

Strengthening of the Blood Safety System in the National Blood Transfusion Service - Implementation of the European Union IPA Project - at the Institute for Transfusion Medicine of the Republic of Macedonia

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Abstract

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The Safety of the Blood Supply in any country is of utmost importance to safeguard patients from serious adverse events of blood transfusion. Implementation of a Quality System in the Blood Transfusion Service, with support of Government and Ministry of Health is a key element to guarantee safe blood. The IPA TAIB 2009 project - Strengthening of the Blood Safety System executed in 2013/14 provided the means to start implementing a Quality System in the Institute for Transfusion Medicine of the Republic of Macedonia. This project aimed to ultimately bring the Blood Transfusion Service to European Union standards, allowing the exchange of blood components and all other types of collaboration with other European Union countries in future. The project put the basis for unification of blood transfusion standards and operating procedures in the whole country as well as set up essential education of blood transfusion personnel.

Introduction

The Institute for Transfusion Medicine of the Republic of Macedonia (ITM) is the main institution in charge of Blood Transfusion Service (BTS) in the whole country, which is the national unified system. The reorganization of the blood transfusion system that has already taken place in a new organizational set up (as of 01.01.2011) was targeted to enable implementation of the EU standards and norms of quality and safety, during the process of collection, testing, processing, storage, and distribution into daily practice, thus providing for efficiency, quality and

safety of blood products in the country. A major challenge is the implementation of common policies for collection, processing and testing of blood and blood components.

The World Health Organization (WHO) has been concerned for global blood safety since 1975 as mandated by successive World Health Assembly resolutions. The objective of the WHO programme on Blood Transfusion Safety is to ensure provision of universal access to safe, quality and efficacious blood and blood products for transfusion, their safe and appropriate use, and also ensuring the blood donor and patient safety <http://www.who.int/bloodsafety/en/>

[1]. Similarly, the Directives and Recommendations of European Parliament (EP) and Council of Europe (CoE), require implementing the standards of quality and safety in well-established blood transfusion services [2-12].

The main purpose of the ongoing project - *Strengthening of the Blood Safety System* is to provide quality, efficient and continuous health care to the population of the beneficiary country through providing safety of blood and blood components, as well as through protecting the population from communicable diseases, through:

1. Appropriate implementation of the national legislation in the area of blood safety, aligned with the EU Acquis, which in fact was already achieved in 2011, and
2. Strengthening the capacities of health professionals working in the field for proper implementation of the blood system and providing adequate and timely supplies of safe blood for all patients in need.

Organizational setup of the project

This project is funded by the European Union, with the Ministry of Health and Institute for Transfusion Medicine of the Republic of Macedonia as beneficiaries. It is implemented by Consortium Partners: HD European Consulting Group (ECG) in Serbia, Institute for Blood Transfusion in Serbia and EPOS Health Management in Germany. Its implementation started in March 2013 and it ends in June 2014.

The Consortium employed several international experts. Two key experts (KEs) and 9 non-KEs worked on this project, as well as 3 local IT specialists. The initial purpose was to establish the following activities: provision of 50 Guidelines on Blood Safety and 50 Standard Operating Procedures (SOPs) to be published in hard cover with ISBN number, in color print and with an appropriate design. Furthermore the aim was the provision of training and capacity building in the field of quality management for 150 qualified health professionals, 30 specialists in transfusion medicine, biologists, biochemists, medical laboratory technicians from ITM, 30 inspectors from the Ministry of Health (MOH), whereas 12 specialists in transfusion medicine from ITM and regional Blood Transfusion centers (n = 3) were planned to be trained in EU Countries for a period of up to 10 days.

Results

With the help of Key Experts (KEs) and non-KEs, 54 SOPs were written according to a format required by the EU standards (EUBIS format). Also 50 guidelines were formulated, in line with the most recent Guide of the Council of Europe (CoE), which

complies with EU standards. The guidelines and the SOPs are printed in the required format in 50 fold and are an important deliverable of the IPA project.

The Guide to the preparation, use and quality assurance of blood components of the Council of Europe 17th edition 2013 was translated in Macedonian language and available in hard cover as well on the website of the ITM. In the Guide, all necessary regulations according to the EU standards are formulated to comply with good manufacturing practice (GMP), good laboratory practice (GLP) and good clinical practice (GCP).

A web based document management system (DMS) was established according to user requirement specifications (URS) as formulated by KEs together with the staff of the ITM. The DMS was validated and accepted by the ITM. The DMS is web based information system, allowing every employee of the BTS to have access to the system. The number of licenses to access the DMS from a local laptop or PC is unlimited. Fifty employees from ITM, regional and hospital transfusion centers were trained theoretically and practically to use the DMS. The first SOPs and guidelines will be entered in the DMS before the end of the project.

