

Extra-analytical Point of Care Testing errors in the pandemic era

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ABSTRACT

Introduction: during the current SARS-CoV-2 pandemic phase, the use of rapid diagnostic devices outside the laboratory has expanded enormously, creating great opportunities but also new risks.

Methods: the present observational study evaluated the type and frequency of errors of the extra-analytical phases through an active search on all unclear or ambiguous cases. 252 241 rapid antigenic tests performed outside the laboratory in different health facilities over a 132-day period were considered. The requests, the patient demographics and the results were later entered manually onto the Laboratory Information System (LIS).

Results: through a number of data checks and internal reports, 2 556 cases of errors in the pre-examination phase were recorded, with a relative frequency of 12,274 parts per million (ppm). The vast majority of errors were observed in this phase; these were due mainly to computer communication problems induced by human errors that made the loading of results or the issuing of the reports difficult. The remaining cases involving erroneous personal data or patient identification amounted to 16 (64 ppm), confirming the relative safety of this phase in decentralized analysis. The errors identified in the post-examination phase were 540, with a relative frequency of 2140 ppm. The assessment of the severity of the errors with Failure Mode and Effect Analysis (FMEA) allowed us to identify in particular, the attribution of the report to the wrong person (20 ppm) and the manual transcription of an incorrect result (20 ppm).

Discussion: this study contributes to the comprehension of the critical issues connected to the Point of Care Testing and made it possible to establish corrective actions: improving staff training, choice of instruments with reading devices and establishing direct computer connection for the entering of the requests and results to the LIS.

Key words: POCT, pre-analytical phase, antigenic testing

INTRODUCTION

In early 2020, health systems worldwide were subjected to an unprecedented challenge that also heavily involved clinical laboratories. In Italy, the spread of SARS-CoV-2 was earlier and more severe than in other western Countries implicating the need to activate additional resources since the end of February. This has involved point-of-care testing (POCT) diagnostics in particular in primary health care, with the aim of identifying the Coronavirus 19 disease (COVID-19) infections early before the patients' access to hospitals. The governance of the decentralized tests is traditionally a clinical laboratory expertise, and includes the choice of devices, the methods of identification of patients, the

analytical and quality control procedures and the issuing of valid reports. The reference documents on the topic are easily available and include guidelines from national and international scientific societies as well as regional regulations (1). The condition of emergency, and the allocation of instrumental and human resources in greater amounts than in any previous experience has led to choices that have often not been in accordance with the ordinary procedures. It should also be noted that quite often these initiatives were directed by the territorial authority of the health system which until then had cooperated on a very limited basis with the laboratories and their POCT governing procedures. Finally, there has been important political interventions in the choices proposed by the scientific experts, particularly when they

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disagreed each other.

A few months later, rapid antigenic tests have been activated in our territory (Venice province, Italy) for testing populations with a low probability of infection such as nursing homes, schools, prisons, travellers in transit, drive-through testing centres in various neighbourhoods, on boats to the lagoon islands and finally within the hospitals for both asymptomatic subjects in clinical departments and health personnel. Molecular tests were reserved to higher-risk subjects such as symptomatic and close contacts of infected patients.

POCT errors were only partially studied several years ago and the literature data are not consistent. However, there is strong evidence that the use of specific POCT in hospitals and in primary care increases the quality of patients care; on the other hand, there is also evidence that uncontrolled use of POCT can have far-reaching negative consequences for individuals as well as for public health (2). The practice of POCT is often not under the complete control of the laboratory and this consequently exposes the testing to the risk of non-adherence to recommended procedures. The risk of error depends on several parameters and in any case is greater from what is observed for the testing procedures performed in the laboratory (3). In 2003, Kost et al. classified the potential errors in the POCT into the different phases of the analytical process and observed how the pre-examination (pre-analytical) phase is less prone to errors due to immediacy and simplification of the POCT procedure. However, the question not yet resolved is whether or not this diagnostic methodology is ultimately safer than standard procedures (4).

