Exploring the Initial Steps of the Testing Process:
Frequency and Nature of Pre-Preanalytic Errors

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BACKGROUND: Few data are available on the nature of errors in the so-called pre-preanalytic phase, the initial steps of the testing process. We therefore sought to evaluate pre-preanalytic errors using a study design that enabled us to observe the initial procedures performed in the ward, from the physician’s test request to the delivery of specimens in the clinical laboratory.

METHODS: After a 1-week direct observational phase designed to identify the operating procedures followed in 3 clinical wards, we recorded all nonconformities and errors occurring over a 6-month period. Overall, the study considered 8547 test requests, for which 15,917 blood sample tubes were collected and 52,982 tests undertaken.

RESULTS: No significant differences in error rates were found between the observational phase and the overall study period, but underfilling of coagulation tubes was found to occur more frequently in the direct observational phase \( (P = 0.043) \). In the overall study period, the frequency of errors was found to be particularly high regarding order transmission \([29,916 \text{ parts per million (ppm)}]\) and hemolysed samples \([2537 \text{ ppm}]\). The frequency of patient misidentification was 352 ppm, and the most frequent nonconformities were test requests recorded in the diary without the patient’s name and failure to check the patient’s identity at the time of blood draw.

CONCLUSIONS: The data collected in our study confirm the relative frequency of pre-preanalytic errors and underline the need to consensually prepare and adopt effective standard operating procedures in the initial steps of laboratory testing and to monitor compliance with these procedures over time.

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In the last 2 decades, significant advances have been made in the understanding of errors in medicine and in reducing the frequency of these errors, including those made in the clinical laboratory. After an initial focus on analytic errors, a body of evidence has demonstrated that the preanalytic steps of the total testing process (TTP) are more error-prone than the other intra- and postanalytic steps (1). Achieving consensus for the comprehensive definition of errors in laboratory testing (2) was a milestone in the effort to reduce errors and improve patient safety in laboratory medicine. Indeed, this definition, which encourages a patient-centered approach, emphasizes the need to evaluate all steps of the testing process irrespective of whether they fall under the direct control of laboratory personnel (3). Most of the available data on errors in laboratory medicine, however, have been collected through laboratory-centered study designs that have identified nonconformities at the laboratory level and have reevaluated results considered implausible with respect to the patients’ conditions or previously obtained results (4, 5). Thus, the preanalytic phase has been demonstrated to be error-prone, but the underlying mechanisms and causes for this have not been fully analyzed because they are mainly related to procedures and personnel outside the laboratory walls. In many countries (and most of the countries in Europe) there are no professional phlebotomists, and most initial procedures of laboratory testing (e.g., test requesting, patient identification, and blood collection) are performed by physicians and ward nurses. This complicates any exploration of the initial TTP procedures, grouped under the term “pre-preanalytic phase,” which are “usually performed neither in the clinical laboratory, nor, at least in part, under the control of laboratory personnel” (1).

The aim of the present study was therefore to evaluate pre-preanalytic errors in a patient-centered scenario, by use of a study design that allowed us to observe the initial procedures performed in the ward, from the physician’s test request to specimen transportation to the clinical laboratory, the ultimate goal being to establish appropriate quality improvement initiatives.
Material and Methods

We conducted the study over a 6-month observation time (October 2010 through March 2011) in 3 clinical wards (ward A, rehabilitation with 21 beds; wards B and C, 2 internal medicine wards with 31 and 32 beds, respectively) in the S. Antonio Hospital in Padova, which has 375 beds and is a public institution of the Italian National Health Care system. All the laboratory tests considered in the study were performed in the clinical laboratory of the same hospital. The study design was approved by the medical administration of the hospital itself, with the active involvement of the medical and nurse staff of the wards. The pre-preanalytic workflow used by the individual ward was analyzed in detail and described in a flow chart. The study design had 2 steps: (a) a direct observational phase lasting 1 week in which a member of the team (T. Zago) was appointed to follow the ward personnel in each clinical department during all steps of test requesting and (b) the identification of all errors and noncompliance events over a 6-month interval (overall study period). In particular, the following information was recorded: (a) how the orders were transmitted by physicians (name and bed number were required); (b) procedures and traceability of manual transcriptions; (c) computerized order entry; (d) patient preparation; (e) tube labeling; (f) identification of the patient by bed number, name, and wristband check at the time of blood sampling; (g) sampling tools and procedures for blood draw; and (h) packaging and delivery of samples. All these operations were described in appropriate instructions, specific for every ward; any violation of operating procedures was recorded as nonconformity even it did not result in an error.

