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INNOVATIVE TECHNOLOGY SUPPORTING ACTIVE
TRACEABILITY: THE “VEIN TO VEIN PROCESS” IN BLOOD
TRANSFUSION

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Background: Traceability and documentation of every step during the “vein-to-vein” process is of utmost importance and its Quality System in the European Union must comply with specifications of Good Practice Guidelines (GPS, Directive 1214/2016)

Aims: To validate the IT SCWeb[®] System designed to assist critical steps of the “vein to vein” process (blood collection, transport and processing, clinical transfusion) by using electronic devices to ensure both active traceability and documentation of each step.

Methods: The SCWeb[®] System is based on IT monitored checklists which guide the personnel to follow the procedure, according to best practices; the system must initially be activated by the operator which is recognized by an auto-signing system based on Bluetooth Low Energy which avoids the operator having to identify himself/herself beforehand. Appropriate privacy protection is provided. The system takes up the task to give instructions and to verify the adherence, by asking an active confirmation of the proper fulfillment of the activities; a continuous registration and documentation is made. Standards and specifications for each step of the different procedures have been configured on SCWeb[®].

Results: In Blood collection electronic check list can track codes and expiration dates of kits, disposables, bags, test tubes, donors, donation number, labelling, skin disinfection, venipuncture and any event during donation. In transport SCWeb[®] System has been integrated with TAG RFID UHF, the technology thus allowing traceability of: timing of collection, check-out and check-in, boxes, thermometers for transportation; in blood processing registration of centrifugation, intermediate and final storage, labelling, plasma freezing and shipment to pharmaceutical company of plasma units and tubes for NAT testing is allowed. In clinical transfusion SCWeb[®] System can track in detail patient identification, presence of consent to transfusion, blood pressure, pulse and temperature recording, verification of the blood unit, vein access and clinical follow up including an alarm at regular intervals to ensure the control of patient's conditions. For each step, every operator, recognized thanks to the Bluetooth Low Energy auto-signing device, must give an active confirmation of the action performed; tracking all the operators involved, the system thus allowing exchanges of different operators during the process, always identifying people responsible for each action.

Summary/Conclusions: The SCWeb[®] system required a very short training allowing its implementation without negative impact on organization and without difficulties by operators who appreciated the help given by the IT check system. The registration of the electronic check list offered a reliable tool for the traceability of the entire process, also granting a paperless and timely available documentation of any part of it through a registration in electronic format of all the actions performed by operators in every single phase of the process. The SCWeb[®] system can be utilized as a barrier against the errors in critical steps alongside the transfusion chain, as a traceability and documentation measure and as a tool for training of personnel in blood processes.