A Novel Integrated Vial Archiving And Tracking System

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Abstract

Enrolling large numbers of research subjects into clinical studies is necessary to test hypotheses, but this requires the management of an even larger number of biological specimens. We have developed an integrated hardware and software system capable of tracking the use and storage of tens of thousands of biological specimens easily and efficiently utilizing a whole storage rack scanning method. By combining digital imaging technology with data entry, the Vial Archival and Tracking System (VATS) is able to rapidly and effectively track all data necessary to accurately manage research specimens in academic laboratories as well as biotech companies.

Key words: bioinformatics, biorepositories, database, data entry, imaging, inventory

Introduction

High-quality, well-preserved, and accurately labeled biological specimens play a critically important role in modern day clinical studies. Acquired during relevant time periods, usually within specified windows or at defined endpoints, research samples may be different types of specimens from the same subject and used for different research or diagnostic purposes,(Albertini et al., 2000;De Paoli, 2005) thus increasing the complexity of specimen management. Furthermore, enrolling a large number of subjects in a research project is often necessary to test hypotheses with enough statistical power to draw defensible conclusions. However, managing tens of thousands of vials of specimens and carefully updating location and content information is an implicit but difficult task of enrolling large study populations. Because informatics greatly improves the management of samples, implementing an electronic tracking system is an essential tool for any laboratory maintaining a vast inventory of specimens (De Paoli, 2005). Until recently, image processing and database technology had not been integrated to provide a cost-effective, efficient management tool for the complex specimen data requirements of academic researchers and biotech companies.

Currently, we are conducting a large population-based vaccine study that will enroll 1,200 subjects. Blood drawn from these subjects will be collected in three different types of tubes – heparin, EDTA, and no additive – and processed for peripheral blood mononuclear cells, DNA, and serum, respectively. These specimens will be further processed for use in cytokine secretion assays, microarray and antibody neutralization assays. By the end of the study, we will be managing over 66,000 vials stored in at least 5 freezers or liquid nitrogen containers. Realizing the need for an efficient specimen management system, but unable to find an adequate and cost-effective solution through off-the-shelf commercial products or an existing institutional system, we collaborated with Mayo Clinic's Division of Engineering in developing the Vial Archival and Tracking System (VATS). VATS is uniquely capable of supporting a laboratory's complex specimen management requirements.

Materials and Methods

Overview

VATS consists of a custom device called a Rack Scanner that images and identifies all vials and their positions within a storage rack, custom and commercial software, and a database accessed over the institutional intranet which stores specimen donor information along with rack, vial, and freezer data (FIGURE 1). The Rack Scanner updates the database directly with vial location details after capturing and analyzing an image of a rack containing specimen vials. An additional program, VATS Admin, is installed on a local, networked computer creating a second interface to the database allowing users to enter details about specimens, racks, and freezers, as well as to select and locate vials to be removed from storage for experiments based on research protocol requirements.

Storage Environment

VATS views all storage locations simply as database entries. Laboratories store specimens in freezers, cold rooms, liquid nitrogen systems, and even on shelves in the lab. For simplicity, a freezer will be used here to represent any storage location. The Rack Scanner is designed to work with vials stored in commercially-made 81-position, 5 ¼ inch square racks (although this could be altered). All freezers are labeled with a unique number, and racks are labeled with an identification number according to a dedicated freezer position: for example, Rack ID 02-07-12 implies freezer 2, shelf 7, and position 12. This rack will always be stored at this location.

A variety of vials with volume capacities of 1.8 to 2.0 mL have been used with the Rack Scanner. All are polypropylene and have flat (preferably attached) caps. The vial's cap is labeled with a unique Vial ID. All the information about the specimen in the vial is associated with the Vial ID in the database. Vial IDs, as well as Rack IDs, are printed locally using commercially available label stock (Tough Spots from Diversified Biotech) and a laser jet printer. In addition to the human readable identifier printed on the labels, Vial and Rack IDs are encoded into ECC200 Data Matrix codes (commonly referred to as 2D barcodes) which are software readable. In our laboratory, thousands of such labels have been used and they have fared extremely well in lab conditions, including multiple thaw/re-freeze cycles.

