Ronald L. Cechner,[1] Ph.D.; Bradford R. Hepler,[2] Ph.D.; and Craig A. Sutheimer,[2] Ph.D.

Improving Information Management in a Metropolitan Coroner's Office. Part 1: Design and Implementation of a Cost-Effective Minicomputer System with Initial Applications for the Toxicology Laboratory

REFERENCE: Cechner, R. L., Hepler, B. R., and Sutheimer, C. A., **"Improving Information Management in a Metropolitan Coroner's Office. Part 1: Design and Implementation of a Cost-Effective Minicomputer System with Initial Applications for the Toxicology Laboratory,"** *Journal of Forensic Sciences,* JFSCA, Vol. 35, No. 2, March 1990, pp. 375–390.

ABSTRACT: We report the development of a system of computer hardware and software which addresses the special needs of forensic toxicology laboratories for real-time data-gathering, analysis, and retrieval. In addition to accessioning, work-list preparation, and result reporting, we implement automatic test ordering based on patient and case characteristics to provide reliable and uniform analyte profiles for puzzle solving. The system also provides extensive real-time event journaling to satisfy strict chain of custody requirements, consistent with both College of American Pathologists accreditation and National Institute on Drug Abuse certification. The toxicologist's expertise has been woven into the fabric of the software so that appropriate new orders are placed as results from previous orders arrive. The relationships among analyte concentrations in various specimens (blood, urine, gastric, and so forth) as a function of time before and after death have been incorporated into other software experts which review final results for inconsistencies. The system has saved many hours of error-prone manual work, streamlined data storage and access, automated data collection from instruments, 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 puzzle-solving skills of the laboratory.

KEYWORDS: toxicology, information systems, computers, laboratories, minicomputers, toxicology laboratories, expert systems

For many years, our laboratory was concerned about potential problems of chain of custody recording, erratic test ordering, lost or delayed data, transcription errors, along with an ever increasing workload. This communication describes the design and imple-

Received for publication 10 Feb. 1989; revised manuscript received 18 May 1989; accepted for publication 22 May 1989.

[1]Associate professor of pathology and biomedical engineering, Department of Pathology, Case Western Reserve University, and director of anatomic pathology and research computing, University Hospitals of Cleveland, Cleveland, OH.

[2]Associate chief toxicologist and chief toxicologist, respectively, Cuyahoga County Coroner's Office, assistant professor of toxicology and assistant professor of toxicology, respectively, Department of Pathology, Case Western Reserve University, Cleveland, OH.

mentation of an information gathering, retrieval, and analysis system for the Toxicology Laboratory in the Cuyahoga County Coroner's Office (CCCO). 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.

Office Environment

The CCCO serves the greater Cleveland area. This jurisdiction encompasses a population of 1.5 to 2.0 million people whose mortality rate is 1% (15 000 to 20 000 deaths/year). Approximately 20% of these deaths become CCCO cases (3000 to 4000 cases/year). The CCCO also offers a referral service to coroners from surrounding counties at a rate of approximately 40 to 60 cases per year and a referral service to local police jurisdictions for testing individuals suspected to be driving under the influence (DUI) [300 to 400/year]. We accept biological samples from area hospitals for comprehensive drug screening in alleged poisonings [*1,2*] and therapeutic drug monitoring applications, which add approximately 300 cases/year to the laboratory workload.

General Design Considerations

We decided to design a system that could be maintained by the current technical staff in concert with an ad-hoc computer support group. To guarantee a long lifetime for hardware and software, we decided to use the hardware of a single, well-known vendor and to use software which was available for use in the local professional community. As novices on a strictly limited budget, we decided to avoid new, poorly tested, or rapidly evolving computer hardware or software.

General Goals and System Specifications

The basic system requirements were defined and alternatives for meeting the goals were studied. Six general goals and several system specific requirements were developed.

