E6. LEGISLATIVE BENCHMARKS AND NATIONAL STANDARDS RELATED TO THE HOSPITAL TRANSFUSION ACTIVITY

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Introduction: The importance, magnitude and increasing complexity of transfusion therapy in modern medical practice, as good as evidence of a residual risk that can not yet be reduced to zero imposed a set of Community requirements (standards and specifications) regarding the organization and the scope of activity for HBBs. The transfusion activity in the clinical service is regulated by national legislation.

Objective: Review of the legislative framework and standards that regulate the hospital transfusion activity, supported by explanations on correct interpretation, implementation and continuous improvement.

Methods: This presentation reviews the EU (Directive 2002/98/EC, Directive 2004/33/EC, Directive 2005/61/EC, Directive 2005/62/EC) and national (Law 282/2005, Order 607 / 2013, 1214/2006, 1224/2006, 1132/2007, 1227/2006 updated, 1228/2006 updated, 1237/2007 updated, 1226/ 2006 updated, 1343/2007) requirements, emphasizing the logical sequence of steps recommended for hospital managers and physicians in charge with HBB coordination to accuratly and effectivly implement these requirements, for the benefit of patients. Risk- assessment based solutions are proposed, supported by examples from practice.

Information on various relevant international guidelines and recommendations for quality assurance and transfusion safety in the hospital are provided.

Results: The presentation provides an algorithm for the implementation of organizational, technical and quality assurance requirements for hospital transfusion activity, adaptable to the type of hospital, in order to ensure a real improvement in this activity and not just a formal compliance to a new set of legal regulations.

Conclusions: Awareness of hospital managers and treating physicians on the real role of transfusion therapy as part of overall curative or supportive measures is a precondition for a successful qualitative and safe transfusion activity, in accordance with the current requirements and standards. Otherwise, the action taken is limited to a superficial, quick and often partial response to formal and legal requirements, leaving space for errors and incidents that may endanger the patient's life.