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ORIGINAL ARTICLE

The role of 2D bar code and electronic cross-matching in the reduction of misidentification errors in a pathology laboratory. A safety system assisted by the use of information technology

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Key words

Mismatch errors • Risk management • 2D Barcode technology • Safety management of patient specimens

Summary

Introduction. Mismatching of patients and specimens can lead to incorrect histopathological diagnoses. Most misidentification errors in laboratories occur during the manual pre-laboratory and laboratory phases. In the past few years, we have examined this vital and challenging issue in our unit and introduced appropriate procedures. Recently, we have paid special attention to the problem of specimen mix-ups in the gross examination phase and the mismatching of blocks and slides in the cutting phase.
Objective. We have focused on the reduction of the potential sources of mismatching of specimen containers, tissue blocks and slides, focusing in particular on the most critical steps which are gross cutting and preparation of microtome sections.
Design. A 2D bar code directly printed on the labels of specimen containers, and directly printed onto cassettes and slides, is now being used; in addition, the system performs an electronic cross-check of tissue blocks and slides, which is managed by the laboratory information system.
Results. The present system permits full sample traceability from the moment samples reach the laboratory to the issuing of the final report. Indeed, the LIS records samples, blocks and slides in real time throughout the entire procedure, as well as the operator's name, and the date and time each individual procedure is done. This facilitates later monitoring of the entire workflow.
Conclusions. The introduction of 2D bar code and electronic cross-checking represents a crucial step in significantly increasing the safe management of cases and improving the quality of the entire work process.

Introduction

Since the publication of "To err is human" in 1999 [1], substantial work has been done to reduce factors that contribute to errors in medical and surgical pathology practice. Procedures in the histopathology unit involve multistep processes with several handoffs of materials, which are all potential sources of error [2]. Errors that may occur at any stage of processing vary in frequency, depending on the laboratory. Several papers have been published that analyze and propose solutions [3-5]. Over the past five years, we have approached this challenging issue in our laboratory, with particular focus on the pre-laboratory and laboratory phases.
The most critical step is the accession phase, which is characterized by incorrect patient identifications and incorrectly-recorded laterality and anatomical sites. Another two steps in the procedure that are particularly prone to error are the gross and cutting phases, which are characterized by sample mix-ups and block and slide mismatching errors.
A significant reduction in the number of misidentification errors on accession was achieved in 2008 with the elimination of handwritten requests and handwritten labels, and by the introduction of an order entry with electronic requests and labels. In addition, direct printing of cassettes and slides by automatics printers interfaced with the laboratory information system produced a considerable reduction in block and slide mismatching errors.
However, data analysis in 2009 revealed continuing block and slide mismatching. For this reason, at the be-

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ginning of 2010, a 2D bar code was introduced, which is directly printed onto container labels, cassettes and slides, in order to reduce mismatching in the gross examination and cutting phases. This new technology is also an effective means of improving sample traceability during the workflow.
The purpose of the present work is to discuss the highly reliable work procedure we have developed, which fully utilizes the benefits of information technology.

