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Considerations for uniform and accurate biospecimen labelling in a biorepository and research environment

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ABSTRACT

Correct labelling of specimens in a biorepository or research laboratory is vital, especially for translational or clinical studies linking clinical data with biospecimens. While patient privacy must be carefully protected, confusing or inadequate labelling can potentially result in the study of the wrong biospecimens with detrimental effects to the accuracy of published findings or a requirement for invaluable biospecimens to be discarded. Labelling guidelines are described in the biorepository of the University of California—Los Angeles Brain Tumour Translational Resource, and in recipient neuro-oncology laboratories to which biospecimens and derivatives are provided. This approach includes specifying identifier types, types of dates and institutions on the biospecimen labels; using multiple identifiers on each specimen when feasible; and developing a three to four-letter alphanumeric code to aid in label recognition. In addition, steps are being taken to educate recipient laboratories on best practices in labelling.

One challenge in biobanking revolves around the need to label specimens accurately while maintaining patient privacy. Mislabelling of specimens can have potentially serious consequences in clinical settings.[1] Similarly, misidentification of biospecimens in the biorepository and research environment may result in misleading data impacting translational studies or clinical trials. Biospecimens may be released to research laboratories with diverse personnel with variable or no training in the rigorous labelling practices of clinical settings. In addition, patients have the right to retract their specimens from research, necessitating accurate identification to comply with such requests. Our researchers routinely undergo training to understand the privacy regulations regarding research. However, in trying to protect patient privacy, biospecimens may be inadequately or confusingly labelled. Finally, the research number assigned to biospecimens in our biorepository has been purely numerical and, in our experience, numbers may be easily transposed or incorrectly transcribed.

Although studies have shown that careful labelling can reduce errors,[2] we are unaware of standard nomenclature or labelling protocols for biorepositories and research laboratories. The US National Cancer Institute Office of Biorepository and Biospecimens best practices document stipulates only that 'each biospecimen container has an identifier or a combination of identifiers that is firmly affixed to the container, clearly and legibly marked, and able to endure storage conditions.'[3] However, we are unable to identify specific recommendations for patient identifiers required by caBIG or the caTissue software. Ultimately, while labelling with a barcode or radio frequency identification (RFID) system to reduce human error is desirable,[4] we recognise that this is not possible in many facilities because of costs or for infrastructure reasons. Even with barcodes or RFID tags, a legible label is an important redundancy.

Consequently, our laboratory has developed standard labelling guidelines for identifiers and dates for use in our biorepository and recipient research laboratories. We describe our protocols for the labelling of glass slides, paraffin blocks and cryovials for recognition by human eye within the brain tumour translational resource.

METHODS

Routine specification of type of identifier

Undesignated identifiers can easily lead to confusion, especially if two different identifiers have the same number of digits or similar numbering systems. Rarely, we have encountered identical case numbers from different institutions for different patients. Therefore, if surgical or autopsy numbers are used, the institution of origin must be specified.

Our laboratory has instituted a standard practice of specifying the identifier type and institution on the biorepository specimen label (see figure 1A). In addition to the surgical or autopsy pathology accession number, the block should also be specified for paraffin blocks and slides (eg, block B3 in figure 1A). As multiple biospecimens from different patients may be requested, we also use a job number to identify biospecimens corresponding to a specific request or job (see table 1). A proposed universal nomenclature for identifier types is shown in table 1, along with abbreviations and suggested situations for usage.

Routine use of two identifiers when possible

One possible source of misidentification is research personnel incorrectly transcribing identifiers onto samples. We believe it is optimal for all samples to have at least two different identifiers so one may act as a back-up should the other be incorrect (see figure 1B). The use of two identifiers is a safety practice that has been advocated for clinical settings.[3] Researchers have a better probability to back-track to patient information in a database. Dates can aid in identification but must be specified as to what date they reflect. A date nomenclature is proposed (see table 2).