Initial Database Configuration

The VATS Admin program is used to enter all peripheral details into the database, such as freezer number assignment, freezer configuration details, storage rack specimen assignment, and specimen storage temperature details. Additionally, the database may be customized to ask unique questions lab personnel must answer each time a specimen is returned to storage, such as volume remaining or concentration.

Rack Scanner

The Rack Scanner is used every time vials are placed into storage (checked in) and removed from storage (checked out). The Rack Scanner's primary function is to efficiently manage data requirements - vial location, current system user, specimen unique questions and answers - anytime a user interacts with a vial.

The Rack Scanner integrates a software-controlled digital camera, custom electronics, a single-board computer, sensors, commercial and custom software, and a custom designed enclosure. The system takes a picture of a rack of vials, decodes the Rack ID and all Vial IDs, and then maps each vial to its location within the rack. Thus, vial location information and user-entered vial details are sent to the database with minimal user interaction.

Specimen Check-In

To place vials into storage (check-in), vials can be placed into any rack taken from a freezer at the appropriate temperature for that specimen. The rack is set into the Rack Scanner which takes a picture of the rack, and processes the image identifying all vial IDs and positions. After the scan is complete, the rack of vials can be placed back into the freezer. The image captured by the Rack Scanner is displayed to the user and vials new to the rack are circled in black (FIGURE 2). Then for each vial being checked in, VATS presents the questions established for that specimen type (e.g., volume remaining in the vial). The user-provided answers, as well as the system-determined vial locations for all vials in the rack, are transferred to the database.

Using the VATS system allows a lab worker to return vials to any rack within the freezer. Vials do not have to be separated by study or specimen type, allowing them to be consolidated into fewer racks. The Rack Scanner tracks the locations, and the VATS Admin program provides the user with the current location of any vial. Furthermore, a freezer inventory can be completed simply by selecting the Inventory function and running all racks through the Rack Scanner.

Specimen Check-Out

Any time specimens are removed from storage, they must be checked out. Using the VATS Admin program, a group of vials to be checked out are associated with a common Run Number. Lab administrators may use specimen donor information and vial information (thaw/re-freeze cycles, volume, etc.) to select the specific vials that will be included in the run. Multiple runs may be required to satisfy the needs of a single research protocol.

Once a Run Number is assigned, it defines a set of vials to be used for an experiment. VATS Admin or the Rack Scanner will display the list of vials and locations associated with any Run Number. Vials for a run are retrieved from storage, put into a "Check Out Rack" and then placed into the Rack Scanner. The Rack Scanner ensures that the vials retrieved are assigned to the Run Number entered. The Rack Scanner updates the database, changing the status of every vial in the run to "checked out." Any vial not associated with the Run is highlighted (FIGURE 3).

Using VATS, lab personnel can separate the tasks of selecting vials for an experiment and conducting the experiment. When the Run Number is provided to the researcher, the only details the Rack Scanner displays are specimen type, vial location, and the intended assay. Limiting information to only what is required in the lab helps maintain patient confidentiality and enforces impartiality, because the researcher ideally knows no differentiating details between the various specimens in a Run prior to performing any assays.

Confidentiality

Specimen integrity and patient confidentiality is further maintained by the security access features of VATS. Users can access VATS only after providing their logon identification and unique password. Access levels define what specific information is available to each user. Lab workers may only be able to view vial locations, while a lab administrator may be able to view demographics of the specimen donor. Whenever the vial record is updated, the activity and the person logged on are archived, allowing for greater control and problem identification and resolution.

Results

While conducting a study encompassing thousands of vials, accurately tracking specimen details and vial locations can consume significant time, especially if details can only be entered one vial at a time. Moreover, laboratories not enforcing a meticulous and detailed planning process prior to storing vials spend additional time locating them for research. An automated specimen tracking system is therefore a crucial piece of equipment for any investigator enrolling large study populations and creating multiple research specimens.

