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ORIGINAL ARTICLE

Risk management: correct patient and specimen identification in a surgical pathology laboratory. The experience of Infermi Hospital, Rimini, Italy

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Key words

Error misidentification • Informatics • Bar code technology

Summary

Because of its complex nature, surgical pathology practice is prone to error. In this report, we describe our methods for reducing error as much as possible during the pre-analytical and analytical phases. This was achieved by revising procedures, and by using computer technology and automation.
Most mistakes are the result of human error in the identification and matching of patient and samples. To avoid faulty data interpretation, we employed a new comprehensive computer system that acquires all patient ID information directly from the hospital's database with a remote order entry; it also provides label and request forms via-Web where clinical information is required before sending the sample. Both patient and sample are identified directly and immediately at the site where the surgical procedures are performed. Barcode technology is used to input information at every step and automation is used for sample blocks and slides to avoid errors that occur when information is recorded or transferred by hand. Quality control checks occur at every step of the process to ensure that none of the steps are left to chance and that no phase is dependent on a single operator. The system also provides statistical analysis of errors so that new strategies can be implemented to avoid repetition. In addition, the staff receives frequent training on avoiding errors and new developments.
The results have been shown promising results with a very low error rate (0.27%). None of these compromised patient health and all errors were detected before the release of the diagnosis report.

Introduction

A large amount of information has been published on diagnostic phase error in pathology, namely the interpretation of morphology and/or immunohistochemistry and the skills required by the pathologist to avoid this type of error [1-3]. However, this is by no means the only type of error that can occur in a complex system where the analysis of histological samples involves many steps and numerous personnel (physicians, biologists, laboratory technicians and administrative staff).
The more complex a system is, the more likely the chance of error [4].
It is difficult to determine the true incidence of errors since there is no single definition of what an 'error' actually is, and also because many different error detection methods are used [5].

Inadequate diagnostic interpretation represents 25% of all errors, although the frequency is reduced to 0.26-1.2% considering only errors that cause harm to patients. About 27-38% of all errors are caused by patient and/or sample mismatching [6].
The present study examines the work done at the Pathology Lab in Rimini Hospital in reducing the risk of error at each step in the pre-analytical and analytical phases.

Materials and methods

In 2009, our lab analyzed 26,963 histological and 7,969 cytological samples, and performed 25,000 Pap tests as well as 90 autopsies. The staff is composed of 8 doctors, 4 biologists, 14 biomedical laboratory technicians and 2 administrative assistants.

