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Preanalytic errors in anatomic pathology: study of 10,574 cases from five Portuguese hospitals

DOI 10.1515/dx-2015-0005
Received February 10, 2015; accepted May 25, 2015; previously published online June 17, 2015

Abstract

Background: Identification of errors in anatomic pathology is an important issue in medical practice. The main objective of this study was to determine the prevalence and characterize preanalytic errors in surgical pathology and cytology samples. We also intended to explore associations between error prevalence and procedures implemented in hospitals concerning the type of requisition forms, use of guidelines for case acceptance and existence of error notification system.

Methods: We analyzed 10,574 cases in five Portuguese hospitals. The pathology laboratories recorded during 20 days all cases submitted with preanalytic errors, using an input form that allowed the identification of sample type, error description, action taken before error, the professional who detected the fail and the test cycle segment where it was identified. Subsequently, particular procedures in use for preanalytic phase were characterized for each hospital.

Results: The prevalence of cases with error was 3.1% (330/10,574), 95% confidence interval: 2.8%–3.5%. Errors occurred in 4.1% (250/6079) of histology specimens and 0.9% (40/4477) of cytology specimens, and included errors in the requisition forms (2.6% error rate) and in the sample container (1.5% error rate). Acceptance of cases with error was the most frequent action (66.9%), followed by rejection (24.4%) and retention (8.7%).

Conclusions: The existence of written norms for sample acceptance and error reporting systems to submitting services and patient safety department were proven to be associated to lower error prevalence.

Keywords: anatomic pathology; error prevalence; patient safety; preanalytic phase.

Introduction

The report on errors associated with medical care by the Institute of Medicine in 1999 [1], has made patient safety a priority in all organizations providing health care, and anatomic pathology (AP) laboratories are no exception. AP is a cornerstone in health care and it aims to produce a complete, precise and comprehensive diagnosis, in a brief period of time [2]. The most common types of biological samples in the AP laboratories are histological samples (biopsies and surgical resections), cytological samples (exfoliative and fine needle aspiration cytology [FNAC]) and clinical autopsies [2]. Due to the unique and irreplaceable nature of most specimens for AP examination, every effort should be made to ensure that they enable a correct and complete diagnosis [3]. According to Clinical Laboratory Improvement Amendments (1988), AP laboratories are included in the highly complex test category, which requires strict quality control and quality assurance policies and procedures [3].

Several studies reported that most failures occur in the preanalytic and postanalytic segments, the first being more prone to error [4–8]. Thus, in order to promote patient safety, reduction of preanalytic errors should be a priority for all health care providers [5, 9, 10].

Preanalytic errors present a challenge for AP services, which should work together with submitting services in order to determine and improve procedures that lead to error reduction. This would create solutions to increase reliability, which would have a positive impact in quality, patient safety and reduction of health care costs.

Most common preanalytic errors are due to clinical failures (wrong clinical procedure, inappropriate ordering, erroneous, incomplete or misleading

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clinical information), and specimen transportation and delivery (container mislabeling, wrong fixative, poor preservation) [11].

To lower the error prevalence it is essential to study its characteristics and know the organizational procedures associated with a lower error rate. There are publications that quantify errors in histology samples [12–16], but none was found that includes cytology specimens. This is the first study that quantifies and characterizes this problem in Portuguese hospitals.

The aim of this study was to determine the error rate and characterize preanalytic deficiencies, both in surgical pathology and cytology samples, for AP examination. Also, it intends to explore associations between error prevalence and procedures implemented in hospitals concerning the type of requisition forms, use of guidelines for case acceptance and existence of error notification system.

Materials and methods

This study involved five Portuguese hospitals in Lisbon and Tagus Valley region. Information regarding number of beds, annual number of cases sent for anatomic pathology analysis and type of requisition form is presented in Table 1. All services were certified or in process of certification by ISO 9001:2008, three of them were public hospitals (Portuguese National Health Service) and the other two were private hospitals.

During 20 days (March/April 2013) the anatomic pathology services from these hospitals prospectively screened all cases submitted for examination (n=10,574) and found 330 cases with preanalytic errors. The registration of cases with errors lasted for additional 3 weeks, because this allowed the test cycle to be completed, and errors not detected on reception but encountered at a later stage, could be included in the investigation.

We considered a case for AP diagnosis one or more biological samples accompanied with a requisition form filled by a clinician. A prevalent case (i.e. case with error) is a case for AP examination in which one or more errors were identified. When multiple fails were noted for the same case, they were all registered.