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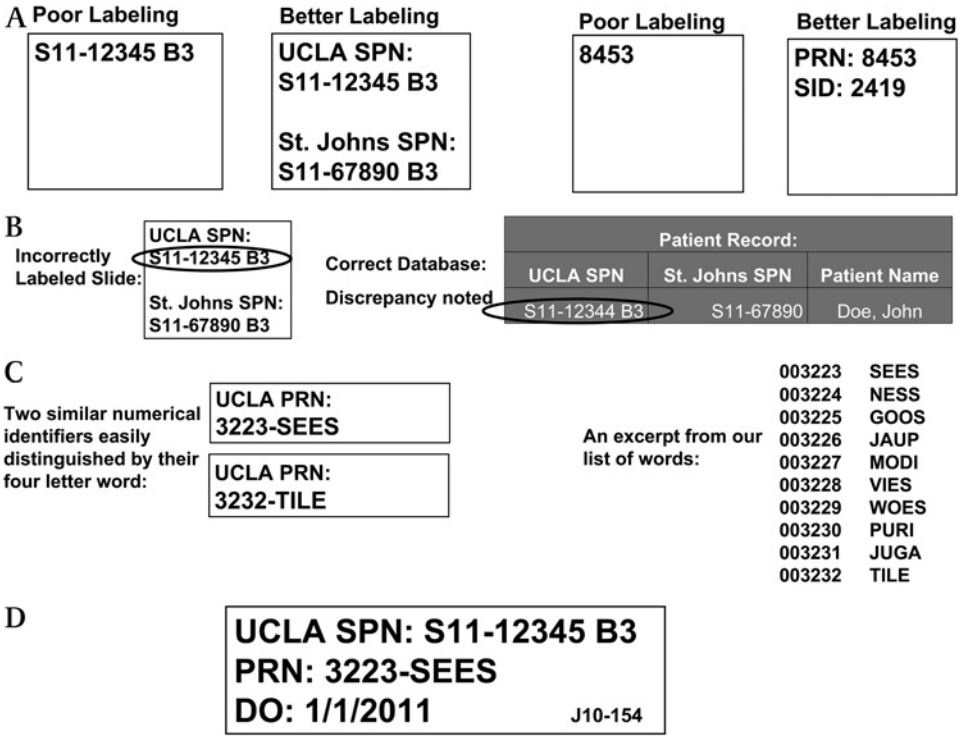

Figure 1 (A) Specification of identifiers. The second label in each example is more useful because it contains two identifiers, each of which are specific as to number type and/or institution. The abbreviations that denote the type of identifier are uniform in the research environment (see table 1). (B) Use of multiple identifiers for error detection and correction. The incorrectly labelled slide can be corrected when one identifier remains correct and can be verified against a database, notebook, or other documentation. The erroneous number is circled. (C) Alphanumeric labelling with a three or four-letter code. The alphanumeric string is more distinct than a purely numerical string. (D) Proposed ideal label. The ideal label shown promotes redundancy and accuracy of labelling by specifying the identifiers, listing multiple identifiers, using an alphanumeric code, listing the date of the operation and specifying the job number.

Incorporation of an alphanumeric labelling system

Purely numerical identifiers are prone to transcription or recognition errors. Recently, a technician started working on a specimen coded 1211 when 12111 was the desired specimen—a situation that might be avoided with an extra letter string (see figure 1C). We have thus created a 4841-word library of unique three and four-letter words attached sequentially to a series of numbers, although not in alphabetical order. The words on the list are chosen from a public list of words,[5] and randomly paired with numbers in a text file. When exhausted, the word library is attached in the same order to the next series of numbers, until 100 000 numbers are paired. In figure 1C, the alphanumeric string is far easier to recognise than the highly similar numbers alone. This alphanumeric list is available upon request. Barcoding software could be easily programmed to include the alphanumeric string.