Materials and methods

The entire process was reorganised in May 2008 when a new laboratory information system (LIS, Armonia Dedalus, SpA, Italy) was integrated with the Hospital Information System (HIS; Trak-care, Traksystem, Australia), with an HL7 interface for receiving orders from physicians through HIS order entry. This eliminated the need for handwritten requests and handwritten container labels. At the same time, the LIS was interfaced with the cassette and slide printers (Leica Microsystems, Bannockburn, IL) to handle cassette and slide printing case-by-case during the gross and cutting phases; this avoids the need for manual code transcription. All of the above has been described in detail in a previous publication [6].
Since 2010, the LIS has used a 2D bar code and has been interfaced with both cassette and slides printers (a Leica printer in the Cytology Lab and Slide Mate printers [Thermo Fisher Scientific, Waltham, MA] at the Cutting Station); the LIS also has been integrated with a Leica BOND-III instrument, which fully automates immunohistochemistry work; 2D bar codes are directly printed onto immunohistochemistry slides at the cutting station: the BOND-III reads the 2D slide bar codes. Extensive bar code printing testing and validation for cassettes and slides was conducted by Leica, Thermo Fisher Scientific and Dedalus, and for scanner configuration by the Dedalus Company and Metrologic Instruments Inc. We chose the Metrologic MS1690 Focus, which is an omnidirectional scanner capable of reading all standard 1D and 2D bar codes.
During set up, we carried out ping testing on cassettes and slides. No input failure occurred. Bar code misreading may be caused by poor quality cassette and slide materials, which can cause variations in printing quality. We always test any new material that will be used.
The following are printed on cassettes: the accession code (e.g. 11-I-11340), specimen container letter (e.g. A, B, C), subpart block number (e.g. 1, 2) and a 2D bar code, which includes a progressive printing number (Fig. 1).
The following is printed on the slides as human readable text: accession code (e.g. 11-I-13800), patient name and surname, type of stain (e.g. HE, PAS), the name of our unit (Anat Pat, RN); in addition there is a 2D bar code, which also encodes a progressive printing number.
The progressive printing number, found in both slide and cassette 2D bar codes, is essential for the univocal matching of a block and its associated slides. It is impossible for two identically identified blocks or slides to exist. For example, if a slide is printed and then the same slide is printed again, the first slide printed is identified in the 2D bar code as 11-I-13500A2**1** and the second one 11-I-13500A2**2**.

Fig. 1. Cassettes and slides with a directly printed 2D bar code and accession code number. Slides also show readable text: name of institution, type of stain (HE: yellow slides and immunostains for Ki-67, progesterone and oestrogen receptors: white charged slides) name and surname of patient.

This is of fundamental importance and is a key point regarding matching of blocks and slides.
Each workstation in our unit is equipped with a PC, monitor and scanner. We have also equipped each cutting station with small slide printers to avoid the need to preprint slides. The LIS manages each individual step via the 2D bar code regarding the processing of samples, blocks and slides by recording the name of the operator and the date and time of the step; in this way, each single case is traceable during the entire work procedure.
The LIS furthermore records any error or problem detected at any stage in the workflow. This function is quick and easy to access by using a keyboard; in this function, a list of predetermined parameters are displayed: e.g. error or problem type, possible corrective action, date, time and operator. Cases where an error has been detected are marked by a special icon, so that the pathologist is alerted and can check the validity of the corrective actions taken before diagnosis.
Errors and problems are subdivided in the following way: accession errors, specimen errors or problems, and misidentification during the processing procedure. Each subgroup is further divided into other sub-categories (e.g. misidentification during gross examination, embedding, cutting, etc.). This system permits rapid analysis of collected data. Once a month, a specially trained technical staff member evaluates data trends.
The unit's workflow, which is bar code based, is described in a consistent and easy-to-read manner.

1. *Accession phase*: after a double check to verify that data on the electronic request corresponds to that on the medical report that accompanies specimens (e.g.

Fig. 2. Downloaded request form and adhesive labels attached to specimen containers. Above: patient data; middle: the two submitted specimens: 1) skin from the lumbo-sacral region; 2) skin from the patient's hip and clinical information; below: the space occupied by detached labels.

bronchoscopy, endoscopic report, etc.), the case is entered into the LIS by scanning a bar code on the paper copy of the electronic request, determining the recovery of the request from HIS (Fig. 2). The LIS provides a lab worksheet with number (e.g. 11-I-14500) both as readable text and as a bar code (Fig. 3), and also provides labels for specimen containers in readable text as well as a 2D bar code. Once a misidentification error is detected, the case is rejected and it will be processed after the error has been corrected.

