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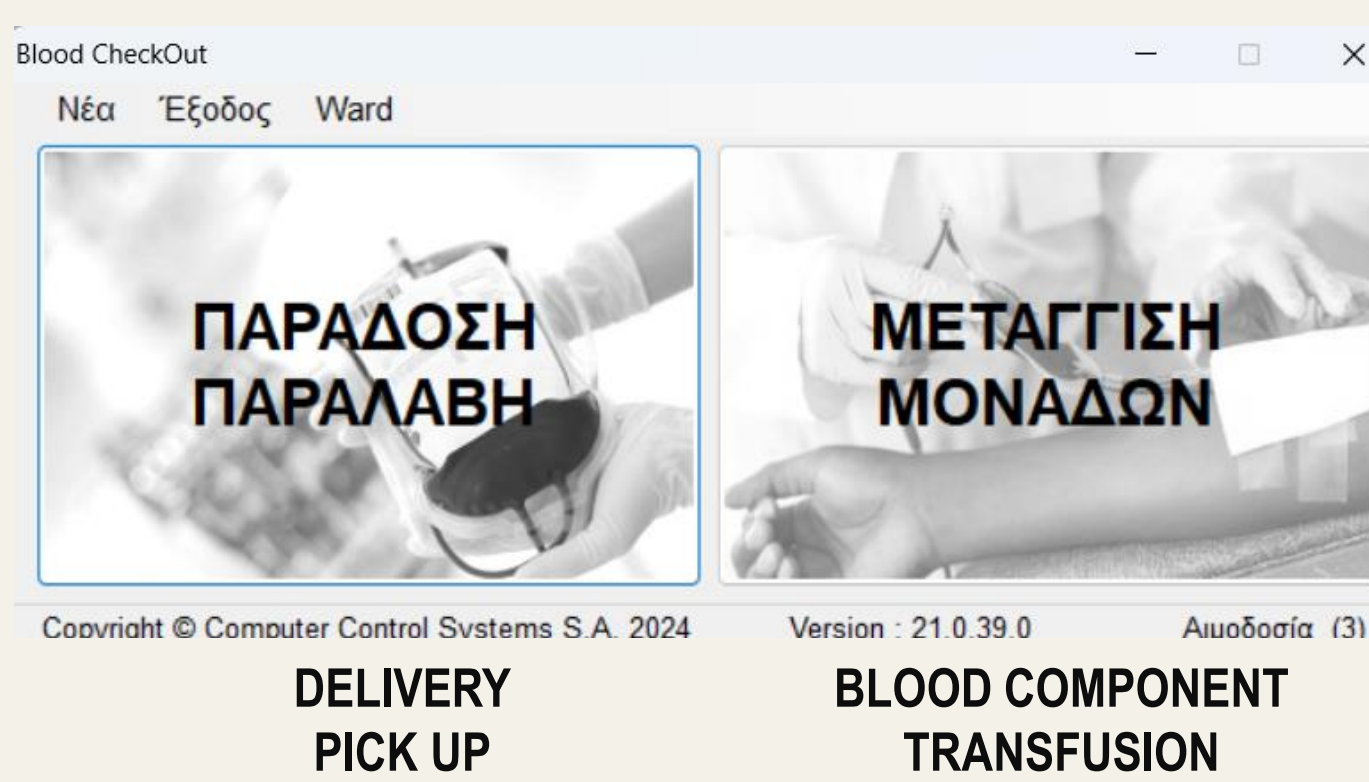
Introduction

Traceability is essential for the effective implementation of any biovigilance system. In the blood sector, traceability refers to the ability to track every individual unit of blood and its derived components from donor to recipient and vice versa. This process is defined by the European Directorate for the Quality of Medicines & HealthCare (EDQM) Blood Guide and EU Directive 2005/61/EC. Traceability information can be captured through manual, electronic, or combined processes. In our Hospital Blood Bank (HBB), the traceability process between donors and recipients was conducted manually by the Transfusion Safety Officer (TSO). The TSO manually reviewed the charts of transfused patients to ensure traceability from donor to recipient and vice versa.

Aim

Our aim is to implement a preliminary bespoke computerized system for documenting the transfusion of blood components (BC) to ensure that each unit is transfused to its designated recipient as issued by the Hospital Blood Bank (HBB).

