QUALITY CONTROL OF PLATELETS CONCENTRATES BETWEEN LEGAL REQUIREMENTS AND IMPLEMENTATION CONSTRAINTS

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Introduction: Directive 2004/33/EC sets up safety and quality requirements for blood and blood components and technical quality control conditions for each product. Transposition of these legal provisions into national legislation has been finalized, which implies blood establishment's obligation to implement them. Quality control for platelet concentrates includes: volume, number of platelets, number of residual leucocytes (for leucodeplated concentrates), bacteriological control and ph at the end of shelf-life., for a certain number of units, determined by using the statistical control process. Correct and efficient quality control assume some managerial measures like organization of the quality control laboratory, appropriate equipment, trained personnel, standard operating procedures, as well as nationally uniform registration, analysis and report. Among all required measurable parameters, ph measurement is the one not yet implemented because of the lack of equipment in the blood establishment.

Material and method: The paper presents the BCSI 1000 equipment and results
of the evaluation performed in blood transfusion centre of Constanta, concerning the method, procedure, implication on the process flow. 50 recovered platelet concentrates and 10 apheresis platelet concentrates were tested along their shelf life, and few days after. All platelet concentrates were tested also by bacteriological control by the end of evaluation period.

Results: Platelet units were randomly selected and splitted in two groups:40 recovered platelet concentrates and 5 apheresis concentrates were tested for ph at the end of their shelf life (measurement at day 6,7,8,9) and the other 10 recovered and 5 apheresis concentrates were tested on a daily basis (day 1 up to day 9). All tested units presented ph values complying with the standard (> 6,2) .Bacteriological control was negative.

Conclusion: The device BCSI 1000 may be the choice for the quality control laboratories, due to the ease of use, results repeatability and reproducibility, non-invasive and non-destructive procedure, which represents advantages compared with other ph-meters.

This will solve the current noncompliance with the standard regarding mandatory quality control for blood components. Still, cost-efficient and effective implementation of this device in routine use in blood establishments would require an unitary approach at national level, based on the centralization of ph control in larger blood establishments.