In the postanalytic phase, we made a critical evaluation of all reported results with the collaboration of the staff from the wards involved in the study. Overall, 13 physicians, 29 nurses, and 3 supervisors were actively involved in the study. Analogously, during the study period, the laboratory personnel were instructed to report every potential quality failure and/or nonconformity regarding the acceptability of biological samples. We evaluated plasma or serum hemolysis using the automatic serum index for clinical chemistry testing (Dimension EXL, Siemens Healthcare Diagnostics) or through visual inspection for other tests, 0.5 g/L free hemoglobin being considered the cutoff. Overall, the study took 8547 test orders into account (15,917 blood sample tubes and 52,982 tests), as shown in Table 1. We evaluated the statistical significance of differences between error rates in the overall study period (6 months) and in the direct observational phase (1 week) using the test for equality of proportions with the statistical software STATA version 10 (Statacorp LP).

Results

Both similarities and differences were found in the preanalytic workflows of the 3 wards involved in the study (Table 2). The steps found to be identical were (a) manual transcription of tests requested for the following day into a medical diary, (b) communication by nurses of daily monitoring for laboratory tests on a whiteboard or an ad hoc worksheet; (c) computerized order entry by a nurse; (d) patient preparation (e.g., fasting or not) during the night shift; and (e) blood collection by a nurse during the day shift. However, major differences were identified: (a) in Ward A, blood collection was undertaken with unlabeled tubes, identification labels being applied later on; (b) in Ward B, patients were not informed that overnight fasting was required, and laboratory tests for monitoring were recorded on a manually prepared worksheet; and (c) in Ward C, tests requested were transcribed twice, first into a diary and second to a manual worksheet by a nurse, before being entered in the computer system.

Therefore the number of transcription steps ranged from 2 to 3 depending on the individual ward, and these transcriptions were carried out without any automated support for the prevention of errors and mistakes. On analyzing the recorded transcriptions, several types of errors and nonconformities were identified, as shown in Table 3. The most frequent nonconformity regarding the acceptability of biological samples. We evaluated plasma or serum hemolysis using the automatic serum index for clinical chemistry testing (Dimension EXL, Siemens Healthcare Diagnostics) or through visual inspection for other tests, 0.5 g/L free hemoglobin being considered the cutoff. Overall, the study took 8547 test orders into account (15,917 blood sample tubes and 52,982 tests), as shown in Table 1. We evaluated the statistical significance of differences between error rates in the overall study period (6 months) and in the direct observational phase (1 week) using the test for equality of proportions with the statistical software STATA version 10 (Statacorp LP).
formities (lack of compliance with existing standard operating procedures) were (a) test requests that were made in the diary without the patient’s name and with the bed number only, and (b) the collection of blood samples without a check of the patient’s identity on the wristband at the time of blood draw. In particular, blood collection with prelabeled tubes resulted in 2 of 3 episodes of sample misidentification, thus underlining the risk of this procedure, which violated existing guidelines (6). Table 4 shows the preanalytic errors detected during the overall study period in comparison with the direct observational phase. The relative frequency of errors was calculated by dividing the number of tests involved by the overall number of tests performed in the 6-month study span (amounting to 52,892) and in the week of the direct observational phase (2349 tests). No significant difference ($P < 0.05$) was found in error rates (for all types of error) between the observational phase and the overall study period, but underfilling of coagulation tubes was found to be a more frequent error ($P = 0.043$) in the direct observational phase. In 3 cases, patient misidentification was particularly noteworthy, since it had a potential adverse impact and posed a risk to patient safety.