Method



Transfusion traceability was achieved using the Blood Check Out - CCS (BCO) software. This software facilitated the recording of timing and user information at each sequential step of the transfusion process, starting from the issuance of the blood component to its final destination in the patient. The results were analyzed using Microsoft Excel 2019.

AUTHENTICATION

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Results

A total of 2821 blood derivative deliveries were analyzed from March to December 2023. Real-time recording of user information (transporter/nurse/physician) was conducted at four key steps of the transfusion chain from the Hospital Blood Bank (HBB) to the patient's bedside clinic:

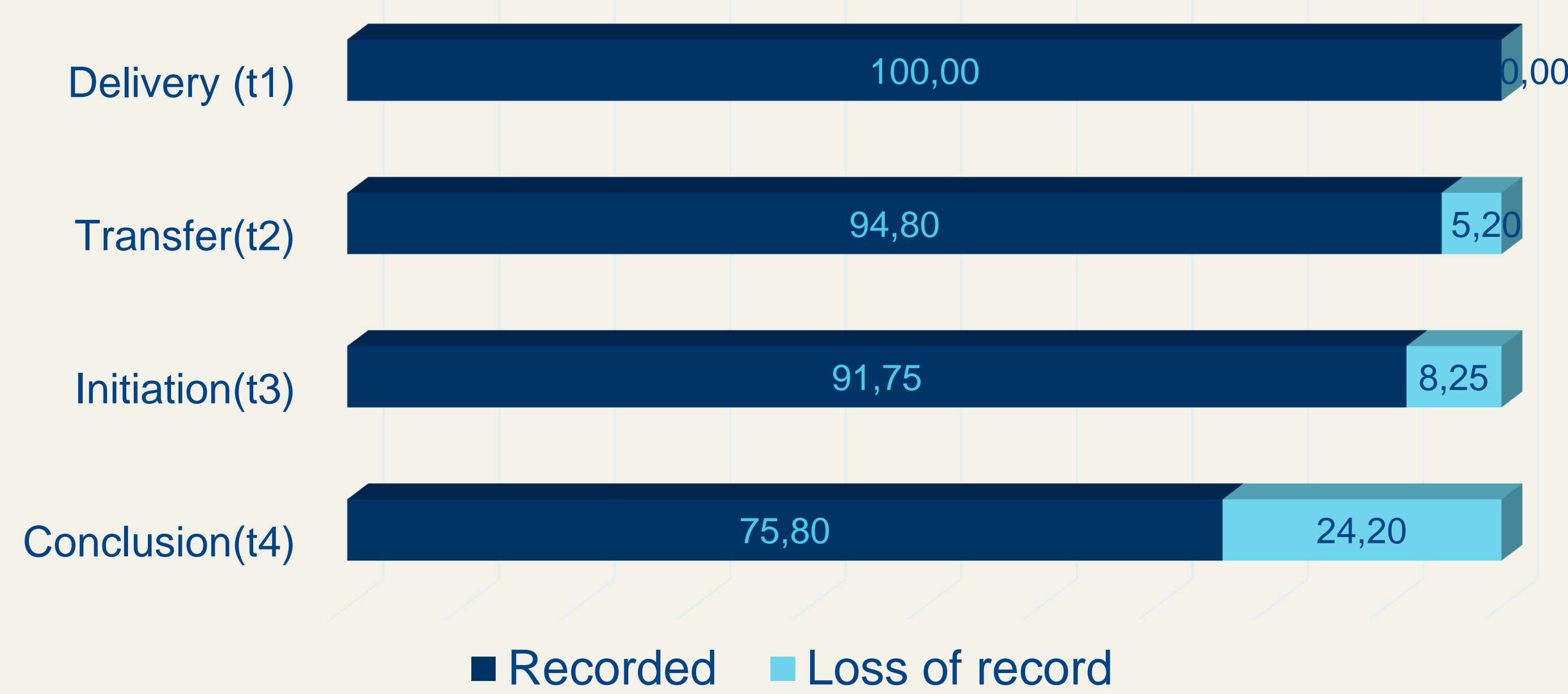
1. Delivery of the blood component by the HBB staff to a designated transporter (t1).
2. Transfer from the transporter to the clinic staff of the recipient's clinic (t2).
3. Initiation of the transfusion by the attending physician (t3).
4. Conclusion of the transfusion by the recipient clinic's staff (t4).