2. *Gross examination phase*: the specimen containers are moved to the gross bench for sectioning and recording of macroscopic findings. Our LIS provides many predetermined parameters for each anatomical site and each medical procedure; for example, the topographic code (SNOMED), the number and colour of the cassette (orange for urgent cases, white for sentinel lymph nodes, yellow for small biopsies, blue for lymph nodes, pink for skin biopsies and green for surgical specimens), section number, and the routine stains or immunostains, if provided. The default setting may be modified at any time during the process. Cassettes are directly printed (Leica Microsystems, Bannockburn, IL) case-by-case during gross examination. The printing process is quick and easy.
3. *Tissue embedding phase*: after processing each cassette is read by the scanner before embedding the tissue. The LIS displays the following: code number, tissue type, fragment number and notes, if recorded during gross examination, including operator name, date, time and status (Fig. 4); after reading, the cassette's status is changed from *processing* to *executed.* When all samples related to a single case are embed-

Fig. 3. An internal lab worksheet: accession number and 1-dimensional bar code and adhesive labels for specimen containers with a 2-dimensional bar code.

Fig. 4. Tissue embedding station: the cassette is read by the scanner. The LIS displays all relevant information and shows a list of embedded cassettes.

Fig. 5. Cutting station: the cassette is read by the scanner, the LIS shows all tissue block information (patient name and surname, code number, tissue type, number of fragments, embedded status, operator and date) and the slide Mate printer prints the relevant information on the slide.

ded in cassettes, the case status is changed from *gross executed* to *embedded*. The LIS sequentially shows a list of all embedded cassettes on the monitor in the work session, and, if required, supplies a printed list.

4. *Cutting phase*: just before cutting, the operator reads the block's bar code with the scanner, and the slide printer prints all the associated slides; after section cutting (and only at this time - before it is picked up) the slide is read by the scanner. If the slide does not match the block, a message error on the monitor alerts the operator (Fig. 5). The LIS displays the changing status of the slide from *requested* to *validated* only if the slide matches correctly. When all slides related to a single case are validated, the case's status is changed from *embedded* to *cut*.
5. *Checkout phase*: at the end of the entire work flow procedure, there is the final check before delivering slides to the referring pathologist. Each slide is read by the scanner, and when all slides of a single case (routine stain, special stains and immunostains) are 'pinged' the case is ready to be sent for medical examination.

Results

The results achieved have been particularly good and of significant importance. Since the introduction in 2010 of 2D bar codes on container labels, we have not had a single case of sample mix up in the gross examination phase in a total of 26,964 histological cases. In the gross examination phase, each case begins with a reading of the 2D bar code on the container label, and the LIS makes it impossible for a code number that is different to the case number in question to be printed on a cassette. In contrast, in 2009 we had 10 errors in a total of 26,961 (0.03%) cases that involved mismatch of samples from the same patient.

Additionally, in the cutting phase we have had no mismatch since automatic cassette and slide cross checking was made possible by the introduction of 2D bar codes in 2010 (26,964 histological cases; 80,571 tissue blocks). In contrast in the same period in 2009, we had 32 mismatches from a total of 26,961 cases (0.11%) (80,361 tissue blocks) caused by the transfer of sections from one block to a mismatched slide. Data analysis showed that mismatch errors were more or less equally distributed between routine cutting (14 cases) and re-cutting. There was a slightly greater error prevalence for re-cutting (18 cases), where the errors involved cases with similar code numbers (e.g. 09-I-23715 and 09-I-23915); 12 of 18 errors involved specimens from different patients, and 4 of 18 involved different specimens from the same patient.

Of the 14 routine cutting mismatch errors, 10 involved different patients. None of the errors for either the gross examination or the cutting phase resulted in adverse consequences for the patient, as they were detected during subsequent steps. The errors were noticed in some cases because the clinical information was not concordant with histological appearance. In other cases, the slide samples clearly did not correspond with the anatomical site indicated in the request when viewed under the microscope. Another particularly important result achieved by the introduction of 2D bar coding is the introduction of automated tracing; it is now possible in real time, to trace a specimen container or missing block and locate it immediately.

Indeed, the LIS manages the workflow, step by step, recording the operator's name, date and time of each single step. We are now able to know what is happening in real time, and to take immediate action to locate a misplaced container or block.

Discussion

The case-by-case direct printing of bar code numbers on cassettes and slides by automated printers managed by the LIS prevents errors caused by handwritten labels and by transcription. Checking correspondence between the code number on container labels and the cassette at the gross station and between block and the slide at the cutting station was previously done visually and was therefore subject to error caused by fatigue and lack of concentration.