Many current databases have begun to bridge the gap between manual and automated data entry, and are commonly used by labs to manage vial details and locations. Without a VATS system, however, these databases lack the ability of using image processing techniques to determine vial locations and update the database without user interaction. By simplifying and unifying the processes of biological specimen entry, retrieval, and maintenance of specimen integrity, VATS greatly helps labs operate efficiently, cost-effectively, and responsibly.

Many laboratories perform multiple studies in parallel. Therefore, whether the task is running assays, publishing results, or entering and tracking specimen data, the need to operate efficiently is paramount. Traditional systems require the user to note vial location and either enter this information manually or always return the vial to the same location. Either way, vial locations are managed individually. This leads to increased time and risk for human error in data entry. Every system, however, requires some level of human interaction, and thus human error is always a limitation, but VATS protects specimens and eliminates many areas of potential errors by making data transfer seamless and implementing programmable quality assurance measures. The Rack Scanner further offers investigators the advantage of automatically recording and updating vial locations for an entire rack within seconds. Therefore, whether one must initially store vials, track customizable details such as aliquot volume and concentration, locate vials within a freezer and retrieve them for research, or return specimens to storage and update the vial details, significant time is saved and human interaction is limited by interfacing with a whole rack of vials simultaneously.

We compared the time it takes to check-in and check-out 240 vials, in groups of 80, using the VATS system and a typical spreadsheet. For each group of 80 samples, VATS saved an average of 24.24 minutes resulting in 72.72 saved minutes overall for the 240 vials (TABLE 1). Therefore, if every vial was checked in and checked out only once during a study utilizing 1000 vials, an estimated 303 minutes of personnel time would be saved.

“Lost” specimens – truly lost or just buried in unorganized clutter in a freezer – impact study integrity and lab personnel’s ability to conduct research. Because VATS assigns every specimen vial and storage rack a unique 2D barcode number, specimens can be stored in any location within the specified storage system. Although users are allowed to limit what a certain storage rack may contain, the less stringent the laboratory’s pre-defined storage specifications, the more efficient VATS can use storage space. Leaving racks partially empty to physically separate specimen types, different study cohorts or different sources is unnecessary because the system automatically updates the location of each individual vial every time a rack is scanned in the Rack Scanner. As vials are used and discarded, any other vial can be placed in the open location. Moreover, freeing larger portions of the storage system for future use can be easily accomplished by consolidating isolated specimens and placing them in racks containing a few empty spaces. Updating the database with this transaction only requires the filled racks to be re-scanned and the system will update the database with the new vial locations. The fewer empty spaces a freezer has, the more effectively that storage space can be used.

VATS is not limited by the number of vials created. As a result, laboratories can confidently make more aliquots from their original samples, reducing the amount of specimen potentially wasted or unnecessarily thawed and re-frozen – which can negatively affect sample viability. Moreover, because vial specific information is entered into the system after the Rack Scanner has captured the image, details such as current specimen type, volume, or concentration are recorded by simply tabbing through entry fields while the specimens are safely stored. This reduces the time specimens spend outside the freezer to an insignificant variable aiding specimen integrity. When a thaw/re-freeze cycle is unavoidable, VATS increments a thaw/re-freeze counter. This counter is available to researchers and may be used when selecting the most appropriate specimen vial for an experiment.

Having a cohort of specimens processed and stored is a great asset when submitting future grants because it greatly reduces the cost of specimen collection for these studies (Holland et al., 2005). VATS magnifies cost-savings as specimens from multiple studies accumulate. Many labs establish different storage methodologies for each study. As a result, one lab may have multiple spreadsheets or binders detailing the contents and locations of specimens currently being stored. Study specific storage boxes or freezer racks are commonly used to reduce the potential that a specimen is placed in the wrong space and accidentally used for the wrong study. However, by using VATS, there are no wrong spaces. All pertinent vial information is available to users, and the system offers a visual double-check making sure the correct vial is being removed for an experiment. If donors consent to allowing their specimens to be used with future studies, their vials are immediately available for research. In addition, progress reports to grant funding agencies are simplified – vial usage is tracked, and all vials used for a specific study are available as a report.