The completeness of recording at each step of the transfusion chain is summarized in Table 1 and Graphs 1,2 & 3.

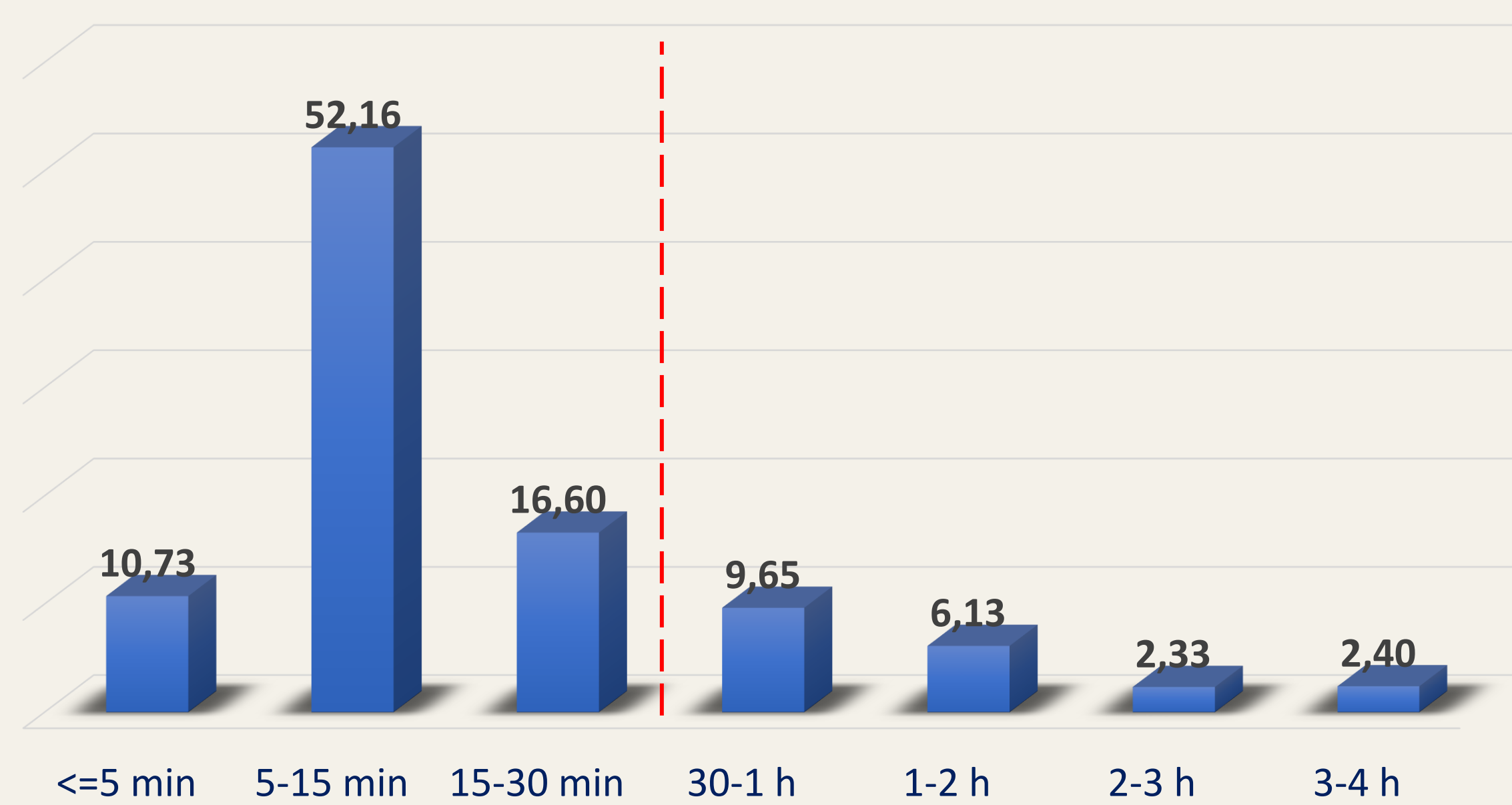
Table 1: Completeness of recording of BCs transfusion steps