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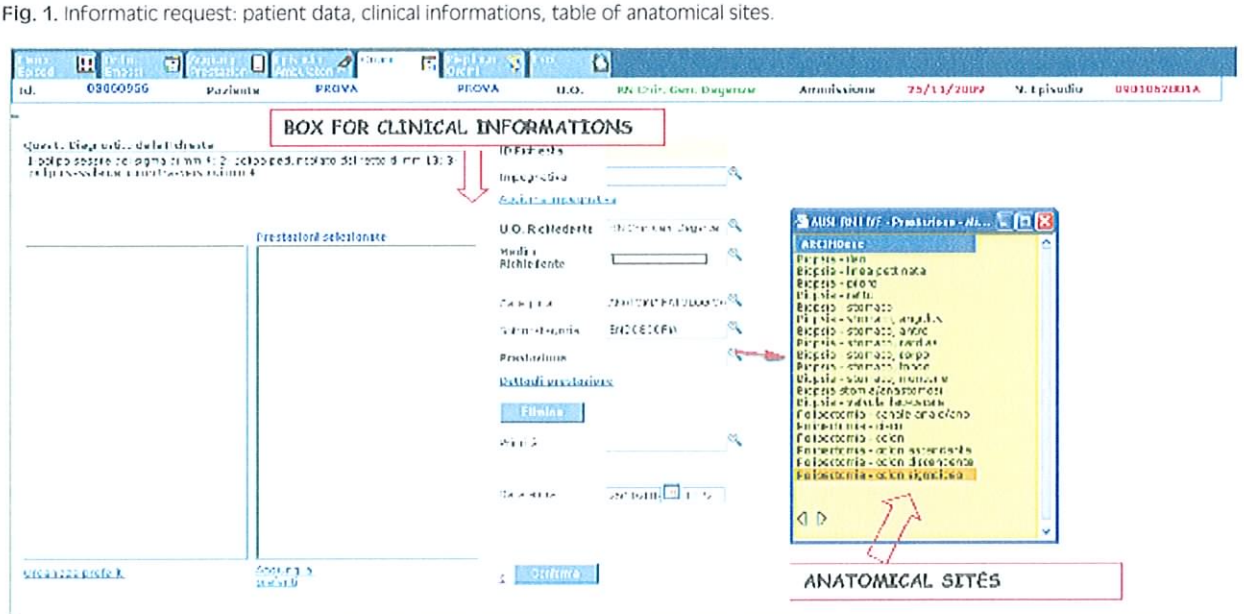
The histo-cytological specimens processed by Rimini Hospital come from various sources, including Rimini Hospital itself and various public hospitals in the towns of Riccione, Santarcangelo di Romagna, Cattolica, Novafeltria and the State Hospital of the Republic of San Marino, in addition to several smaller private hospitals.
In our experience, most of the misidentification defects of patients and samples mainly occur because of the misreading of data (personal data, anatomical site of sampling and laterality) when handwritten on the request form and sample container label.
Another problem with request forms filled out by hand is that the names of the department requesting the sample and the responsible clinician are often not identifiable or have been omitted.
Patient and specimen mismatching errors also happen because samples boxes get mixed-up with that of another patient at the gross examination step.
The same type of error occurs during the cutting phase when one patient's section is placed on the slide of another patient.
In a limited period during 2007, non-compliance (NC) detected in our lab in the acceptance phase showed that errors related to personal data accounted for 24% of errors (name surname 11% and date of birth 13%), while that related to samples accounted for 28% of errors (9% wrong site and 19% non-correlation of sample type and site on the request form).
In light of the above, in 2007 we decided to replace the laboratory information system (lbs), which had become obsolete in recent years, and reviewed working procedures, taking into account critical elements and weak points in the entire process.
Without going into excessive technical detail, the system is structured as follows: the two database systems – Rimini hospital's system (Trak-care, Traksystem Australia) and the new lbs (Harmony, Dedalus company, Italy) were fully integrated using HL7 messages so that patient identification data (name, sex, date and place of birth, domicile, residence, social security number) are directly acquired from hospital records and transferred to the unit's local database.
Data for the anatomical sampling site, laterality (when applicable) and sample type (incisional biopsy, excisional, shave, punch, partial resection, needle biopsy, etc.) were coded identically by the two systems using tables.
To aid in rapid access, anatomical sites were grouped into subcategories according to strict topographical criteria or under the name of the department/ward that usually performs this type of procedure (Fig. 1).
All histological and cytological requests are received via-Web.
The work of designing the system was challenging and took approximately one year, and requiring the cooperation of the Rimini Hospital Information Technology department (ITD) and medical staff at various hospitals in the Rimini area.
Training of medical personnel was done by expert staff from Rimini Hospital's ITD and pathology lab. The training was given to homogenous groups (e.g., operating room staff and surgeons of the various divisions, polyclinical internists, etc.) in classrooms equipped with PCs.
The training took place over the two months immediately preceding the implementation of the new procedure, and primarily involved medical and paramedical staff who work in the operating theatre; training for staff of all other departments was started in groups (three departments per week) in the months that followed.
Requests and labels have data recorded twice (clearly

Fig. 1. Informatic request: patient data, clinical informations, table of anatomical sites.



printed by machine, as well as being recorded on a barcode). This system incontrovertibly identifies patient access by date and test type (Fig. 2).
Within a few minutes after a request is made, the system inserts it in the Reservation List (Fig. 3) via-Web.
For special procedures, such as prostate biopsies - which are often multiple - or for Pap tests, specific pages were created to facilitate correct insertion of all necessary information.
Upon acceptance of specimens in the pathology lab, we carry out the usual cross check between data on the request form and that on the container/s, as well as cross checking the request and any other accompanying documentation (e.g. surgical reports, endoscopic reports, etc.).
The next step is alternating anatomical sites. This is a particularly important and is a crucial step for small biopsies (endoscopies, bronchoscopies, etc.) and is designed to avoid two consecutive numbers representing the same type of tissue.
Once the above is done, lab staff proceed with accession using lbs Armonia. This step consists in giving an identification code to the patient and his or her samples (both machine printed and with a new bar code). The code used is structured as follows: year / I (histology) / C / cytology), A (autopsy) / sequence number (e.g.: 09-I-3874).
The assignment of a code to a patient and his or her samples, utilizes the data contained in the request form barcode, which is read with a barcode reader. This avoids the human error that can occur when the data is manually transferred from a form or a list displayed on a computer screen.
After the creation of the patient/sample code, a new worksheet and new labels for each case (patient) are created and attached to the sample container. Following this, the histological analysis can be initiated.