Since the recent massive use of POCT for COVID-19 diagnostic, we have observed several defaults in the management of the data; their registration and an active prospective study in a defined period of time was then started, in order to obtain solid indications for improvement.

The aim of this study was the identification of the errors in the extra-analytical phases of the process, describing the type of errors and their frequency.

METHODS

Rapid antigenic tests were introduced in June 2020 and by the beginning of the second epidemic phase in Italy (October 2020) the entire process was well established. At each local testing site, administrative staff entered the requests and patient demographics onto the Laboratory Information System (LIS); nursing staff did the nasopharyngeal swabs and completed the tests; clinicians signed the results which were then manually entered onto the LIS by administrative staff at the central laboratory. For each subject, two bar code labels were produced: one for the test device and the other for the result registration sheet which cumulatively reported 10 tests from different subjects.

An immunochromatographic method was used for 87% of tests (mostly Panbio Covid-19 Ag Rapid test device, Abbott SRL, Rome, Italy) and an immunofluorescence

method was used for the remaining 13% (Standard F Covid-19 SD Biosensor Korea, from Relab SRL, Genova, Italy). A systematic review of the diagnostic characteristics of the two methods showed an average sensitivity of 75.1% and 88.1% and specificity of 99.5% and 99.1% respectively, when applied to symptomatic subjects. In the case of asymptomatic subjects, the average sensitivity was 48.9% and 69.2%, while specificity was 98.1% and 99.1% respectively (5).

When the immunofluorescence method was used, a bar code scanner for the sample identification was available and it was possible to print the test result. When the immunochromatographic method was used, the result was visible on the device for visual reading. In any case, after performing the test, the nurses reported the results (by visual reading or printed) on a registration sheet by ticking the pre-printed "positive" or "negative" boxes. The clinicians signed the sheets by checking the results and the sheets were then forwarded to the laboratory. Here, the sample check-in function of LIS was used and then the patient demographics and the results were manually entered onto the LIS.

Two training meetings were established: the first specific for the administrative staff and the second one dedicated to the nurses for the swab's obtainment and the analytical procedure. However, it was possible to train only a small number of personnel, given the elevated number of people involved and the workload pressure. Consequently, many operators have been trained by more expert colleagues rather than by the staff in charge of the training. This constitutes a limitation of the training accuracy.

Following an initial phase to fine-tune the errors active search strategy, the study was launched on October 7th 2020 and conducted for 132 consecutive days (until mid-February 2021) examining a total of 252 241 tests with an average of 1 911 tests per day (range 5 – 5 493). Table 1 shows the number of the test examined in the study, according to the different testing sites.

The design of the study involved the administrative staff, the nurses and, in some cases, the subjects themselves.

When the inspection of the data revealed a possible inaccuracy or incoherence, these were recorded in worksheets and an active investigation was started by reviewing the registration forms, consulting the computer traceability data, examining the requests and the reports or by interviewing people involved in the specific case, including the subjects in some circumstance. When it became necessary to correct personal information such as date of birth, city, address, postal code or more rarely, the name itself, we proceeded to a more precise identification of the subject through identity cards, according to standard procedures. The different types of errors thus identified were then divided in two main classes (pre- and post-examination).

Finally, an assessment of the clinical risks associated with the errors identified, was carried out using the Failure Mode and Effect Analysis (FMEA) procedure, as described (6). For this purpose, at the end of the data collection,

Table 1
Number of tests in the different testing sites

Origin	Number	%
Venice airport passengers	18 618	7.4
Venice harbor passengers	3 728	1.5
Drive through testing	46 319	18.4
Prisons	1 935	0.8
Health personnel	40 237	16.0
Factory workers	1 859	0.7
Hospital in-patients	18 404	7.3
Residents and staff in old age homes	64 683	25.6
No close contacts of infected people	27 132	10.8
Preventive screening tests	25 739	10.2
Students and schools' staff	3 587	1.4
Total	252 241	100.0

a team involving a laboratory manager, an experienced nurse, the POCT coordinator, and an administrative operator was established. These professionals attributed risk values which were based on the collected information and on their clinical expertise and experience. This team was then able to calculate the overall Risk Priority Index of every single phase of the pre- and post-examination processes. It could be postulated that other types of mistakes could also have been made. For example, it is possible that an operator has incorrectly interpreted the coloured bands of the devices: the active search of errors used in this study could not detect this type of errors. However, this limitation does not affect the results here described.