Goals

First, we needed a centrally managed, interactive, real-time data sharing environment which would permit intra- and interdepartmental access to common data. This would reduce duplication of effort in transcription and paper movement. Second, the system had to shift the focus of the professional and technical staffs to tasks more appropriate to their training, for example, minimize the technical staff's clerical jobs. Third, the system had to catalog all events which transpired while a specimen was in our custody. This is a special need peculiar to the forensic science laboratory. Fourth, it was desirable to improve the tracking of in-process specimens to minimize the time required to determine status and to increase specimen throughput. Fifth, the system had to permit the construction of real-time interfaces for data acquisition from laboratory instruments and connection to personal computers. We also considered the allocation of jobs to persons and machines in such a way that the strengths of each would be maximized. Finally, the budget constraints of the CCCO dictated that the initial capital costs could not exceed $40 000 to 43 000 for hardware, software, and initial development.

Specifications

The Laboratory—The Toxicology laboratory comprises a single floor of 243 m^2 (2700 ft^2). It is staffed by two Ph.D.s, five forensic science professionals, a secretary, and a

laboratory aide. The laboratory uses an integrated analytical approach for the investigation of alleged poisoning [*1,3*]. It is able qualitatively to identify, confirm, and quantitate where appropriate a large number of analytes [*3*]. For the testing for these analytes, the laboratory has been divided into five work stations. The majority of the workload falls into seven groups, including volatiles, acid/neutrals, benzodiazepines, enzyme immunoassays, opiates, chemical spot tests, and organic bases [*1–3*]. Testing includes appropriate numbers of standards and controls [*4*]. The incidence and frequency of analyte findings using this approach has been previously reported [*1–4*].

System Selection: Criteria, Requirements, and Design

Turnkey versus programmed systems—We found that there were no turnkey systems (preprogrammed software) within our price range which would fill our particular needs without costly modifications. Since we were interested in developing new and highly specialized applications, we decided to program the system ourselves. This was an important, and frequently debated, decision, but the group felt it knew the laboratory environment exceptionally well, saw the need for a Coroners Office Toxicology Laboratory computer system package of professional quality, and had the experience to create one.

System software requirements—First, the programs had to be written and documented so that outside consultants could easily maintain them if necessary. Second, adequate time was needed for gradual development so that the operating environment could be tailored to the needs of the Coroner's Office. Programs were developed and tested on a project-by-project basis, allowing ample time to refine the applications. Stringent requirements for the system software similarly included maturity, and long-term support by the vendor, with telephone access to vendor experts. Third, the hardware had to be current, supplied by reputable vendors, and have a good record of reliability and customer support with room for upgrade and expansion.

Two additional requirements were the need for the hardware and operating system to be able to run commonly used commercial spreadsheet, word-processing, and statistics software and that our data be compatible with outside agencies whose computers were different from our own.

Finally, it was essential that there be the potential, with currently available technology, for all major hardware elements of the system to communicate via a local area network.

System Design—Three fundamental approaches were considered to meet system specifications. The first was a single personal computer (PC), the second was a network of PCs, and the third was a centralized mini- or supermini-computer.

Single simple PC—The single PC was ruled out because its most common operating system (disk operating system, DOS) supports only one user at a time, because of the lack of adequate backup, and because of the expense for standard magnetic tape interfaces and the rapid changes in PC technology. Although PCs can be configured with multiuser operating systems such as UNIX and with large disks, the cost is comparable to that of a traditional mini/supermini but without the sophistication and software capabilities of the latter.

PC network—Several reasons negated use of the PC network. First, PCs of substantial quality, durability, and expandability and with adequate mass storage and backup capacity were expensive, ranging from $6500 to $13 000 (excluding software) per unit. Second, the PC market is changing so rapidly that one technology is being replaced by another about once per year [*5*], thus making hardware and software quickly obsolete. The efficient design of migration paths from older hardware and software to new versions has been subordinated to other concerns in the PC market until recently [*6*], while it has been a major concern to the minicomputer manufacturers.[3] This is important for easy

[3]J. Kowacek, network software specialist, Digital Equipment Corp., Cleveland, OH, personal communication, March 1988.

expansion in the future. Finally, although high-quality PC networks are just beginning to mature [*7,8*], reliable network backbones have been used on minicomputers for many years, for example, ETHERNET, and there are a few network software products which are widely accepted and which also have been used for many years (DECnet [Digital Equipment Corp.] twelve years, and SNA [IBM Corp.] eleven years [*9*]). It seems inevitable that carefully crafted networks of PCs will eventually compete strongly with medium- and large-scale systems [*10*]; however, except for small, stereotyped applications, the use of a pure PC network was very difficult to justify at the time that we began our work (1986).