A proposed ideal label

In our opinion, an ideal sample label would have at least two identifiers and a date labelled as to type (see figure 1D). In this case, a surgical pathology number and patient research number are used. A specimen identification number can be substituted for the surgical pathology number. We routinely include a job number because it facilitates gathering materials relevant to a specific job request and, to a lesser degree, can help narrow possibilities in the event of mislabelling. In situations in which the institution review board status of a study requires a higher degree of anonymisation, this labelling schema will not be possible. In that setting, at the time of distribution it may be appropriate to use a patient research number or unlinked number known only to the biorepository as well as an appropriately identified date for redundancy.

Placement of the label

As lids or caps may be separated from the cryovial body, labels with two or more identifiers should always be placed on the body of the container wherein the biospecimen resides. In addition to the more detailed label on the cryovial body, we also affix a small label to the cap of the cryovial with one identifier to minimise the possibility of confusion. The use of a label printer is strongly preferred over handwritten labels and can achieve legibility even when lettering is small. Cryovial-specific labels and solvent-resistant labels are commercially available and should be used when relevant. The placement of slide labels at

Table 1 Identifier types, abbreviations and usages

Identifier	Abbreviation	Usage	Example
Autopsy pathology number	APN	Links a specimen to its autopsy case	APN: A11-12345 B1*
Surgical pathology number	SPN	Links a specimen to its surgical case	SPN: S11-54321 A1*
Patient research number	PRN	Unique patient identifier in research database	PRN: 9876-LOST
Specimen identification number	SID	Specifies particular specimen of a patient who may have multiple specimens	SID: 5318†
Medical record number	MRN	Unique patient identifier in clinical database	MRN: 111-11-11
Unlinked number	UN	Used when specimens are to be completely anonymous and untraceable	UN: 698
Job number	J	Used to group multiple specimens that are part of the same job requested of the biorepository	J10-113

*Note that blocks (B1, A1, respectively) are specified for the autopsy pathology number and surgical pathology number.
†The specimen identification number (SID) is a numeric only to distinguish from the patient research number (PRN). SID and PRN are generally used together on a label.

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Table 2 Date types and abbreviations

Date type	Abbreviation
Date of operation	DO
Date of autopsy	DA
Date received	DR
Date of experiment	DX
Date of culture	DC
Date frozen	DF
Date of procedure	DP
Date immunostained	DI

the top of a slide as customary is appropriate. While imprinting or writing an identifier on the top edge of a paraffin block cassette is common, additional adhesive labels can be attached to the side or back of the plastic cassette. This approach is needed to attach our biorepository identifiers to paraffin blocks received from outside institutions. Placement of the labelled cassette in a small plastic bag can provide containment for the label coming off and for the tissue if the paraffin should melt because of high ambient temperatures.

Education of biorepository and research laboratory personnel

We suggest that it is valuable to educate sample recipients of proper labelling practices, because specimens are no longer under the control of the biorepository once given to recipient research laboratories. Even within the same laboratory, labelling practices may differ. One person's labelling nomenclature is potentially incomprehensible to other members of their own laboratory—a situation that is exacerbated upon their departure. The provision of a uniform labelling system and nomenclature would alleviate this situation.

CONCLUSION

By specifying types of identifiers, institution names and dates, using multiple identifiers, using an alphanumeric code, and educating recipient laboratories on these practices and standard nomenclature, we suggest that biorepositories will be able to reduce misidentification of specimens in translational research. One or more of these practices may apply depending on the situation. While different institutions may find other nomenclature more appropriate, similar practices to ours may still be applicable. Automated labelling, bar codes and RFID tags have roles to play in the biorepository, but the redundancy of a legible label is desirable. Furthermore, for individual researchers or for biorepositories without such resources, we suggest that uniform labelling practices are vital.

Take-home messages

- Mislabelling of biospecimens in the research laboratory or biorepository may impact the accuracy of research results including clinical trials.
- Labelling with two identifiers can mitigate an error in one of the identifiers.
- Specification of the type of identifier can minimise confusion related to identical numbers originating from different labelling systems.
- A three to four-letter alphanumeric code rather than a purely numerical identifier may aid accurate reading of a label.

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