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Computer Assisted Systems for Forensic Toxicology

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Abstract - We report the development of a computer hardware and software that addresses the special needs of the forensic toxicology laboratory for real-time, data gathering, analysis, and retrieval. In addition to accessioning, work-list preparation, and result reporting, we implemented automatic test ordering based on patient/decedent case characteristics in the accessioning stage to provide reliable and uniform analyte profiles for case solutions. The system also provides extensive real-time event journaling in order to satisfy strict chain of custody requirements consistent with the College of American Pathologists Accreditation, Substance Abuse and Mental Health Services Administration (SAMHSA) certification and the American Society of Crime Lab Directors (ASCLD).

The relationships among analyte concentrations in various specimens (e.g. blood, urine, gastric,) have been incorporated into the software as functions of time before and after death before the next step in the case life-cycle. These recommended tests are continually reviewed to educate and verify lab procedure. The system has saved many hours of error-prone manual work. It has streamlined data collection and made a broad spectrum of expertise available to the laboratory at all times. These features have decreased error rates, increased productivity and enhanced the forensic skills of the laboratory.

KEY\WORDS - toxicology, information systems, computers, laboratories, accessioning, toxicology laboratories, expert systems, epidemiological.

1. Introduction

This communication describes the design and implementation of a highly successful information gathering retrieval and analysis system used in the toxicology laboratory of the Office of the Cuyahoga County Coroner (OCCC) from 2003 to 2008. For many years our laboratory was concerned about potential deficiencies or omissions with respect to chain of custody recording, erratic test ordering, lost or delayed data, transcription errors, and all of this with an ever increasing workload. (The implementation of systems to address other information management problems in the areas of primary drug standard inventory, general supply inventory, purchasing and receiving and equipment maintenance will be addressed in subsequent communications.)

The OCCC serves the greater Cleveland area. This jurisdiction encompasses a population of 1.5 to 2.0 million people whose average mortality rate is 1% (15,000 to 20,000 deaths a year). Approximately 20% of these deaths become OCCC cases (3000 to 4000 cases a year). The OCCC also offers a referral service to coroners from surrounding counties (40 to 60 cases per year), and serves local police jurisdictions by testing individuals suspected to be driving under the influence (DUI/DUID) (up to 400 per year). We accept biological samples from other forensic agencies and area hospitals for comprehensive drug screening in alleged poisonings and therapeutic drug monitoring (TDM) applications adding another 300 cases per year. Since 2000, the toxicology laboratory of OCCC has processed over 35,000 tests per year using TOXLAB02. Due to this heavy workload we found it necessary to design a more efficient system. We are presenting TOXLAB02 here for others that may be interested in adopting it.

2. General Design Considerations

We designed a system that could be maintained by the budget constraint of a single technical staff member, with minimally a bachelor's degree in computer science. We chose Microsoft's operating systems platform because it could be regularly upgraded and is compatible with the systems of major toxicology laboratory instrument manufacturers. For instance, Linux an open-source operating system was not used because of security concerns. Our desire was to design a system on a platform with proven reliability and functionality.

3. General Goals and System Specifications

The basic system requirements were defined and alternatives for meeting the goals were studied. A primary concern of the design was the incorporation of over 60 fundamental and commonly required tests such as GC/MS, GC's, HPLC, Chem. 7, Immunoassay and ELISA (enzyme-linked immunosorbent assay). To our knowledge, no software with these capabilities was commercially available. Six general goals and several system-specific requirements were developed:

1) A centrally managed, interactive, real-time data sharing environment that permits intra- and inter-departmental access to common data. This would reduce duplication of efforts in transcription and excessive paper usage.

2) A system that maximizes the efficiency and time management of professional and technical staffs to (e.g. minimizes the technical staff's clerical duties).

3) A system that catalogues all events that transpire while a specimen is in our custody. This is a special need essential to the forensic science laboratory.

4) A system that improves the tracking of in-process specimens to minimize the time required to determine status and to increase specimen throughput.

5) A system that permits the construction of real-time interfaces for data acquisition from laboratory instruments and personal computers. We also considered the allocation of jobs to persons and machines to maximize the strengths of each. The current lab structure employs networkable GC/MS, GC's, HPLC, Chem 7, Immunoassay and ELISA instruments. Networkable computer workstations are also available to all staff members for case work.

6) A system that meets the laboratory procedure standards of the American Society of Crime Laboratory Directors (ASCLD), with initial capital costs for hardware, software and initial development that do not exceed $400,000.

Specifications

The toxicology laboratory occupies 482 m^2 (4736 ft^2) of a single floor. It is staffed by two Ph.D.s, seven forensic science professionals, a secretary, and a laboratory aide. The laboratory uses an integrated analytical approach for the investigation of alleged illegal activity. To organize testing the laboratory has been divided into thirteen groups, with the ability to be expanded into twenty. Testing employs the appropriate standards and control proficiencies for GC/MS, GC's, HPLC, Chem 7, Immunoassay and ELISA screening. We are presently using 14 of these instruments and 14 workstations.