Step	N	Traceability %	Acceptable time range %
t1	2821	100	BC transportation (t2-t1 <=30min) 79,49
t2	2664	94,80	
t3	2578	91,75	Transfusion Duration (t4-t3 <=4 hours) 56,53
t4	2100	75,80	

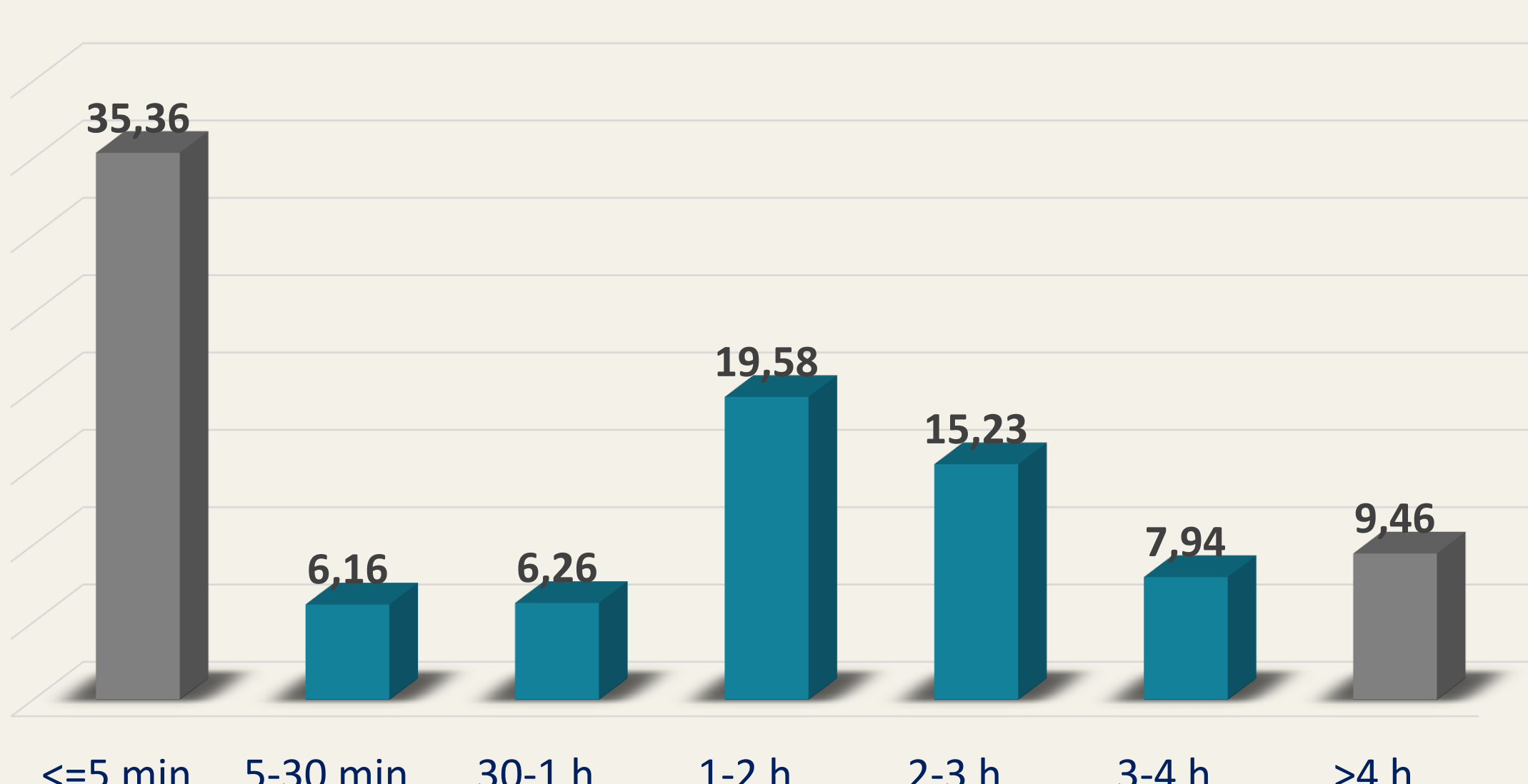
Graph 1: Completeness of recording of BCs transfusion steps



