded on December **14th 2011** and started functioning independently from July 1st 2012
- IBTMN was taking over existing transfusion services / centers / units, which operated within health institutions and it has integrated **complete transfusion activity** on the territory of Montenegro

Institute for Blood Transfusion of Montenegro – IPA project

- During the project the **EU IPA* 2010** named "*Blood transfusion in Montenegro*" complete work of the Institute has been covered by the National Law of Blood Provision (Official gazette MN N 1/2014) and six regulations harmonized with the EU Directives (2002/98, 2005/61/2005/62, 2004/32/33)
- In addition, all current **EU requirements**, such as **GPGs** are implemented in the Law
- For all IBTMN activities, EDQM guidelines and recommendations of WHO are followed

*Instrument for Pre-Accession Assistance (IPA)

<https://ec.europa.eu/neighbourhood-enlargement/instruments/funding-by-country>



Before & After EU IPA 2010

Before



After



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Today, our institution has 2 very important ISO Certificates

ISO 9001:2015



ISO 27001:2013



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Montenegrin Blood system

- The new organization in accordance with the Decision of the Government of Montenegro, includes **one (1) Blood Transfusion Center** - Referent Institution of the Institute in **Podgorica** and **nine (9) Organizational Parts (OP)** throughout the territory of Montenegro, localized close to **regional hospitals**.
- The testing of blood (ABO,Rh + K, Screening, TTI), processing and storage are centralized at the **Reference Institution of Blood Establishment in Podgorica**. The final products are distributed to OP for storage and issuing. Throughout this process, we have achieved our goal – **to ensure equality in the availability of medicine of the same quality to all citizens of Montenegro**
- Activities of OP are blood collection, storage of blood/blood components and clinical transfusion
- Immunohematology tests for patients and pregnant woman are performed at these facilities (OP)

Blood Sector in Montenegro – Figures

By establishing the IBTMN we overcame the main problem of decentralised and fragmented blood system and successfully started to implement **a Quality Assurance System**.

- Blood donation 19216/year
- Blood donors: 16600/year
- Blood donors rate: 3,1%
- RBD – 56%
- VNBD – 44%
- Donors deferral rate is around 12 %
- Around 2% of collected bloods are destroyed due to positive serological test results etc.

B-PTS/B-QM PROGRAMME – OUR EXPERIENCE (1)

10 YEARS OF
CO-OPERATION

2010 - The participation of our transfusion service in **B-PTS Studies** started **10 years ago** at the beginning of implementing this programme by EDQM
B-PTS studies we started as Centre for Blood Transfusion – Clinical Centre of Montenegro as the biggest TS and continue in 2012 as IBTMN

- We had **2 visits** of B-QM expert teams
 - 1 B-TV in **2014**
 - 1 B-MJV in **2017**

Still, we did not have the courage to apply for a B-MJA.

B-PTS/B-QM PROGRAMME – OUR EXPERIENCE (2)

- **B-PTS studies** were recognized as an opportunity to introduce external control for measurement of the performance of our laboratories, check the performance of equipment, reagents, work processes and results
- **B-TV** help us acquiring new knowledge and getting to know and understand the QMS concepts
- **B-MJV** – our intention was to check whether we are on the right track, is our work alright and where we made mistakes

B-PTS/B-QM PROGRAMME – IMPACT

- **B-PTS:**
 - have proven to be very useful for regular control of our laboratory work and ensuring safety in the obtained results → *only independent control before components reach the hospitals.*
- **B-TV:**
 - brought the 'QMS closer to staff & staff closer to QMS'
 - clarified the various activities and,
 - parsing terms contained in the QMS starting from regulatory framework
- **B-MJV:**
 - significantly helped us to check whether we are on the right track, whether what we have done to date is correct and where we made mistakes

The most beneficial

→ Confirmation of the correctness of our work and pointing out deficiencies & **risks**

B-QM PROGRAMME – CHANGES INTRODUCED

Important changes

- Switch from a product quality oriented system to a quality management system
- appointing a **quality manager**,
- improvement of the documentation of the quality system (some validated procedures had not been documented appropriately
- improvement of communication and contractual arrangements between BE and IT company, key to *secure donors and patient data*.
- advice on improving the documentation of CME as well as some advice about unification of procedures and ensure its up to date & *fit for purpose*

All remarks were successfully implemented in the following period.



B-PTS PROGRAMME – IMPACT & CHANGES INTRODUCED



Favourite B-PTS Programme Aspects

- Regular external control
- Challenges in screening → **It help us to change some of our assays which were not enough sensitive**
- Possibility of consultations
- Continuous security in the reliability of the results obtained in the blood testing units

B-PTS/B-QM PROGRAMME – IMPACT

Why would you recommend these Programme

We sincerely recommend these programs because it will significantly help everyone to rethink their systems, consider criticality and risks of their processes, develop risk-based QMS and focus on continuous improvement because, new challenges are ahead of us and we must be ready for them.

Reforming a System is essential. However, it need to be continuously improved, and benchmarking is essential



THANK YOU FOR YOUR ATTENTION!