Fourteen specialists in transfusion medicine from ITM, the regional centers (RC) and hospital centers (HC) were theoretically and practically trained in Slovenia for 10 days in quality management, according to a curriculum of the WHO training courses, organized by KEs with the help of experienced quality managers from Slovenia and The Netherlands. Pre- and post-assessment indicated a significant knowledge gain by the participants. They now represent the core group to train others in the blood transfusion quality management (QM) and to implement what they have learned. An activity plan for improvement of the quality management in 2014 has been made and shall be performed by the 14 specialists in transfusion medicine and the quality managers of ITM. Various documents on validation, GMP, GLP and clinical transfusion practice were made available.

Thirty other specialists in transfusion medicine were trained in the same way in Skopje in a 3-day course.

Three groups of 50 health care workers from ITM and 30 inspectors from MOH were also trained during 2 days by NK experts in quality management in Blood Transfusion.

In all courses the following subjects were discussed with the participants:

- Testing of blood and blood components;
- Storage of whole blood and blood components
- Labeling of blood and blood components;

- Keeping records of all processes in the BTS
- Traceability of each blood donation and components;
- Quality assurance of blood components, including trend analysis
- Maintenance and record keeping of equipment
- Reporting for adverse reaction related to use of blood and blood components (hemovigilance);
- Keeping records of blood and blood component;
- Self inspections and auditing.

Anonymous pre- and post-assessments showed a significant improvement of knowledge in quality management of the participants of all courses, with range 51.3% - 64% in pre-assessment and 57.6% - 80% in post-assessment. Also, participants of all courses answered an anonymous questionnaire for appreciation, indicating high appreciation of the training with 4.4 median score in the scale from 1 to 5.

Also, a "Masterplan", i.e. a final document describing further necessary steps in developing national Blood Transfusion Policy was established, in which KEs gave their vision how the ITM should proceed in the next 4 years to benefit optimally from the unified system and how a quality system, including hemovigilance, should be further implemented, with the aim to comply to GMP, GLP, GCP as required by EU standards.

In the Masterplan the following recommendations were done:

- Having a National Quality Policy, assigning a Quality Managers with well-defined responsibilities and implementation of a Quality System, as started in this IPA project, is of highest priorities and need full support of the authorities (MOH, Central Financing and Contracting Department - CFCD) and the directory boards and staff of ITM, RC and HC.
- Establishing of a Competent Authority for independent inspection of the BTS and training of inspectors is of key importance.
- National Guidelines for specifications and standardization of all transfusion procedures from donor to patient (vein to vein), including a hemovigilance system based on EU requirements should create the framework for the quality management of the national BTS.
- Traceability of blood from donor to recipient.
- Documentation of all personnel files (training, education etc.), equipment, reagents and

materials used should be registered.

- Installation of a modern, preferably web based blood bank information system to enable the registration of donor/ donation, storage and processing of whole blood and components, all laboratory activities, and computer controlled labeling and issue of blood components.
- A 4 year activity and budget plan should be made to achieve the various items mentioned before.

Discussion

We believe that this IPA project had a considerable impact on the development of the Quality Management System of the ITM, as well as other regional and hospital Blood Transfusion establishments. Approximately 225 employees of the BTS, coming from all over the country were trained in quality management. A core group of 14 transfusion specialists from ITM, regional and hospital transfusion centers were trained in quality management in Slovenia, and they are now engaged in making SOPs for all procedures and describing guidelines and specifications, applicable for the Macedonian BTS.

Translation into Macedonian language of the most recent (2013) Guide of the Council of Europe is available and can be used as reference to make uniform guidelines and SOPs in the whole country. The Guide is available in hard cover as well online via the website of the ITM. This will influence significantly the quality management of the BTS.

The 54 SOPs and 50 guidelines that were established during this project, represent only the beginning of future documentation in regard to quality management.

The impact of the DMS is very important, since all trained employees have now access to uniform guidelines and SOPs for the whole of the country. All documents related to quality (SOPs, regulations, audit results etc.) can be registered in the DMS. All employees at ITM, regional and hospital centers (n= 19) can now obtain an official and controlled access to the DMS and documents included within, since the number of licenses for the DMS are unlimited.

The prepared SOPs and guidelines represent the core of future document collection that will be contained within the DMS. All together several hundreds quality related documents are expected to enter DMS in next years, allowing a centralized managing and supervision of documentation.

We are convinced that with the results of this IPA project, a sustainable start of Quality Management in the Institute for Transfusion Medicine of Republic of Macedonia as well as in regional and

hospital Blood Transfusion centers has been achieved. However, 15 months of the project taking place is a relatively short period for implementation of sustainable improvement of the BTS. Therefore, the Key Experts advise to continue to help the Macedonian BTS for the next 4 years, in order to achieve a sustainable organization, in compliance with all EU standards.

Disclaimer

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