4. System Selection

Criteria, requirements, design and limitations

We sought to design an application - specific programming module set that encompassed the current job areas of the laboratory: accessioning (the acquisition of sample material), chemist (the first level of drug analysis), supervisor (reviews chemist results and assigns new or re-testing), manager (reviews supervisory results, monitors work load and recommends further testing along with reporting functions), invoicing (to outside agencies) and medications (case drug inventory).

The system software was developed according to the following requirements: (1) software that allowed maintenance by outside consultants; (2) gradual development of software so that the operating environment could be tailored to the needs of the coroner's office; and (3) compatibility with all hardware platforms (e.g., Java, VM Ware or X-86). Programs were developed and tested on a project-by-project basis to allow ample time for refinement of the applications. Stringent requirements for the system software primarily included maturity of a stable platform.

Two additional requirements were the ability to run commonly used commercial spreadsheet, word-processing, and statistics software and production of data compatible with the systems of outside agencies. The system was also required to allow integration of all major hardware elements into a commercial secure local area network.

Three fundamental approaches to meeting the system specifications were considered during the design process. The first was a single personal computer (PC) the second was a network of PCs and the third was a centralized server computer.

The single PC option was not ruled out because its most common operating system (Windows XP) supported up to ten concurrent users, it had adequate backup capability and a low cost. Previous generations of the PC could not claim the versatility of scalability. PCs have substantial quality, durability, and expandability and provide adequate mass storage backup with limited expense. The PC software market is also rapidly catching up with previous generations of software development for main-frames. In fact, the efficient design of migration paths from older hardware and software to new versions has become a concern of PC developers. High-quality PC networks have matured in concert with reliable networks and have been used with mini-computers for many years.[6] For these reasons, single PCs and PC networks became the core background for the development of our systems.

In designing the development path, we first developed a single PC-based system, then a version of the same system with multi-user capability. Second, we developed a server with a smart-client-based system. Next, we implemented a highbred virtual server, a smart-client system for a larger decentralized laboratory. We realized that the second generation had been designed by few and the third generation has not been built by anyone. The first generation was named 'Toxlab02', the second is named 'Pathways' and is in beta testing at the OCCC. The third generation is in the development stages at the OCCC.

The goals set above were most economically achieved by a centralized mid-range PC with network expansion potential. A PC such as the Dell Precision 360 has high-speed processors and a wide range of peripheral hardware support, including multi-Terabyte disk arrays, DVD backup and full and mature network connectivity. These systems are well supported by mature multi-user, multi-tasking operating systems, database packages, and network products.

Microsoft Access was chosen for data management because it parallels XP platform development. In addition, Access has the ability to migrate to Microsoft server software using the file server component.[1]

To satisfy the need for special logic experts and automated accessioning experts, high-level language software was integrated into the system. The accessioning expert creates a list of tests to be performed on a case based on a combination of three factors (type of samples, type of case and manner of death). The automated function tracks development of testing ordered by these three factors, and lets the accessioned know which testing is currently being prescribed by the lab manager. It serves to eliminate errors due to forgetfulness based on combinations of sample types, case types or manner of death parameters. This requirement could only be fulfilled through a mature, well-supported high-level language program such as some components of the Microsoft Visual Studio Suite.

The lab needed a combination of products that objectively exceeded our expectations, that implementation then could meet our subjective requirements. This was manifested in a method that avoided any tendency to 'profile' a case. Profiling presupposes the nature of the development path of artificial intelligence (AI) experts. An AI expert allows a system to evaluate current work performance, and make suggestions to the chemist based on these results. In addition, an AI expert will "learn" and thus improve functionality over time. The system shell used for AI was word processable in order to increase efficiency. The 'learning from self' became impracticable for half of the project as the complexity of the experts became specifically known.[2]

The appropriate operating system software had to be multi-user and multi-tasking. The mature real-time Microsoft operating system XP (Experimental) was chosen. This system could support the concurrent use of 10 terminals and 10 printers for data entry and lookup functions. In addition, it is accompanied by a rich set of simple instructions and has a user-friendly reputation. Log-in is controlled by passwords that can be changed by the user or the system manager, and can be set to expire. In addition, all application programs access a common self-developed security system that prevents usage by unauthorized persons and limits the use of the programs to specific users.

With this configuration, the manager is able to produce professional-quality final documents. Transmission of the documents is not permitted in order to maintain the lab's level of security and control of its products.

5. Start-Up: Operational Experiences

Hardware installation took about two days. Installation of cable required 200+ man-hours. The operating system was installed by the hardware vendor. Initial installation of the software was accomplished by an in-house network specialist. Thereafter, software loading was automated and any user could update software from the server at any time.

Users had requested the ability to automatically print cases from within application programs. While automation was not possible, a user may issue a "click print" command to any system printer, including networked printers in the local area network. Many programs allow users to select a specific printer to use for their output. Batch processing of case load and results is easily accomplished with this system. The user also receives automated chain of custody in a case folder and in printed form for use in the lab. Batch work and chain of custody forms are held in a library of Microsoft Excel forms. These forms can be modified, added or deleted to meet the needs of new instruments and changes in the laboratory environment. All forms are saved as part of chain of custody for each technician.