RESULTS

The pre-and post-examination errors were 2 556 and 540 respectively. The particularly high number of errors in the pre-examination phase was caused by a specific issue. Actually, when the tests were repeated regularly for the same groups of people (such as guests of nursing homes), a transfer to the LIS of multiple requests at one time was activated through an Information Technology (IT) procedure to avoid the entering of the single requests. The procedure was particularly prone to errors and sometimes all the requests had to be removed and re-entered. All these errors have been assigned to the pre-examination phase. The overall incidence is therefore 12,274 parts per million (ppm) corresponding to 1.2%. Table 2 shows the errors classified as pre- and post-examination errors. The most common consequences of these errors have been delays in obtaining the reports and lack of communication with the computer systems appointed to the reports distribution or transmission to the personal health files. Errors in the identity of the subject have been found to be at greatest risk of diagnostic error or treatment, both for the patient himself and for her/his close contacts. A total of 5 cases were found, with the attribution of the result to the wrong person (frequency

20 ppm): this is not a particular high number, but they are of considerable severity. Less severe errors concerning the missing of some personal data, but without risk of mistaken identity, have been identified 11 times, frequency of 44 ppm. However, these led to a delay in the availability of the reports.

3 false negative and 2 false positive results have been observed (12 and 8 ppm, respectively) (post-examination phase, Table 2). These errors have been attributed to input errors because of the manual entry of data at the laboratory. These wrong results can produce detrimental effects since they may involve incorrect diagnoses, such as false negative subjects who continue to have social relationships, or false positive subjects put in isolation.

To also evaluate the severity of the errors in addition to their frequency, we analyzed the data with the Failure Mode and Effect Analysis (FMEA) system (5) (Table 3). This type of analysis highlights that the steps of subject identification and manual input of so many results are the ones most at risk of causing negative consequences on patients.

These evaluations allowed us to establish corrective actions.

DISCUSSION

The topic of laboratory errors has been investigated for several years by studies considering the typical intra-laboratory workflow and only few papers are related to investigations carried out outside the laboratory (POCT). Two studies in particular have shown the relative frequencies of errors in an emergency laboratory in 1997 and 2007 respectively (7,8). In agreement with other studies, the most critical phase was found to be the pre-examination phase. In a special issue of *Chimica Clinica Acta*, Plebani M. discussed the safety of POCT analyses highlighting that, in theory, this tool eliminates some of the most problematic steps in the testing process, including specimen transport and conservation; the pre-examination phase was thus considered less

Table 2
Type of error and relative frequency in the pre- and post-examination phase

Phase	Type of error	Number	%	ppm
Pre-examination	1 requests not transmitted	2 540	1.01	10 070
	2 incorrect personal data	11	<0.01	44
	3 exchange with namesake	2	<0.01	8
	4 wrong identity	3	<0.01	12
	subtotal	2 556	1.01	10 133
Post-examination	5 missed registration sheet	29	0.01	115
	6 missing result	475	0.19	1 883
	7 result not readable	17	0.01	67
	8 double result *	14	0.01	56
	9 transcription error: negative result, positive reported	2	<0.01	8
	10 transcription error: positive result, negative reported	3	<0.01	12
	subtotal	540	0.21	2 140
Total		3 096	1.23	12 274

ppm, parts per million

* both positive and negative boxes are ticked in the result registration forms.

vulnerable compared to laboratory process (3). Despite the large number of studies available in searchable scientific papers with the terms “POCT error”, “POCT mistake”, “POCT risk management”, a limited number of publications included original error frequency data at different stages of the process. The performances of POCT technology have been adequately analyzed only in the field of analytical performance of several specific analysers but there is a lack of papers examining the extra-analytical phases.

