Letter to the Editor

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Preanalytical errors before and after implementation of an automatic blood tube labeling system in two outpatient phlebotomy centers

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To the Editor,

Total quality in diagnostic testing entails standardization or harmonization of all activities throughout the testing process, thus including the manually intensive, and still largely operator-dependent, steps of the preanalytical phase [1]. Several lines of evidence confirm that most diagnostic errors are actually attributable to problems occurring during or immediately after collection of biospecimens. In particular, inaccurate patient and sample identification, along with collection of unsuitable samples (i.e. spurious hemolysis, insufficient volume, undue clotting, wrong collection tube), are the most frequent causes of test results suppression [2, 3]. Although the implementation of preanalytical workstations has been advocated as a valuable means for reducing the burden of human errors and, therefore, for decreasing the vulnerability of the preanalytical phase [4, 5], evidence in support of the effectiveness of these devices in a real world scenario remains limited [6]. Therefore, this retrospective interventional study was aimed to verify whether the implementation of Inpeco ProTube (Inpeco, Lugano, Switzerland) automatic blood tube labeling device may be effective to reduce the rate of preanalytical errors recorded in two outpatient phlebotomy centers of a large University Hospital.

The ProTube is an automatic blood tube labeling devices, which features several important functions for limiting manual operations and for ultimately lowering the risk of preanalytical errors, as thoughtfully described elsewhere [6]. Briefly, the device guides phlebotomist step-by-step throughout the sample collection process, enabling univocal health card reading, barcode identifier scan, automatic connection to patient data, recognition of blood tubes to be automatically labeled by their cap color, printing and attachment of labels to blood tubes and final check-out of blood tubes after collection. Our analysis of preanalytical errors rate was divided in two comparable periods of time, i.e. before implementation (21 months, between January 1, 2014, and September 31, 2015, in the University Hospital of Verona; 24 months, between January 1, 2014, and December 31, 2015, in the General Hospital of Verona) and after implementation (21 months, between April 1, 2016, and December 31, 2017, in the University Hospital of Verona; 24 months, between March 1, 2016, and February 28, 2018, in the General Hospital of Verona) of ProTube in each ambulatory of the two local outpatient phlebotomy centers. Operators' familiarization with the new device required 6 and 2 months in the two outpatient phlebotomy centers, respectively. This time was necessary for customizing all those operations, which were previously carried out manually by the staff of the two phlebotomy centers. All potential confounding variables were minimized throughout the study period. More specifically, preanalytical errors occurring in the two outpatient phlebotomy centers were automatically recorded in a digital database constructed according to the current recommendations of the International Federation of Clinical Chemistry and Laboratory Medicine Working Group "Laboratory Error and Patient Safety" and the European Federation of Clinical Chemistry and Laboratory Medicine Task and Finish Group "Performance specifications for the

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Table 1: Rates of preanalytical errors before and after implementation of Inpeco ProTube in two outpatient phlebotomy centers.

Type of error	Before implementation (%)	After implementation (%)	OR (95% CI)
Misidentification	0/677,762 (0)	0/680,072 (0)	–
Hemolysis	61/135,945 (0.045)	81/132,608 (0.061)	1.361 (0.976–1.898); p = 0.069
Undue clotting	88/125,264 (0.070)	93/117,885 (0.079)	1.123 (0.839–1.503); p = 0.435
Wrong blood tube	45/677,762 (0.007)	18/680,072 (0.003)	0.399 (0.231–0.689); p = 0.001
Sample lost	79/677,762 (0.012)	38/680,072 (0.006)	0.479 (0.326–0.706); p < 0.001
Underfilled tube	26/125,264 (0.021)	12/117,885 (0.011)	0.490 (0.247–0.972); p = 0.041

OR, odds ratio; 95% CI, 95% confidence interval.

extra-analytical phases" [7–9]. The study was carried out using blood collection tubes produced by the same manufacturer (Kima, Padova, Italy) and was extended throughout a comparable period of time (i.e. 45 months before and 45 months after implementation). The phlebotomy staff and all the standard operating procedures for venipuncture, sample transportation and error registration remained unchanged in both the outpatient phlebotomy centers before and after implementation of ProTube. The rate of preanalytical errors was reported as percentage of total outpatients phlebotomized or blood tubes collected (when appropriate) in the two local phlebotomy centers, before and after ProTube installation. The significance of differences before and after the intervention was assessed by χ^2-test, whereas risk variation was expressed as odds ratio and 95% confidence interval (Medcalc, MedCalc Software, Ostend, Belgium). The implementation of ProTube in the two outpatient phlebotomy centers was cleared by the Medical Direction of the University Hospital of Verona. The study was carried out in accordance with the Declaration of Helsinki and under the terms of all relevant local legislations.

The results of this study are shown in Table 1. No significant variation was found in the rate of hemolyzed specimens and those with undue clotting, whereas a substantial reduction was observed for samples collected in the wrong tube (i.e. ~60%), samples lost and for underfilled tube (i.e. both ~50%). No identification errors occurred either before or after the implementation of ProTube.

Taken together, the results of this study attest that the implementation of an automatic blood tube labeling device in two large outpatient phlebotomy centers was effective to reduce the burden of certain preanalytical errors, especially those related to collection of wrong tubes, samples lost and underfilled tubes, whereas no substantial variation was found in the rate other types of common preanalytical errors. Interestingly, the lower rate of underfilled tubes recorded after introducing ProTube was probably achieved thanks to the compelling need of checking out the tubes after collection, which would allow a more accurate recognition of filling volume, as well as to the more standardized positioning of the label on the tube, thus permitting to more precisely checking blood filling. These results supplement earlier data published by Piva et al. [6], who showed that ProTube enables a more efficient management of the entire blood collection process. Interestingly, the substantial reduction of the three preanalytical errors (wrong tubes collection, samples lost and underfilled tubes) recorded after implementation of ProTube is probably attributable to the better compliance to phlebotomy practice enabled by the automated labeling system device, which not only permits enhanced traceability of blood samples at the collection site but also requires systematic check-in and check-out of blood tubes, thus improving collection of the correct sample type and reducing the risk that phlebotomists will forget to collect all the samples needed. Notably, although no identification error could be recorded before or after implementation of ProTube, it is reasonable to envision that the univocal health card reading combined with barcode identifier scan and automatic prelabeling of blood tubes features characterizing this device may also contribute to mitigate the risk of identification errors [10].

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