We chose to develop the first generation laboratory applications in Visual Basic 6.0, which allows Microsoft Access databases to be read or written with batch programs. Total development time for the specifications for all the applications was approximately 6000 man-hours. Each application was programmed, tested, modified, and retested until it achieved production quality. At that time, parallel trials were performed against the older system. When these trials were completed, the programs were not permitted to operate in the production environment until a change mechanism had been implemented to migrate from the previous generation of software.

All applications developed for the toxicology laboratory used two strategies to minimize development effort and time, and maximize data availability. The first was the use of subroutines further amplified by the use of Graphical User Interface (GUI), and standardized program logic Gang of Four (GoF) design patterns that could be easily incorporated into new applications. The second strategy was the use of the SQL relational database, which permits the development of applications or segments of applications, somewhat independently, while guaranteeing that any application can access and display data from any other application. The data are shared by referencing a common key such as case number in the data dictionary of each database. Selected information requests from many independent sources can thereby be collected and used together.[53]

The TOXLAB02 applications were completed in a period of fourteen months. During this time the laboratory staff was trained to use the system. The staff also contributed to the specifications and design of the software. With the completion of each new module the programmer prepared technical and user documentation, in cooperation with the director. The documentation process required 1000 man-hours and further improved the efficiency and functionality of the programs. When the effort to establish this computer system began, the OCCC toxicology laboratory was a member of the American Society of Crime Lab Directors (ASCLD); the documentation, chain of custody, validation processes and reports were designed to meet this organization's requirements for certification.

Programs may be run on any PC in the laboratory by clicking on the desired module or through a GUI multi-set interface. Several persons may simultaneously use the same program. Data locking features use the pessimistic model, which allows a toxicologist to change information on a case presently viewed by another toxicologist. In the event of an update by the first viewer, the second viewer is advised that information has changed and given the option to update the information by reloading the screen.

The TOXLAB02 program permits new cases to be entered with demographics, case detail and a specimen list. The program automatically generates test orders via (AUTO-ORDER-EXPERT) based on several variables. Each entry is placed in the chain of custody record, in real time, to provide an audit trail of activity.

Chemist/supervisor/manager modules permit scientists to alter any data item in a database master record and to change automated orders, depending on their security. All changes, deletions and additions to these programs are journaled as part of the chain of custody for each case, to provide an audit trail of activity.

The work-list module assembles a bench-by-bench work-list of all cases for which work is pending. Printouts use bold-face fonts to alert the toxicologist to cases that are urgent and/or infectious in nature. All cases are printed in reverse chronological order, so that older cases appear at the top of each individual bench-group worksheet. A work-list may be run on demand by the user and may also be automatically scheduled.

The results module is the main result entry and modification program. It contains a large expert system. Toxicologists may select individual cases through batch mode, declare results, and receive notification of any tests that need to be scheduled based upon these results. This module is dependent on the work-list module. The work-list module organizes samples by type and test;

this facilitates entry of results (i.e., positive, negative, quantity not sufficient and unsuitable findings) with a single key stroke. Qualitative and quantitative results may be changed or deleted before the supervisor's review and approval of the case. The appearance of certain sample-specific results will cause the program's expert to automatically create new test orders for the same or other samples. When all non-negative results have been entered, the toxicologist declares the case to be "ready" for the supervisor's review, in the computer. Every result is journaled in real time to provide an audit trail of all activity.

The manager module permits the lab manager to find and review all cases for which all ordered results have been completed. If the lab manager approves the case, it is internally identified as "approved" and ready for printing. This event is journaled in real time and provides the desired audit trail to verify results for toxicological consistency. This module also prints final reports of cases previously approved by the supervisor. The reports cannot be changed in any way, except by a manager using the manager program. All final reports generated in the laboratory are printed and journaled.

Epidemiological research is the net result of creating a data structure of this type. These programming tools are certain to create a bright future in Toxicology with the use of computers.

6. End of Life Cycle

The life cycle policy is designed to specifically determine the length of time for product management and to schedule development of an updated product. In general, a minimum of 10 years of support is accepted for computer software. The system discussed in this article has been operational for seven years. The life cycle combines two time periods: five years of main vendor support or two years after the successor product (N+1) is released, whichever is longer; and five years of extended support or two years after the second successor product (N+2) is released, whichever is longer. We concur with these standards and promote the knowledge gained from previous generations of software development.[4]

7. Conclusions

The implementation of computerization in the forensic laboratory is a foreseeable extension of the field of Toxicology with the advent of inexpensive computer systems. As we know the software has been developed for a forensic laboratory which does extensive testing – far beyond the pale of the standard "alcohols" type lab. The accuracy of the information, the speed in which it is available and the security involved, became challenging road marks to meet and exceed.

The computer has become a valuable tool that when appropriately applied can and has produced a cost-effective efficient and accurate aid to the forensic toxicologist. The system we have had in operation for the last 7 years has provided us with an operational tool and a source for looking back at the foot prints in the sand to see what we have done.

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