The goals set above were most economically achieved by a centralized mid-range minicomputer with network expansion potential. Minicomputers such as the DEC PDP 11/73 have high-speed processors, a wide range of peripheral hardware support including large disks, magnetic tapes, multichannel communications, and mature network hardware. These systems are well supported by mature multiuser, multitasking operating systems, many languages, database packages, and network products.

Results

Computer System

Hardware (Fig. 1)—A study done by the Price Waterhouse Company [*11*] served as a guide to our choice of equipment. We decided that a DEC PDP 11/73 minicomputer

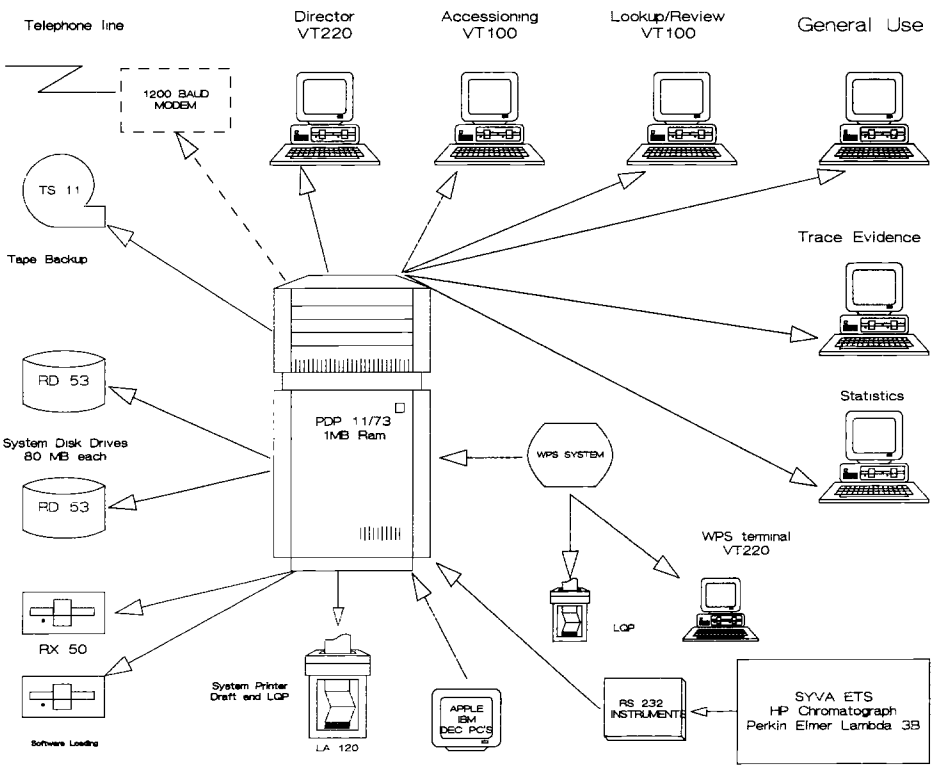

FIG. 1—*Hardware system: hardware configuration, terminal, and printer distribution in the Coroner's Office and toxicology laboratory.*

with 2-megabyte (MB) random-access memory, two floppy diskette drives (software loading devices), 2-80 MB fixed-disk drives, an industry standard ½-in. (1.3-cm), nine-track, 1600-bits/in. tape drive, (for data exchange with other mainframe systems) 24 channels of communication with 1 modem channel, 2 printers, 5 terminals, and a stand-alone DECMATE III commercial-grade word-processing (WP) system would serve our need and was within our budget. Hardware maintenance contracts totalled $6400 per year and were adjusted downward as experience was gained. Software support, $7200 per year, was also adjusted downward as more experienced personnel became available to program the system.