Fig. 2. Printed request.

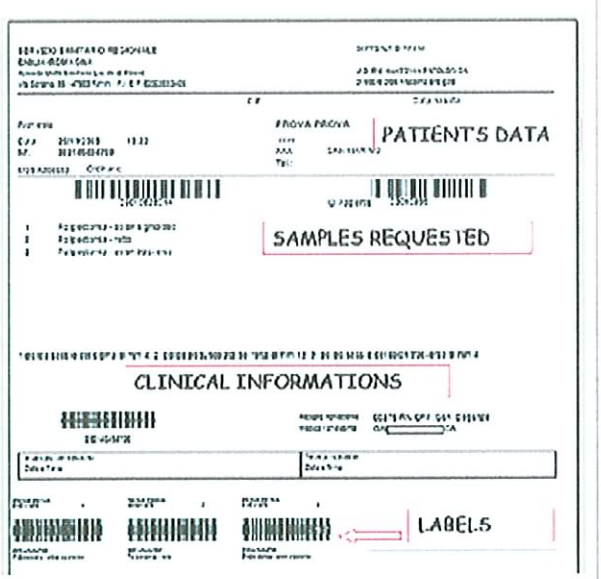
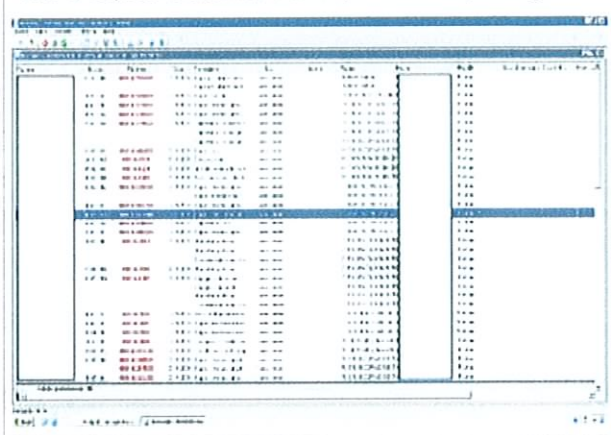


Fig. 3. Reservation List of submitted specimens; from left to right: name surname/ date of birth/ identification code of request/ date of request/ anatomical site/ departement requesting.



Our efforts to improve risk management involved the examination of two other critical points for patient safety, namely correct cassette identification in the gross tissue examination phase and accurately matching the sample block and slide in the cutting phase.
During the gross tissue examination phase, the patient code is directly machine printed onto the cassette and not before, thus reducing the likelihood of confusing different samples and codes. The code printing is done by linking the software with the cassette printer (Leica Microsystem) and by reading the bar code on the worksheet.
Similarly, during cutting, automatically printed slides with patient data (name and surname) are obtained in the same way (direct linking between lbs-Armonia and the slide printer (Leica Microsystem). Direct printing avoids the use of adhesive paper labels, which are the cause of many preventable errors. Each time, the technician takes a limited number of paraffin blocks with consecutive code numbers, finds them in the section of lbs that handles this phase of the work and prints the corresponding slides, both for routine staining sections (H&E) and for recutting sections, special stains and immunohistochemistry, all of which are requested via computer by staff at the time of diagnosis and reporting.
Slides belonging to different patients are placed on separate supports in order to make it more difficult to confuse slides between different patients and to confuse different specimens from the same patient.
To assess the quality and effectiveness of this method, non-compliance (NC) is recorded on a specially-created section of lbs. This is a rapid process as it involves using a simple function key (F6) or by clicking on an icon in the menu bar. Our internal operating procedures require that NC registration takes place at the moment of detection by the person who first becomes aware of the NC, regardless of professional role.
NC is classified into 3 types: those relating to requests, those relating to the sample and those for cytology, which is classified separately because of the nature of cytology specimens.