**Discussion**

Although several articles have described preanalytic errors in terms of unacceptable samples, such as hemolysed, clotted, and/or insufficient specimens (4, 5, 7–9), few data available in the literature relate this type of quality failure to mechanisms and procedures which, if not followed, expose patients to the risk of errors and the related adverse events, particularly in the case of patient misidentification. The data reported in the present study confirm the relative frequency of preanalytic errors, including the misidentification error rates, found to be 359 parts per million (ppm), a rate that is similar to that previously reported (270 ppm) (5). Considering the complexity of the processes and procedures related to the pre-preanalytic phase and the difficulties entailed in designing a study methodology that enables the detection of all potential defects and errors, a frequency higher than that actually found would be anticipated. The novelty of the present study relates to the information gathered on the effective standard operating procedures used in the wards for test requesting, particularly the transcription of physicians’ orders before computerized entry, information recording, and blood drawing. Of particular concern is the finding that 29,916 ppm (about 3%) of tests requested by physicians were lost in translation or mistaken. The 3 cases of patient misidentification were found to be related to human errors due to poor or nonexistent compliance with established procedures and/or inappropriate training of personnel. Two of these cases occurred in wards B and C, which used prelabeled tubes for their blood collection procedure. Although a detailed description of these cases is forth-
coming, it should be stressed that there is existing consen-
sus on how to reduce errors in medicine with the so-called system approach. The basic premise of this model is that humans are fallible and errors are to be ex-
pected, but the errors are consequences rather than causes, and they originate in systemic factors (10).

Countermeasures are based on the assumption that although the human condition cannot be changed, the conditions under which humans work, including the defensive measures, barriers, and safeguards applied, should and must be improved on. In the cases identified in our study, underlying organizational problems were recognized in the number of manually performed transcription steps, the lack of any control tool, lack of any support from information technology, and finally, the excessive workload and responsibility assigned to the nurses.

The implications of the above problems were made painfully clear by the 3 cases of misidentification we observed.

Case 1. The nurse correctly entered the computerized order for a test request into the system, but then made an erroneous selection of the patient’s name, because the computer displayed only the initial few letters of the patient’s name. No check of the patient identity was made on the printed labels and, when collecting the blood, the nurse verified the test order by following the bed number only, without making the necessary wristband check.

Case 2. In a stat request made by a physician, the patient’s name was omitted, only the bed number being entered. On entering the request in the computer, the nurse selected the patient’s name by making reference to the bed number list of the patients hospitalized in the ward. The wrong selection was made, because there was a patient with the same bed number but with additional information for the duplicate bed number (“bis”); this suffix applied to the bed number is a conventional means for identifying extra beds in the wards, brought about by an excessive number of admissions. The wristband check was not made.

Case 3. A test was requested by a physician for a patient identified as “bed 4 bis.” The appropriate computerized order entry was made for the effective patient in bed 4 bis, but blood was drawn from the patient in bed 4. The wristband check was not made.

Although these episodes of misidentification had no adverse events on the patients involved, their potential risk should never be underestimated and appropriate actions should be taken to prevent further errors (11). Regarding the effect of errors on patient care and safety, we identified only one case that translated to a wrong therapeutic decision, owing to an error in the blood collection procedure. A patient with severe hypokalemia was given a supplementary 40 mmol KCl solution in 500 mL saline, through a central venous line. A serum potassium was requested to monitor the infusion, and the nurse, after draining away 2 mL of fluid from the infusion catheter, disposed of the contents and collected the blood. When a critical K⁺ value (6.8 mmol/L) was communicated to the clinicians, the infusion was interrupted. Results from a new sample, obtained after the value had been discussed with the laboratory staff, confirmed that the previous sample had been diluted and contaminated with the infusion solution. This error was clearly due to noncompliance with existing operational procedures. Although no other adverse events or serious effects on patient care were found by us, similar episodes reported in the literature by other authors underline the risk of this type of error and the consequent missed or delayed diagnoses (12, 13).