Operating System Software—The appropriate operating system had to be multiuser and multitasking. Because we had to interface real-time analytical instruments, the mature real-time DEC operating system, RSX-11M-plus (micro-RSX), was chosen. This system will support 16 to 24 terminals or printers being used for common data entry and look-up functions, high-density mass storage devices, floppy disks for data exchange, and industry standard magnetic tape. The operating system has a rich set of simple instructions and a long reputation of being easy to use by computer novices. Log-ins are controlled by encrypted passwords which can be changed by the user at will and which are expired and changed by the system manager. In addition, all application programs access a common self-developed security system to prevent unauthorized persons from using programs and to limit the use of "key" programs to specific terminals.

Database Language Software—This package had to permit novice users to design simple programs for data entry and retrieval and design processing logic and reports interactively in a way which was self-documenting. The package RDM (Responsive Data Manager from Interactive Technology, Inc.) filled these needs. RDM can access files created by other programs on the system, and vice versa. This development tool permits the construction of either relational or hierarchical databases with six files open simultaneously and no limit on the number of files accessed by one application. Screen design with many video attributes available can be done interactively or coded with a "macro" language. Any field can be the virtual key for complex interactive searches without special programming, and the entire product is based on the use of a common data dictionary for files, screens, and reports.

General-Purpose Language Software—When the need for special logical processes, for example, expert systems, arises, programming the application in a high-level language can save time and produce a product much faster than and superior to other alternatives. To fill this need we chose a mature, well-supported, high-level language, DEC BASIC-PLUS-2, which has some features of BASIC, FORTRAN, COBOL, and PASCAL. It allows a full range of scientific calculations as well as a rich set of instructions for file management. It has simple instructions which permit the intermediate-skill user to interface analytical hardware directly.

The production laboratory system needed fast multiaxial access to data, to online instrument channels simultaneously, and it had to support interaction with a network as well. Basic-plus-2 easily filled all of these needs. We evaluated PROLOG on a PC for implementation of our anticipated expert system(s), but found that development time was excessive, software support was poor, and, most important, our expertise could not be implemented simply and understandably with table-driven logical processes which could be programmed by novices. We simply did not see the need for complex shells which distracted us from the job of quickly making a useful expert. In addition, an expert system shell for the minicomputer was very expensive and, like all artificial intelligence (AI) shells, was still undergoing considerable development.

Word Processing Software—As demonstrated elsewhere [*12*], commercial-quality WP can increase efficiency, accuracy, and maximize throughput in the clerical functions of the office environment. The special features of WP minimizes paper use, reduces the chances of new error introduction in editing (retyping), and improves morale of the

clerical staff considerably. We have seen document throughput triple in a surgical pathology office with the introduction of professional WP hardware and software [*12*].

We purchased a stand-alone DECMATE III WP system with communications software. With this configuration, the WP specialist is able to produce professional-quality documents and, if necessary, transmit them to the minicomputer where users can edit the document with the system editor. In a similar fashion, users on the minicomputer can produce documents with the system editor and transmit them to the WP system for final, high-quality printing. Text from this system can be exchanged with RDM databases and Basic-plus-2 indexed files by user-written programs and RDM-supplied utilities called from the programs.

Networking—An ETHERNET network is installed on the current system and communicates with a new MICROVAX II computer in the general office via DECNET software. Users on the PDP-11 laboratory system can become MICROVAX users and access all of its resources (for example, VAX MAIL). Likewise, users and programs on the MICROVAX can access files on the PDP-11 as though they resided on the MICRO VAX. All the programming to accomplish this is done in Basic-plus-2. In addition, any user on either system (MICROVAX or PDP-11) can access a Logicraft 386ware DOS server, which makes most popular DOS-based programs available to all users with dumb terminals (VT2xx-VT3xx). Because bit-mapped graphics cannot be done on the DOS server, we have installed three 286/386 PCs, which are connected to the thickwire ETHERNET backbone and which use the MICROVAX computer as a server. These users can tap the power of *any* DOS based program while storing spreadsheet data, graphics, computer-aided design (CAD) files, and so forth on the disk(s) of the MICROVAX. In this way, *all* PC users can share DOS data and can readily exchange these data with those stored by non-DOS applications on the MICROVAX. With this arrangement we serve the needs of the sophisticated PC user and the needs of the minicomputer user for PC tools and permit data sharing among all of the systems. The use of a DOS server by MICROVAX/PDP-11 systems and the simultaneous integration of PCs into a minicomputer environment will be the subject of another publication.

