

Detectives in the laboratory: investigation of a seemingly unexplained error

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Summary

An unexplainable error that occurred in the normal laboratory routine is described: a positive result for the anti-HCV antibodies detection was found in a single blood tube collected from a patient, while the other samples taken simultaneously were anti-HCV negative. After the first checks that did not highlight any special problems, an internal committee composed of the chiefs of the units involved was established. This committee, using investigative analysis with the Root Causes Analyses model was able to understand the error.

Introduction

Errors in medicine laboratory may regard each of the main phases of technical procedures: pre-analytical phase (before the arrival of the sample), analytical and post-analytical phase (after issuing the report). On the total number of errors, the literature reports that only 7-13% is due to errors in the analytic phase, while 46-68% is due to errors in the pre-analytical phase and 18.5-47% in the post-analytical phase (3,8,25).

In the pre-analytical phase, the main problems relate to inappropriate tests request (23), patient and specimen misidentification (1,10,22), inadequacy of the sample (hemolysed or curdled sample, insufficient or inappropriate quantities, wrong container,

etc.) (7,17) and handling, storage and transport of the sample to the laboratory (19). In the post-analytical phase, the most encountered problems concern the denied or delayed computer accessibility to the test results (11) and incorrect interpretation of the laboratory report (19). In the analytical phase, problems regard the different stages of the procedures in the laboratory: in the first instance, the sample preparation (centrifugation, aliquotting, pipetting, dilution and sorting specimen into batches for their introduction into automated analyzers) was extensively evaluated as an important source of error (19). The availability of instruments using primary collection tubes and the introduction of automated work stations for the sample preparation drastically reduced these errors (5). Among the errors in the analytical phase, however, those related to the contamination (by other samples) (4) and to interference from different substances present in the same sample (heterophilic antibodies, anti-animal antibodies, autoantibodies, etc.) were extensively investigated (9,14,19). Even the analytical accuracy was widely discussed in the literature and, for example, the impact of calibration errors was carefully considered, with regard to the negative consequences that may have on clinical outcome (12,16). The wrong validation, the delay in reporting and the transcription errors were also reported (2, 18). The automatic validation process (19) and the computerized final report without manual transcription minimized the errors. But, where there are still manual methods (typically in bacteriology), the error of transcription is still widely possible.

Although standardization of methods, advanced automation of procedures and technological improvements greatly improved the reliability with a substantial decrease of the errors (24), errors can nevertheless occur. Given the importance of errors in healthcare, documents on Risk Management were produced that consider both human behavior as a source of error (aberrant behavior), and the conditions (technological, relational and human factors) in which the error occurred, all seen as the outcome of a system failure (15). Effective activity of Risk Management regards the knowledge and error analysis, the detection and correction of error causes, and the monitoring of implemented measures for error prevention (15). In order to implement structural survey, able to recognize the causes that have produced the error, a *reactive analysis* (15) which is conducted backwards compared to the timeline of error, can be used. For this purpose, the Root Causes Analyses (RCA) can be implemented. These analyses, starting from the errors found in a system, are suitable to look for causes through an inductive method which proceeds in depth with questions that explore the *why* of every action and each of its possible deviation (6). This activity is not always easy to take, especially if the error occurred is acknowledged at a distance of time. Moreover, the complexity of the operations performed in the laboratory does not always allow a quick identification of the critical point. We describe a seemingly inexplicable error occurred in the normal laboratory routine after which we used a RCA, which led to fully understanding the error.

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Description of the error

A hospital employee came to the Blood Drawing Center for testing her 3-year-old daughter. Blood chemistry and infectivolog-ical tests were prescribed by the general practitioner treating the child for unspecific symptoms of malaise. The number of primary-test tubes for the different tests was high: one tube for blood count (sent to the Blood Transfusion Centre), one for biochemical tests, one for electrophoresis and one for autoantibodies (all three sent to Clinical Chemistry Laboratory) and one for infectivolog-ical tests (anti-CMV, anti-EBV, anti-Adenovirus etc. sent to the Microbiology Laboratory). The woman and a physician of the Microbiology Laboratory, agreed to add more tests in case of neg-ativity of the first infectivolog-ical tests. Given this possibility, as the amount of blood in the tubes was little, being the child very young, it was requested to keep as many blood tubes as possible. A primary-tube (in this case the one for electrophoresis) was then immediately taken back from the Clinical Chemistry Laboratory and stored in a refrigerator of the Microbiology Laboratory. As the different infectivolog-ical tests were negative, the physician of the Microbiology Laboratory requested to add tests for the markers of viral hepatitis, including anti-HCV. These tests were then per-formed on the *electrophoresis tube* because this tube contained more blood than others. The results for markers of hepatitis were all negative except for anti-HCV. Despite a value not particularly high, it was also positive after execution of the confirmation test in immunoblot. Being the woman anti-HCV negative, and being her daughter known by the laboratory staff, the question of the possi-ble route of infection was immediately raised. Since the risk fac-tors for HCV were not known for the child, it was decided to review the results of anti-HCV search also on the blood remained in the primary-tube for anti-CMV and anti-EBV (still stored in the Microbiology Laboratory) and in the secondary-tube for autoanti-bodies (stored in the Clinical Chemistry Laboratory). On both tubes the result for anti-HCV was negative. While the tube for autoantibodies was a secondary-tube (after separation of the sam-ple), the tube for anti-CMV/EBV and the one for electrophoresis were primary-tubes. Given that one of primary-tubes (for anti-CMV/EBV) was anti-HCV negative and one (for electrophoresis) anti-HCV positive, both tubes having been processed directly in the analyzer for anti-HCV, the discrepancy was not due to the manipulation of the tubes. The little girl was then redrawn, and the neg-ativity for anti-HCV was confirmed. Following the seemingly inexplicable inconsistency of such data, an internal investigation conducted in collaboration between qualified staff from the Microbiology Laboratory, Clinical Chemistry Laboratory and Blood Drawing Center was initiated.