There is also a lbs section called RM (risk management), in which each type of 'error' occurring in the entire lab work flow is recorded. By 'error', any potentially harmful event and any adverse event that occurs during the lab workflow, is intended (Fig. 4).
The information collected includes corrective action to be taken, the time and date when the error took place and the reporting operator. The name of the operator who detected/corrected the error and the time/date when the correction occurred is also reported.

Results

The system adopted allows the safe identification of the patient and his or her samples. Importantly, this is done at the place and time of the medical procedure. This is different to the previous procedure when identification and data recording was carried out by pathology laboratory staff (at the administration office) hours or even days after the medical procedure took place.
This is a crucial point in terms of patient safety and is in line with recent guidelines from the Italian Ministry of Labour, Health and Social Affairs contained in the *Handbook for Safety in the Operating Room: Recommendations and checklists, specific objectives in regard to the proper identification of surgical specimens* [7].
The goal of correct patient identification has been achieved through the elimination of easily misinterpreted handwritten data and by eliminating manual data transcription into another system (hospital to lbs). Data transcription inherently involves a high risk of operator error.
The checking of all accompanying paperwork for samples is particularly important as it is the only means to check if a patient identification error occurred during entry. The alternation of samples from different anatomical sites – a fundamental part of the DPR AIP / PS 01 procedure at the acceptance phase – is carried out to avoid container labelling errors, allowing the pathologist to realise that an error has occurred previously, at the time of reporting.
During the accession phase, a bar code is a more reliable method of obtaining a code number compared to finding the patient manually in a list; the list is used only in the rare event that the bar code is unreadable or the barcode reader fails to operate correctly.
In the gross examination phase, the identification code is obtained using a barcode reader and is then automatically printed directly on the cassette. This is quick and easy and avoids their preparation in advance. It also offers a huge advantage in terms of safety, there is no risk of confusing pre-labelled cassette on the workstation. Likewise, during the cutting phase, the identification code, patient name and surname are printed directly on the slide, avoiding the use of adhesive labels.
Recording errors and NC ensures constant monitoring of the quality of work.
An examination of NC histology data in 2009 (Fig. 5) showed a net reduction of patient/sample misidentification.
After the introduction of the new system outlined above, the two most frequently reported types of NC were related to initial inexperience of the operator with the information technology employed, and almost none of these were serious in nature.
Only 5 cases of NC were serious, and all 5 involved the requesting physician retrieving the same patient twice during data entry, leading to misidentification of the second patient. It is important to note that none of these resulted in serious consequences, as they were detected before accession (since paper documentation accompanying the patient sample was checked as part of standard procedure).
To try to eliminate repeating such an error, all staff who processed the data (staff of the Rimini Hospital pathology lab, ITD personnel and director of Risk Management for the hospital) for the NC cases in question met together to carry out an error audit. It was agreed that a new training course for the informatics technology employed in the system should be instituted for the staff concerned. The software was modified so that if one patient is recorded as having the same type of procedure in a short period of time (i.e. within minutes), the doctor quickly receives a query message to make sure that a mistake has not been made.
The percentage of NC in histological cases was 0.68% (Fig. 6), representing 183 cases of NC for 26,963 cases in

Fig. 4. Type and numbers of 'errors': near miss and adverse events.

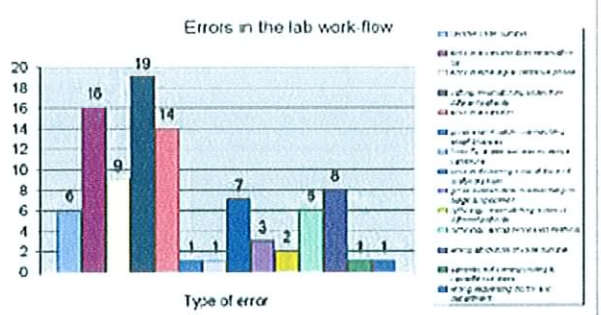


Fig. 5. Type and number of NC.