Table 4. Number of preanalytic errors identified during the overall study period (6 months) with respect to the direct observational phase (1 week).a

<table>
<thead>
<tr>
<th></th>
<th>Overall study period</th>
<th>Direct observational phase</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tests involved, n</td>
<td>Frequency, ppm</td>
</tr>
<tr>
<td>Underfilled coagulation tube</td>
<td>33</td>
<td>611</td>
</tr>
<tr>
<td>Clotted sample</td>
<td>47</td>
<td>871</td>
</tr>
<tr>
<td>Empty tube</td>
<td>2</td>
<td>37</td>
</tr>
<tr>
<td>Hemolysed sample</td>
<td>137</td>
<td>2537</td>
</tr>
<tr>
<td>Diluted sample</td>
<td>4</td>
<td>74</td>
</tr>
<tr>
<td>Incorrect sample shipping</td>
<td>62</td>
<td>1148</td>
</tr>
<tr>
<td>Wrong patient identification</td>
<td>19</td>
<td>352</td>
</tr>
<tr>
<td>Total</td>
<td>304</td>
<td>5630</td>
</tr>
</tbody>
</table>

a Error frequencies were calculated on 53,987 and 2,349 tests, respectively.
The present study has several limitations. First, only 3 clinical wards were involved, and they cannot be considered entirely representative of the current situation in laboratories. However, this selection was considered sufficient for making an in-depth evaluation and monitoring the effective workflow and related procedures, thus allowing nonconformities and errors to be identified in a clinical setting. Second, the findings of the study revealed differences in operating procedures and their implementation in Italy, where the lack of qualified phlebotomists makes it difficult to make any comparison with other countries, the US in particular, for the types of error that occur and the corresponding error rates. Therefore, our data are relevant only for institutions that employ ward personnel (nurses and medical doctors) for blood collection. Third, we did not investigate an essential step of the preanalytic phase, the appropriateness of test requests; this aspect is a major concern for patient safety. Fourth, although accreditation and certification programs are mandatory, there is widespread lack of compliance with existing operating procedures in Italy; moreover, little attention is paid to developing effective operating procedures in the initial steps of laboratory testing. This latter problem may be symptomatic of a cultural issue, there being a lack of appropriate training for personnel and, even more dangerous, a failure to raise awareness regarding possible adverse events due to errors in laboratory testing. However, the strength of the study lies in its exploration of the initial steps of the testing cycle and its focus on the role of the clinical laboratory in understanding and improving on the procedures performed in the preanalytic phase.

Conclusions

Our findings show the complexity of the preanalytic phase and the difficulty involved in reducing errors in laboratory medicine, particularly with respect to procedures performed outside the laboratory walls by healthcare personnel (physicians and nurses) who are not under the direct control of the laboratory; moreover, they confirm previously reported data that the rates of preanalytic errors are higher for inpatients than outpatients, owing to the performance of outpatient procedures by personnel under direct laboratory control (14). Therefore, the main take-home message is the need to prepare and adopt standard operating procedures for safely performing patient identification and preparation, test requesting, and blood collection. Such standard operating procedures should be developed by use of a consensus process that includes both the laboratory and the wards. This approach should also be used to improve on appropriateness in test requesting, an aspect that is beyond the scope of the present study. The appropriate training and education required for these procedures should be developed collaboratively between the ward and the clinical laboratory, thus enabling all involved to understand the important and complementary roles each plays. Technological tools, information technology in particular, play a key role in assuring traceability and higher safety in all the preanalytic steps, but the active and cooperative involvement of human resources is mandatory to reduce errors.

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References