The preanalytic segment encompasses all procedures from clinical test selection, test ordering, specimen collection, patient and specimen identification, specimen transport and delivery to the laboratory [7, 13]. Errors originated after case delivery to AP services were out of the scope of this study.

For data entry we used two input forms. The Input Form A was a sheet for registry and characterization of cases with errors. Information was collected on sample type, requesting service, error description, action taken, who detected the fail and in which phase of the process (Figure 1). This form was distributed and filled by professionals of all the AP services, whenever an error concerning preanalytic segment was identified. Attached to it was a document containing a glossary and error examples, in order to reduce registry subjectivity. The Input Form B was a questionnaire for characterization of preanalytic procedures in use in services/hospitals regarding patient identification, requisites for reception/rejection of cases, use of electronic requisition, the professional who was responsible for case reception and systems used for error notification. This questionnaire was answered by the laboratory manager.

These instruments were created on purpose for this investigation, based on similar studies [12, 13, 17], then reviewed by a panel of 10 experts (5 technicians, 2 pathologists, 1 engineer specialist in quality management in healthcare, 1 quality manager of anatomic pathology service and 1 specialist in social sciences surveys), and subjected to a pretest in five AP services. To correct operational problems, informative sessions were conducted in all services before error registry began.

Results were introduced and analyzed using Statistical Package for Social Sciences 20.0 (SPSS Inc., Chicago, IL, USA). We performed descriptive statistics analysis, inferential analysis to determine the prevalence of errors with 95% confidence of the real prevalence of errors, and χ^2-test as bilateral hypotheses testing for a significance level of 5% to determine associations between prevalence of cases with error and organizational procedures.

Results

Organization characteristics

Concerning patient identification, all hospitals presented good practices, labeling requisitions slips and sample containers with the patient's full name and identification number. Written guidelines for preanalytic phase (i.e. information about correct specimen preservation and handling) existed in all hospitals. Criteria for case acceptance were written in four services and informal (non-written) in one. Three hospitals used both electronic and paper

Table 1: Number of beds and anatomic pathology cases for each hospital involved in the study (data refers to the year 2013).

Hospital	Approximate number of beds	Cases submitted for AP analysis (year 2013)	Requisition form
Hospital A	400	10,000	Electronic
Hospital B	300	26,100	Paper
Hospital C	250	56,500	Mostly electronic but also paper
Hospital D	350	53,400	Mostly paper but also electronic
Hospital E	800	17,150	Mostly paper but also electronic

Sample type	Biopsy ☐ Surgical resections ☐ Fine needle aspiration cytology ☐ Exfoliative cytology ☐ Other ☐, please specify:_____
Error description	Concerning requisition form: Absence of requisition form ☐ Patient identification ☐ Clinical information ☐ Sample identification ☐ Clinician identification ☐ Concerning specimen container: No sample ☐ Patient identification ☐ Sample identification ☐ Inadequate fixative/preservation method ☐ Sample damaged during transport ☐ Other ☐, please specify: _____
Action taken	Case accepted: Error corrected after contacting the requesting service ☐ Error detected at the reception, but the case was accepted ☐ Error detected after reception ☐ Case retained – reception pending of correction of the error ☐ Case returned: Sample returned in fixative ☐ Sample returned with no fixative (fresh) ☐ No sample ☐
Error detection	AP service: Administrative staff ☐; Technical staff ☐; Medical staff ☐ Other service ☐ Process phase: Reception ☐; Accessioning ☐; Analytic ☐; Postanalytic ☐.

Figure 1: Input Form A – information requested for error characterization.

requisition, one used only electronic and another just paper requisition. Case reception was performed by technical staff in four services, in one of the hospitals administrative personnel were responsible for this task. Also, the error report to submitting services and/or patient safety department was a common practice in three hospitals. The main procedures implemented on the five hospitals are summarized in Figure 2.

Hospital D mentioned they had a recent reformulation in preanalytic circuit, comprising of formative sessions conducted with all personnel involved in the procedures and the nomination of a person in each submitting service to be responsible for all interaction with the AP service.