Graph 2: BC transportation



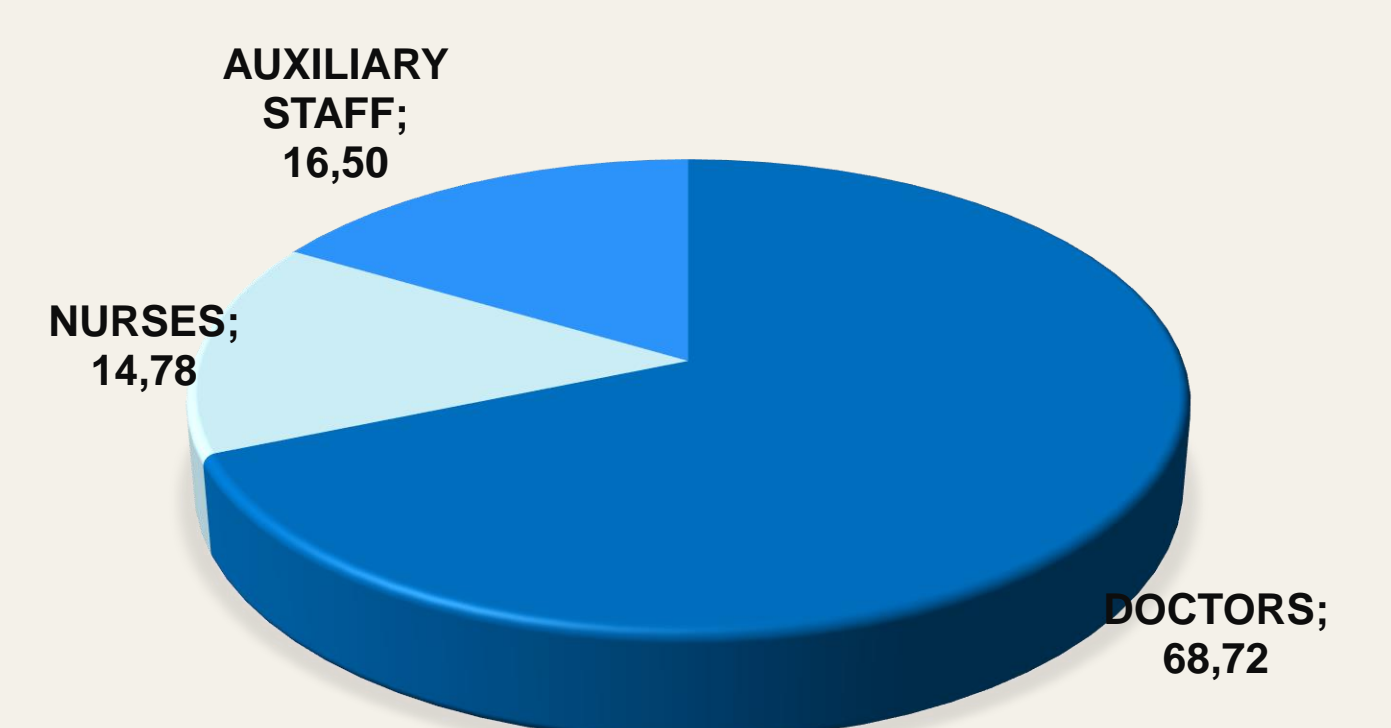
Graph 3: Transfusion Duration



The initiation of transfusion was not recorded in **8.25%** of cases, while the end of transfusion was not recorded in **24.20%** of cases.

In 43.83% of cases, the recording of steps in the system was conducted by a single user.

Furthermore, the retrieval and transportation of units were carried out by medical professionals, with doctors comprising 68.72%, nurses 14.78%, and auxiliary staff 16.50%.



Conclusion

It appears that clinic staff may not fully appreciate the significance of electronically documenting steps in the transfusion chain. Despite advancements in electronic documentation over time, recording of critical steps, notably the initiation of transfusion, remains deficient. The manual method of traceability surveillance, though labor-intensive, yielded superior results (traceability >95%, data not provided). The mandatory concurrent use of electronic and manual systems during the program's validation phase appears to be the primary reason for traceability loss. Following program validation, concerted efforts should focus on educating and communicating with personnel to ensure real-time, mandatory utilization. This initiative is expected to elevate traceability percentages to anticipated levels.