The design of our study allows the identification of only a part of the errors, without the conceit of establishing their real quantity. Despite this, it offers an analysis of how to verify the extra-analytical safety level of the POCT. Our data were obtained directly in the field starting from interviews with healthcare professionals, patients or subjects and also from inconsistencies in the data registration systems. For this reason, they represent an underestimate of the real errors frequency. For example, the error of transcription of the qualitative result (from positive to negative or *vice versa*) was highlighted in detail (Table 3), but it was impossible to evaluate the errors of visual reading of the analytical result from the device by health professionals in the decentralized facility.

The overall incidence in the pre- and post-examination phases, compared with the data reported in the literature from automated systems linked to LIS, is not directly comparable to POCT process for various reasons: the different and simplified procedural phases, the qualitative results, the manual data management. However, it was possible to observe that errors in the patient identification phase are not far from those observed in POCT procedures: 64 ppm in the present study compared to

55 ppm in the laboratory flow in a College of American Pathologists study in 2006; on the other hand, in a 2012 Italian study that evaluated misidentification only among inpatients, the frequency was as high as 352 ppm. (9,10). Unfortunately, at the best of our knowledge there are no more recent data related to this topic but the question of a safe patient identification remains critical in all medical disciplines (11). Our FMEA study also highlights the severity of this rare but dangerous type of error.

Referring to the post-examination phase of the POCT, it was possible to compare our data with a 2009 study that examined the manual transcription of the results obtained by nurses with portable glucose meters in a hospital environment (12). The frequency of errors in the post-examination phase in the present study is 2140 ppm compared to 31 776 ppm in the 2009 study. Very similar results have been obtained more recently in a hospital setting in Seattle (Washington, USA) when the transcription of results onto the computer system was carried out manually (13), with an overall frequency that has been estimated at 32 000 ppm. It becomes thus evident that if this activity is delegated to laboratory trained personnel (as in our study) instead of being disseminated among a number of nurses (as described in reference 10) the safety of the data increased substantially.

The diffusion of analytical decentralization in a vast territory has represented an unprecedented challenge, but also a tool for powerful containment of the pandemic.

Therefore, in conclusion, several considerations can be made in order to be prepared for possible future epidemics:

- strengthen the role of clinical laboratories in the POCT

Table 3

Assessment of the risks associated to the identified errors, according to FMEA .

Process phase	Step	Responsibility	Potential cause of failure	Effect of potential failure	Severity (1-10)	Occurrence (1-10)	Detection (1-10)	Risk Priority Index (RPI)
Pre-examination	Subject identification	POCT administrative staff	Choice of a namesake	Incorrect clinical decision, delay	9	1	4	36
			Wrong identity	Incorrect clinical decision, delay	9	1	4	36
			Incomplete personal data	Lab report not issued, delay	2	2	3	12
	Creating massive request files	IT staff	Incorrect date, test, bar code format	Check-in fault creating a new file, new labeling, delays	3	9	1	27
Post-examination	Sending of the result registration sheet	POCT administrative staff	Sheet not sent or missing	Lab report not issued	4	1	2	8
	Filling in of the registration sheet	POCT nurse	Result not ticked	Need of further information, considerable delay in issuing the report (or no report at all)	3	6	1	18
			Double result *		3	3	1	9
			Unreadable result		3	1	1	3
	Check in of result sheets in the LIS	Administrative and laboratory staff	Missed check in	Lab report not issued	3	1	2	6
	Loading results on the LIS	Administrative and laboratory staff	Wrong entry of a positive result	Isolation of the subject and his/her cohabitants	8	1	5	40
			Wrong entry of a negative result	Possible spread of the infection	9	1	5	45

FMEA, FAILURE MODE and EFFECT ANALYSIS; IT, information technology.