Cases screened and error rate

A total of 10,574 cases for AP examination were screened, most of them were histology specimens (57.5%) and 43.3% were cytology samples (Figure 3). Cases identified as

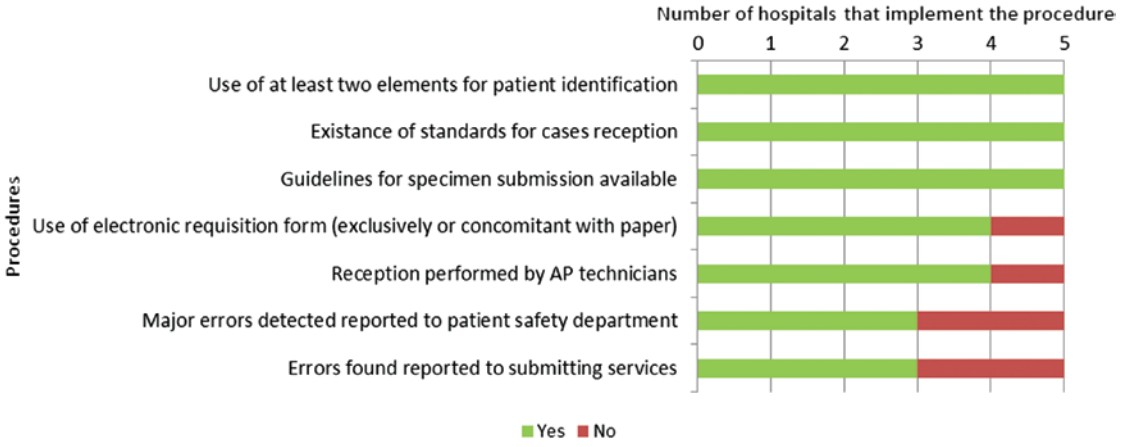

Figure 2: Summary of procedures implemented in the organizations.

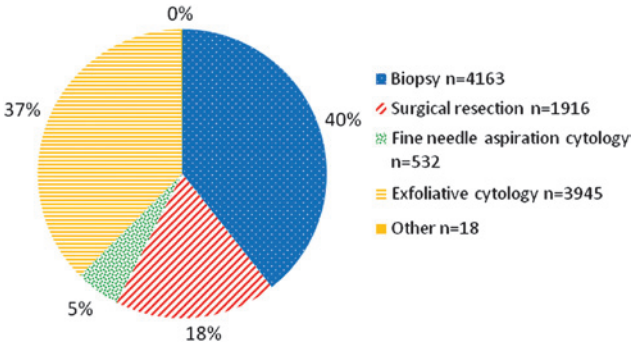

Figure 3: Frequency of samples in the study.

"Other" encompass specimens with lower expression, as clinical autopsies and cases whose registration number comprises two different specimens (e.g. biopsy and cytology).

Three hundred and thirty cases with error were found on 10,574 screened cases, thus the error prevalence was 3.1% (95% confidence interval: 2.8%–3.5%). There were 109 cases with more than one error, so the total number of errors measured was 481. Cases with one error were the most frequent (67.0%), followed by cases with two errors (20.3%) and, for last, with three errors (12.7%).

Prevalence of cases with error for each hospital and specimen type can be observed in Table 2. The deficiency rate varies, per hospital, from 0.5% to 6.5%. The item "Sample type" was filled in 90.0% of the cases (297/330). Grouping sample types, the prevalence of errors for histology specimens (4.1%) was greater than that for cytology specimens (0.9%).

Error characterization

The total number of errors recorded was 481 spread over 330 cases. Errors associated with filling the requisition form accounted for 65.5% of errors reported, in this

Table 2: Error frequency and rate for each hospital and specimen type.

Variable	Categories	Error frequency, n	Statistical sample, n	Error rate	p-Value χ^2-test
Hospital	Hospital A	39	601	6.5%	p<0.001
	Hospital B	45	1951	2.3%	
	Hospital C	161	2515	6.4%	
	Hospital D	21	4142	0.5%	
	Hospital E	64	1365	4.7%	
Specimen type	Biopsy	185	4163	4.4%	p<0.001
	Surgical resections	65	1916	3.4%	
	FNAC	12	532	2.3%	
	Exfoliative cytology	28	3945	0.7%	
	Other	7	18	38.9%	

category the most frequent fails were due to deficient sample identification and lack of clinical information. In the sample container we encountered 31.6% of errors, mostly incorrect sample identification and inappropriate fixative (Table 3).

In Table 4 we observed that the majority of cases with error were accepted (66.9%), and 24.4% returned to submitting services, of these 73.7% (n=56) were in fixative fluid and 14.5% (n=11) were fresh samples with no fixative, the remaining 11.8% (n=9) had no sample accompanying the requisition form. Case retention occurred in two hospitals (A and E), and corresponded to 8.7% of actions taken, this means that the requisition form and/or vial container stayed in AP services while errors detected were solved in submitting services.