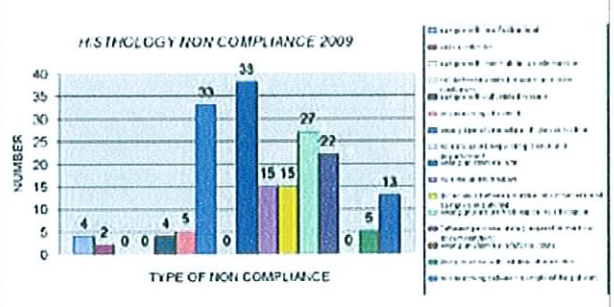


Fig. 6. On 26963 histological cases, 183 NC equal to 0.68%.

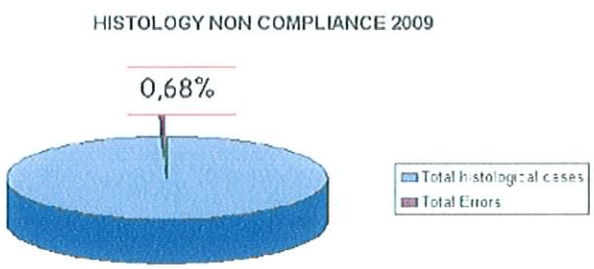
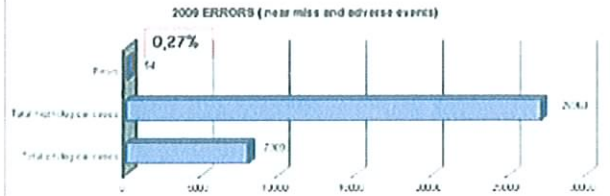


Fig. 7. On a total of 34.932 cases the 'errors' was 94 equal to 0.27%.



a one year period. To better understand how these errors occurred and how to avoid them in the future, we carried out statistical analysis, and for the more serious cases of NC, an error audit was done. This useful although hard work produced significant changes in protocols and has fostered greater collaboration between the different operators involved in each stage of the work process.
Data error statistics (Fig. 7) show that the error rate recurrence is 0.27%. It is important to note that none of the errors resulted in a harmful event for any patient. All errors were detected before diagnosis, with the exception of one case, where the patient's physician noticed the error before delivering the report to the patient. A recurrent error rate of 0.27% corresponds with estimated probability: the rate is low and demonstrates that good work standards are being achieved (Tab. I).

Conclusions

The adoption of this highly innovative system in May 2008 was the result of a joint effort that involved the staff of the Pathology Lab and the ITD, as well as the medical, nursing and administration staff for every department in the various hospitals of the Rimini region.
By using the described system, regardless of the software employed (there are several commercially available programs), and the procedures outlined herein, patient identification can be safely managed and pathology sample errors resulting from misinterpretation of handwritten data on sample labels can be eliminated.
The system allows us to clearly identify the physician and the requesting department, to deliver the report and to reliably obtain and communicate clinical information that is essential for a correct and appropriate diagnosis. In general the procedure described, supported by computer and barcode technology, allows the unequivocal identification of the patient and his or her samples at all stages of these complex work processes, from acceptance to delivery of the final report.The detection and recording of NC and events, and their statistical analysis, has allowed us to monitor error frequency and to identify the critical points in the workflow where errors are more likely to occur. Accordingly, this allowed us to develop appropriate initiatives to remove problems.
In 1999, a publication emerged that completely changes approaches to error management: J. Reason's *To err is human* [8]. Instead of an approach that focused on the human element of the system, this study focused on the failures of the system itself and how to learn from these [9].
Reason [10] clearly established that error is inherent in human beings due to carelessness, excessive workload and stress, and therefore cannot be completely eliminated. Precisely for this reason, for patient safety and in the interests of the operators themselves, it is necessary to create pathways and work systems that minimize the chances of making a mistake.
Reason writes that 'We can not change the human condition but we can change the conditions under which men work' [11]; this is achieved through risk analysis and implementation of safety procedures [12-14].
We believe that the changes in our pathology unit follow this principle, and therefore represent a significant contribution in the management of risk in pathology.

References

Tab. I. Estimates of the probability of occurrence of the error.

Probability of errors	Range of probability	Score	Action
Very frequent	> 20%	9-10	Score >8 Immediate action
Frequent	14-20%	7-8	Score 7-8 Improvement in 2 months
Likely	7-14%	4-6	Score 2-6 Improvement in 6 months
Occasional	0.3-7%	2-3	Score 2-6 Improvement in 6 months
Remote	< 0.3	1	Score 1 Maintenance of actual workflow

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