Conducted survey

Since it was established that the little girl was negative for anti-HCV, attention was focused on the tube that had repeatedly given the positive result.

The first hypothesis taken into account, was an exchange of tubes at the time of collection (error during pre-analytical phase). The survey carried out with the Blood Drawing Center staff did not, however, show abnormalities. All the test-tubes had been auto-matically labeled by the computer system of the Center. The col-lection had been properly performed by the nursing staff and there had been no situation of confusion at the time of sampling or par-ticular anomalies (*e.g.* change at the last minute of a test tube for difficulty of collection, or the like). The mother was present with the child in the withdrawal box, she saw all tubes correctly labeled

and the nurse, having checked the identity of the girl, collected the blood with no difficulties. The sampling was performed only to the girl and not to the mother, so the hypothesis of a yet possible exchange with the mother was rejected (by the way, the mother was known to be negative for anti-HCV). In addition, the subse-quent verification of the primary-tubes did not show any overlap-ping label. Moreover, it is impossible that a label is attached on a unlabeled full blood tube (of a different patient) in that the blood collection is performed only on pre-labeled tubes). The nurse who performed the sampling denied that at the time there were other anomalies.

As a second hypothesis, the possibility of a contamination of the tube with anti-HCV positive result (error in analytical step), was taken into account; in the Microbiology Laboratory, the tube was inserted uncorked into the analyzer for automatic execution of tests (as in all normal routine) without further manipulations. For the draft of the sample the analyzer (as for other analytical steps) used disposable tips. The tube came from the Clinical Chemistry Laboratory where it had been processed for electrophoresis and then delivered to the Microbiology Laboratory. Also in this case the tube, uncorked, was inserted into the electrophoresis analyzer, which uses for drafting a high-washing fixed needle to avoid phe-nomena of carry over.

In the absence of satisfactory explanations, it was decided to fol-low the entire route of the suspected tube, trying to stimulate all the involved technicians to remember every unusual detail, even the smallest, about what had happened. As a result, the technician of Microbiology Laboratory who had performed the analysis for anti-HCV, recalled that she had noticed that the tube for electrophoresis was capped with the original cap. She had, therefore, thought the tube was not used or that the electrophoresis system (she did not know it because the system belong to a different Laboratory) would use a needle piercing the original cap (as with blood count tests). The graduate of the Clinical Chemistry Laboratory rejected this hypoth-esis because the electrophoresis analyzer uses uncorked tubes. Normally the tubes are then re-corked with new caps that are differ-ent from those of the original tube.

Further investigation therefore focused on the procedures at the time of electrophoresis. The technician who had performed the electrophoresis, remembered to have uncorked the tube, performed electrophoresis and finally to have given the tube to an attendant to be delivered to the Microbiology Laboratory, but to have corked it hastily with one of the caps of the uncorked tubes waiting for elec-trophoresis routine.

In conclusion, the tube was not re-corked with a clean cap, nor with the original cap, but with a cap belonging to a test tube of another patient, which explains the contamination.

Conclusions

In front of unexplained errors, it is often difficult to understand the dynamics, partly because they manifest themselves after a long time when it is more complicated, if not impossible, to reconstruct all the events. In our case, in fact, only the knowledge of the patient immediately raised doubts about the test result and allowed the reconstruction of the events in a short time. The establishment of a committee that involved all the implicated Units, allowed us a 360-degrees investigation and to set up a methodology that result-ed in the understanding of the error.

In this case the error was human. According to Rasmussen (20), human behavior can be divided into three different types: skill-based behavior (automatic behavior to a given situation),

ruled-based behavior (implementation of practices prescribed by rules) and knowledge-based behavior (behaviors adopted when man is faced with an unfamiliar situation). Based on this model, Reason (21) identified three types of error: execution errors caused by a memory failure (lapses), errors committed during the practical execution of the action (mistakes) and execution errors that occur in skill level (slips). In this last category all actions that are performed in a way other than planned are classified, that is, the subject knows how to behave but it does not, or inadvertently runs incorrectly.

What had happened was what Reason calls *violation* (21), that is a deviation from the written procedures. Starting from the consideration that error is an inevitable part of human reality (13), it is crucial to recognize the circumstances that favored the occurrence of the error to put in place a set of actions that make it more difficult for people to repeat mistakes. In our case, the deviation from normal codified procedures for the proper management of samples of a known patient to whom particular attention had been paid, consisted of the technician's acting hastily and superficially, so the *slip* took place at the level of skill-based behavior. The rest, it is common sense that the inconveniences take place *always* to known people to which favors are done, where the input to the change of an automatic behavior can lead to an error.

To conclude, by gathering the resources of all the involved staff, a proper investigation was carried out, which led to understand the specific mistake and to implement appropriate solutions capable of preventing the perpetuation of errors.

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