All professional categories detected errors, but the technicians were the ones who reported more. Overall, the majority of deficiencies were found in the analytic segment (54.4%), but this tendency only occurred in Hospital C, were most errors (99.4%) were perceived in this phase. In the remaining four hospitals error identification took place mostly during reception (84.3%).

Association between laboratory practices and prevalence of cases with error

Concerning the requisition form, hospitals were grouped into three categories: "Only paper requisition"; "Electronic and paper requisition"; "Only electronic requisition"

Table 3: Characterization of 481 errors found.

Localization	Error description	Number (error rate)	Total of errors, n (%)
Requisition form	Absence of requisition form	51 (10.6%)	315 (65.5%)
	Patient identification	6 (1.2%)	
	Clinical information	76 (15.8%)	
	Sample identification	169 (35.1%)	
	Clinician identification	13 (2.7%)	
Sample container	No sample	7 (1.5%)	152 (31.6%)
	Patient identification	2 (0.4%)	
	Sample identification	124 (25.8%)	
	Inadequate fixative/preservation method	15 (3.1%)	
	Sample damaged during transport	4 (0.8%)	
Other			14 (2.9%)

Table 4: Characterization of the 330 cases with error.

Variable	Categories	Error frequency		Total cases observed	Error rate
		Absolute frequency	Relative frequency		
Error type	Requisition form	167	50.6%	10,574	1.6%
	Sample container	48	14.5%		0.5%
	Requisition form and sample container	101	30.6%		1.0%
	Other	13	3.9%		0.1%
	Sample container and others	1	0.3%		0.0%
Action taken	Case accepted	208	66.9%		311 records
	Case retained	27	8.7%		
	Case returned	76	24.4%		
Professional that detect the error	Administrative	3	0.9%		330 records
	Medical	2	0.6%		
	Technician	323	97.9%		
	Professional extra AP service	2	0.6%		
Phase of error detection	Reception	140	43.8%		320 records
	Accessioning	4	1.3%		
	Analitic phase	174	54.4%		
	Postanalytic phase	2	0.6%		

(Table 5). The exclusive use of electronic requisition was associated with a higher error rate (4.2%), of the 25 cases with deficiencies in this category 21 (84.0%) were due to absence of requisition form, and the remaining 4 (16.0%) regarded the completion of all required fields. In services that only used paper requisition we found 38 case deficiencies, almost all (n=37) were related with missing information. The use of electronic requisition had a lower error percentage (0.7% vs. 1.9% in paper requisition) concerning the correct completion of requisition form.

The existence of written guidelines for case acceptance was associated with a lower error rate (2.1%; 169/8059) when compared with hospitals that had informal guidelines (6.4%; 161/2515) ($p<0.001$).

Hospitals that notified submitting services and patient safety department when an error was detected had lower deficiency rates (Table 6).

Discussion

This study measured error rate in the preanalytic phase for AP examination cases. In general, the hospitals studied had already implemented procedures that guarantied quality and patient safety, as they were certified by ISO 9001:2008 norm.

Error prevalence measured for preanalytic errors in AP cases was 3.1%. The rate obtained for histology samples (4.1%) was lower than 6.0% and 8.3% reported in surgical pathology by other authors [12, 13]. For cytology specimens a lower prevalence was obtained (0.9%), but we did not find any values in literature to compare.

When we analyzed the error rate by type of sample, the lowest prevalence was associated with exfoliative cytology (0.7% deficiency rate). It should be noted that 78.8% of exfoliative cytology samples were gynecological cytology, a fairly standardized screening exam, which may explain the low error rate.

The existence of multiple samples per case, more often associated with biopsies or surgical specimens, increases the probability of error (on requisition form and sample container) and it may lead to a higher deficiency rate.

Error rate in the requisition form was greater than the one found in sample containers which was similar to other results published [16]. The majority of deficiencies in requisition form were related to failure in identification of sample origin followed by absence/inappropriate clinical information. Errors detected in sample containers were mostly due to sample identification followed by improper preservation. Both type of errors, in requisition form and sample containers, may lead to delays and erroneous diagnosis [14, 16].

Errors related to damaged samples or inappropriate fixative were found in 19 of 481 fails registered. These can influence diagnosis, as the sample could be deteriorated, compromising the analytic phase.

