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EU-Q-BLOOD-SOP: DEVELOPMENT OF PAN EUROPEAN QUALITY MANAGEMENT IN TRANSFUSION MEDICINE.

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Background: Quality management systems in blood transfusion are of high importance for the safeguard of blood and blood components.

Aims: The EU-Q-Blood-SOP Project is co-funded by the European Commission and supports the public health program on 'quality and safety of blood' in delivering a practical SOP-based tool that will contribute to the understanding and management of quality processes in blood services. The EU-SOP tool will assist blood establishments in preparing for the inspection of their services related to the implementation of quality relevant elements required by the EU Directive 2002/98/EC and its technical annexes. This SOP 'tool' will address the responsibilities of blood establishments, including those that carry out routine activities and those that are highly specialized, as well as hospital blood banks.

Methods: In order to find out the current status of SOPs, their structures and any potential manuals or regulations that are in place in the various participant institutions and countries, including the current inspection practice, a questionnaire has been designed by the project team and has been send-out to the participating blood establishments from 16 EU Member, Acceding or EFTA states.

Results: Based on this questionnaire differences and commonalities in the approach to basic structural questions in quality management and specific aspects considering SOPs have been evaluated and summarized in a survey report. It identifies some of the perceived high risk areas in blood collection, preparation, laboratory testing, storage and distribution. 7 of 15 (47%) participating blood establishments considered, that their present SOP system needs to be changed in the light of the European blood legislation, based on Directive 2002/98/EC and its technical annexes. These were mainly participants from the new Member States and Applicant Countries. 4 of 15 (27%) participants (2 from Applicant Countries and 2 from established EU Member States) indicated that their blood establishment is not inspected by governmental authorities.

Summary: Currently used standards for quality management systems are heterogeneous. The new EU-SOP methodology comprises precise quality requirements, requisites and quality terms linked to the EU Directives and based on GLP/GMP-standards that have to be specified (filled-out) in order to complete the documents. These quality requirements will be set-up in a modular fashion, in order to tailor the SOPs to meet local circumstances.

These results are presented by the project team and advisory board on behalf of the Projects participants (DRK BSDBH, Germany; HBRK, Belgium; NBT, Bulgaria; MOH, Cyprus; VFN, Czech Republic; EBS, Estonia; EFS, France; HNBT, Hungary; BTS, Iceland; NBTS, Ireland; ISS, Italy; IBT, Malta; IHBP, Poland; FMP, Romania; Sanquin, The Netherlands; SNBTS and NBS, United Kingdom). The project is co-funded by the European Commission, Directorate C.