Even if the mismatch rate was low in the gross examination and cutting phases, and in keeping with data reported in recent literature [7], an error that mismatches a slide to the wrong patient can have serious consequences on clinical outcome.

For this reason, we worked closely with the LIS provider to design a system that would prevent this type of error. The result is that we have up-graded our LIS with the introduction of 2D bar codes on labels of specimen containers, and direct printed on cassettes and slides. The biggest leap in improved quality was achieved by the introduction of electronic cross-match managed by LIS. Another important advance is that there is now sample traceability throughout the entire workflow.

In a recent paper, Zarbo et al. [8] describes a workflow dependent on bar code reading and illustrates the use of traditional bar codes on specimen container labels, in specific labels for slides and use 2D bar code only for cassettes.

Unfortunately, in their laboratory, electronic requests are not yet employed and cases are accessioned manually from handwritten requisitions, which are often incomplete and unclear, as noted by Dimenstein [9]. The labelling of slides represents an additional manual step that is time consuming, prone to error and finally more expensive than directly printing on them.

The electronic checking introduced in the cutting station overcomes the problem of operators failing to follow standard procedures, which was an issue that Zarbo emphasized in his report. The LIS prevents proceeding to the next case and alerts the operator is procedures are not followed. Furthermore, if the slide's bar code is not

read by the scanner, the case is not validated. The introduction of electronic cross checking of blocks and slides is an effective means of preventing inevitable human errors in the cutting phase caused by fatigue, lack of concentration and heavy workload.

During the development of this project, the only concern was the possible increase in processing times. However, during the first three weeks after the adoption of the new workflow we experienced only a small delay in slide delivery, which was caused by the need to train all operators; such training is obviously necessary when introducing new organizational procedures. All technical staff have very positively accepted this new working procedure. In addition, in recent years much has been accomplished in training all operators in risk management, and on-going work has been done with the entire team to identify the causes of mismatching and improving workflow. The knowledge of when, where and why misidentification errors occur, which is a fundamental prerequisite for their successful reduction, has been facilitated by the LIS, which allows quick, easy and complete error reporting at each step of the work flow, as previously described.

In summary, the work over the last few years has been focused on simplifying workflow procedures as much as possible by utilizing information technology, and the employment of bar coding to minimize operator caused error. The process was streamlined by eliminating some potentially error prone procedures, most importantly eliminating manual accession input in the LIS by using a direct electronic request entry. It is important to note that in this manner, the patient and his or her samples are correctly identified at the time they are taken, in the place they are taken and by the clinician who performed the medical procedure, and not later in the pathology lab by a member of administration or technical staff. During gross tissue examination, LIS case data can be accessed by reading the 2D bar code on container labels, avoiding mix-up of specimens; the direct printing of cassettes one case at a time avoids the need for them to be prepared in advance and eliminates the risk of confusing cassettes from different patients. The direct printing of slides, one block at a time, at the moment of cutting of sections, eliminates the need for labelling, which is a time consuming step. More importantly, it also eliminates a potential source of error because traditional labelling is a manual procedure that is visually checked. Furthermore, labelling is more expensive than direct printing of slides. The introduction of electronic cross-checking using 2D bar codes directly printed onto blocks and slides represents a very important qualitative leap. In our experience, it represents the best method for avoiding block and slide mismatching.

The redesigned workflow with 2D bar codes has another advantage: real time case traceability throughout the entire procedure. Gradually we redesigned the entire workflow procedure over a period of years. The support we received from top management was crucial for its success. In our experience, no single piece of technology can eliminate errors in a complex system such as a pathology work flow composed of multiple handoffs. Each laboratory has to consider the individual requirements of their own workflow.

The LIS and bar code technology play a leading role in making the entire process far safer. However, there is also the need for standard operating procedures for each step, accompanied by an efficient system of recording errors for every phase (pre-lab, lab and post-lab) and rigorous daily compliance with all procedures.

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