Recently the National Cancer Institute (NCI) published its First-Generation Guidelines for NCI-Supported Biorepositories (Niederhuber, 2006). Among the issues covered are guidelines for “Data Management and Inventory Control and Tracking” and “Biospecimen Collection and Processing.” Specifically these include: dividing research specimens into aliquots or fractions whenever possible, using a computerized inventory tracking system that tracks the specific position of every stored aliquot with appropriate security/access-control safeguards, assigning a unique identifier to each research specimen upon collection, and updating the biorepository database every time research specimens are moved within or out of the biorepository (Niederhuber, 2006). Compliance with these guidelines is currently voluntary, but this may change. VATS was developed independently of these guidelines, but is aligned with many of the recommendations. As a result, VATS is a viable option for research labs planning to work toward compliance with these NCI’s guidelines.

Discussion

As research laboratories accumulate more biological specimens or begin enrolling large populations for studies, the need for an efficient and cost-effective vial tracking system is central to the productivity of the lab. Here we have introduced a solution to the vial management problem through an integrated digital imaging Vial Archival and Tracking System. This system saves time and significantly reduces human error associated with vial tracking. Because it continually updates the database as multiple vials are scanned simultaneously in a storage rack, vials can be placed in any storage location allowed by the parameters set up by the administrator. Saving space, time, and funds along with potentially creating a future sample cohort, VATS is a flexible and useful tool for research laboratories. Requests for information on implementing this system in other research laboratories may be addressed to the corresponding author.

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Illustrations

Illustration 1

Installed VATS System

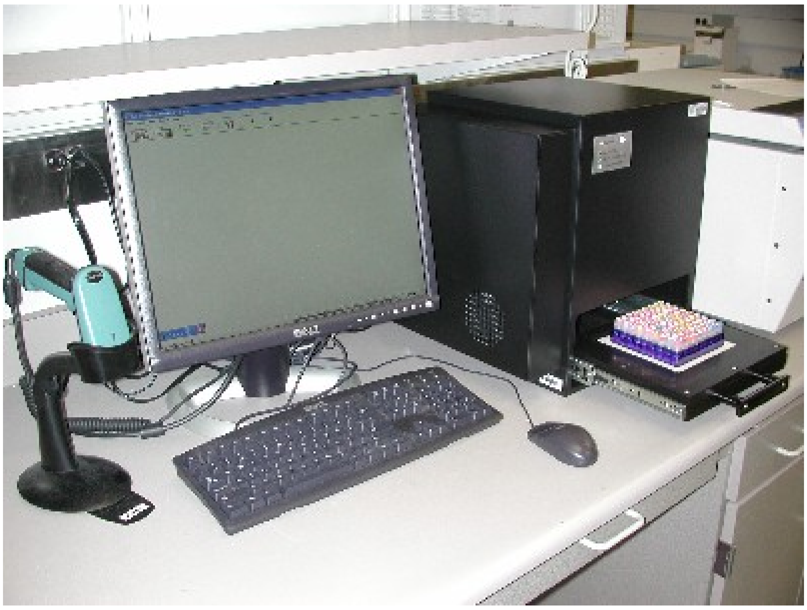

Illustration 2

TABLE 1: Timing comparison Using VATS system vs. using a typical spreadsheet

	Check-in (min)	**Check-out (min)**	**Total**	**Time Saved (min)**
Excel Spreadsheet				
Group 1	31.17	9.63	40.8	
Group 2	26.26	9.4	35.66	
Group 3	24.77	7.95	32.72	
VATS System				
Group 1	3.43	9.12	12.55	28.25
Group 2	3.37	8.67	12.04	23.62
Group 3	3.3	8.57	11.87	20.85

Each group contained 80 vials