* both positive and negative boxes are ticked in the result registration forms.

- management;
- prefer, whenever possible, analytical systems connected online;
- promote continuous training of non-professional operators on the risks connected to POCT procedure focusing on identity errors;
- establish control filters and quality indicators.

It can be also noted that the data obtained in the present study endorse the proposals of the study group of the IFCC about the choice of quality indicators of the extra-analytical phases, with particular attention to the errors of identification of the patient and the attribution of the result (13).

The experience from this study guided some improvement actions for the future such as: more investments in training and connectivity; replacement of manual methods with those equipped with an instrument, bar code reader of the patient's code and transmission of the result directly to the LIS.

These choices will also make possible to reduce the number of full-time staff devoted to upload the results.

A final consideration is that our study concerns a specific test (rapid antigen test for COVID-19) and cannot be easily and fully applied to other types of POCT. The relevant information which can be widely extended, however, concerns the risks of manual management of data which is unfortunately a common practice for a high number of these tests situated in facilities where connectivity is lacking.

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CONFLICT OF INTEREST

None.

References

1. Rampoldi E, Patrucco G, Casati M, et al. Implementation and management of the point-of-care testing (POCT): essential indications. *Biochim Clin* 2021;45:312-26.
2. Florkowski C, Don-Wauchope A, Gimenez N et al. Point-of-care testing (POCT) and evidence-based laboratory medicine (EBLM) – does it leverage any advantage in clinical decision making? *Crit Rev Clin Lab Sci* 2017;54:471–94.
3. Plebani M. Does POCT reduce the risk of error in laboratory testing? *Clin Chim Acta* 2009;404:59-64.
4. Kost GJ. Preventing problems, medical errors, and biohazards in point-of-care testing. *Point Care* 2003;2:78–88.
5. Dinnes J, Deeks JJ, Berhane S et al. Rapid, point-of-care antigen and molecular-based tests for diagnosis of SARS-CoV-2 infection (Review). *Cochrane Database Syst Rev* 2021;3:CD013705.
6. Liu HC, Zhang LJ, Ping YJ et al. Failure mode and effects analysis for proactive healthcare risk evaluation: A systematic literature review. *J Eval Clin Pract* 2020;26:1320-37.
7. Plebani M, Carraro P. Mistakes in a stat laboratory: types and frequency. *Clin Chem* 1997;43:1348-51.
8. Carraro P, Plebani M. Errors in a stat laboratory: types and frequencies 10 years later. *Clin Chem* 2007;53:1338-42.
9. Valenstein PN, Raab SS, Walsh MK. Identification errors involving clinical laboratories: a College of American Pathologists Q-Probes study of patient and specimen identification errors at 120 institutions. *Arch Pathol Lab Med* 2006;130:1106-13.
10. Carraro P, Zago T, Plebani M. Exploring the initial steps of the testing process: frequency and nature of pre-preanalytic errors. *Clin Chem* 2012;58:638-42.
11. Lippi G, Mattiuzzi C, Bovo C, et al. Managing the patient identification crisis in healthcare and laboratory medicine. *Clin Biochem* 2017;50:562-7.
12. Carraro P, Plebani M. Post-analytical errors with portable glucose meters in the hospital setting. *Clin Chim Acta* 2009;404:65-7.
13. Mays JA, Mathias PC. Measuring the rate of manual transcription error in outpatient point-of-care testing. *J Am Med Inform Assoc* 2019;26:269-72.
14. Plebani M, O'Kane M, Vermeersch P, et al. EFLM Task Force on "Performance specifications for the extra-analytical phases" (TFG-PSEP). The use of extra-analytical phase quality indicators by clinical laboratories: the results of an international survey. *Clin Chem Lab Med* 2016;54:e315-7.