When an error is detected, the most common action was case acceptance. Seventy six cases with deficiencies were returned to submitting services to correct the faults found, 10 of these cases were returned with no fixative, posing a deterioration risk which might have compromised

Table 5: Cases with error according to requisition type.

Variable	Categories	Error frequency, n	Statistical sample, n	Error rate	p-Value χ^2-test
Global errors in requisition form	Paper only	38	1951	1.9%	p=0.009
	Electronic only	25	601	4.2%	
	Both	205	8290	2.5%	
Errors in filling of requisition form	Paper only	37	1951	1.9%	p=0.036
	Electronic only	4	601	0.7%	

Table 6: Error reporting and error rate.

Variable	Categories	Error frequency, n	Statistical sample, n	Error rate	p-Value χ^2-test
Errors reported to requisitioners	Yes	124	6108	2.0%	p<0.001
	No	206	4466	4.6%	
Errors reported to patient safety department	Yes	130	7458	1.7%	p<0.001
	No	200	3116	6.4%	

the diagnosis. The rate of cases returned was higher than reported by Nakhleh and Zarbo (24.4% vs. 2.0%) [12]. Case devolution delayed the diagnosis, and could have interfered with prognosis and treatment [18].

Retention of deficient cases is a good practice, because it avoids the risk of losing the sample during transport and it allows keeping the sample well preserved until the error is corrected, however, only two hospitals used retention when receiving a case with error.

Professionals that reported the majority of errors were technical staff (97.9% of records). Overall, most preanalytic errors were detected in analytic phase (54.4%) followed by reception (43.8%), similar values were found in the study of Nakhleh and Zarbo [12]. This tendency should be considered carefully, since it occurred in only one hospital where reception was performed by administrative staff, in the other hospitals most errors were detected at reception (values vary between 71.4% and 95.3%). When technical staff was responsible for case reception, error detection occurred mostly in this phase, but when this task was performed by administrative personnel, errors were detected later, in analytical phase. This corroborates the importance of having skilled and knowledgeable professionals performing an effective screening of submitted cases.

Despite being reported by Hill et al. [19] that the use of electronic requisition reduces the occurrence of errors, in this study we obtained the opposite result. The advantage of using electronic requisition was related to the complete filling of all mandatory information such as patient and physician identification, clinical information and specimen site. However, there could still be issues related to insufficient or unintelligible information is (e.g. use of acronyms). The disadvantage of this method was the difficulty that submitting services had to verify if the requisition had been issued or not. We observed that in the hospital where only electronic requisition was in use, most errors were related to samples sent without request.

The existence of written guidelines for AP samples acceptance has shown to be associated to a lower error rate, this enhances the need for each service to create and disclose these orientations, as recommended by norms of laboratory accreditation [3, 20].

Error reporting system is one of the pillars of quality and patient safety [21, 22] and its implementation is mandatory in AP services [23], the opportunity given to us by fails is learning from them, preventing similar errors in the future [24]. It is essential that submitting services are notified about their fails, as we noted in this study where services who reported errors had a lower error rate.

Non-adherence to error registration by professionals of the services that participated in this study was the factor that may have caused bias in the results, leading to lower error prevalence. To minimize this factor some actions were taken, such as the validation of instruments for data collection and informative sessions in all services.

In summary, concerning patient identification, an issue of paramount importance, all hospitals involved in the study demonstrated good practices. The prevalence of error was lower in cytology than in histology cases, and it was more frequently associated with requisition form than specimen container. We observed a high rate of returned cases due to deficiencies, some of them returned with no fixative, which may have compromised sample integrity. Reception made by technicians detects more non-conform cases than when this task was performed by administrative staff. The use of electronic requisition improved the correct filling, but increased the number of errors related to sample containers with no requisition form.

Finally, practices that proved to be associated with a lower error rate were the existence of written norms for sample acceptance and error reporting systems to submitting services and patient safety department.

According to Vincent [25], interventions to improve patient safety must be based on adverse events (errors that cause damage to the patient) rather than only on errors, so for future studies it would be interesting to investigate the consequences of each error on pathological diagnosis, and if it has, or not, consequences for the patient.

Acknowledgments: The authors would like to thank the hospitals staff who collaborated in this study and the reviewers who contributed to improve this article.
Author contributions: All the authors have accepted responsibility for the entire content of this submitted manuscript and approved submission.
Research funding: None declared.
Employment or leadership: None declared.
Honorarium: None declared.
Competing interests: The funding organization(s) played no role in the study design; in the collection, analysis, and interpretation of data; in the writing of the report; or in the decision to submit the report for publication.

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