Interfaces to Real-Time Analytical Instruments—A characteristic of the system which will be useful as better hardware is developed for positive specimen identification is its ability to be programmed for real-time, two-way communication with analytical instrumentation. So far we have interfaced a Hewlett-Packard (HP) 3393 gas chromatography (GC) Integrator attached to a HP 5890, a Perkin-Elmer Lambda 3B spectrophotometer, and a SYVA ETS. The importance of this aspect of the computerization of the laboratory lies in using the computer as a means of tracking samples and results and further reducing human transcription errors. The incidence and frequency of this type of error have been studied in other contexts [*12*], and we expect reductions similar to those found elsewhere.

Start-up and Operational Experiences

Hardware/Software Installation—Hardware installation took about two days, and cabling required approximately 20 man hours. Operating system installation required 2 h, the application design package (RDM) ½ h, and the language processor (BASIC-PLUS-2) 1 h. The Digital PDP 11/73 with all central hardware, disk and tape units, communication controller and journaling printer take 0.5 m^2 (6 ft^2) of floor space. The current system, application and development software, and all files for all systems occupy 40% of the space on one disk and 4% of the other (see Fig. 1). Both disks are backed up daily and require only one tape change per day. Terminals operate at 9600 to 19 200 baud. Printers operate at between 45 characters per second (CPS) (letter quality) and 180 CPS and can use paper up to 35 cm (14 in.) wide, multipart forms, and labels. Responsibility for back-up tape and paper changes is shared among the laboratory staff on a rotating basis. Back-ups are mostly incremental and are automated. Almost all queueing of print

jobs is done from within application programs automatically. However, anyone can issue a "print" command to any of the system printers, including networked printers (laser) residing on the MICROVAX. Users have the option from many programs to select which printer to use for their output. The modem, for remote or longer distance interbuilding access to the computer, operates at 1200 baud.

Software Development—We chose to develop all of the laboratory (TOXLAB) applications in BASIC-PLUS-2. RDM databases can be read or written with batch programs in Basic-plus-2 and using RDM-supplied utilities. The specifications for all applications took a total of approximately 150 manhours to develop. Each application was programmed, tested, modified, and retested until it was of production quality. At that time, parallel trials were performed against the corresponding manual system. When these trials were completed, the programs were permitted to operate in the production environment.

All of the applications developed for the toxicology laboratory used two strategies for minimizing development effort and time and for maximizing data availability. The first was the use of subroutine libraries, which are standardized pieces of program logic which can be easily incorporated into new applications. The second strategy employed was the "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, and by the data dictionary, which describes the data in each database. Through this mechanism, selected bits of information from many independent sources can be collected and used together.

The TOXLAB applications were substantially completed over a period of eight months. During this time, the laboratory staff were trained to use the system as a general tool and they contributed to the specification and design of the various programs. With each new module, the programmer, in cooperation with the laboratory director and staff, prepared technical and user documentation. Excellent documentation is as important as efficient bug-free programs, and 300 manhours were required in the documentation effort alone.

Programs are run by typing a three-letter acronym [XXX] (see examples in Fig. 2) on any terminal in the laboratory. Several persons may use the same program simultaneously. Although two or more persons may look at records in the same file (even the same record), only one person at a time is permitted to alter a record.

The general configurations and relationships of the programs for the TOXLAB application is shown in Fig. 2. Brief system and program descriptions follow.

TOXLAB Software—General program functions of the laboratory TOXLAB program can be seen on the flow chart in Fig. 2. The [LAB] program permits new cases to be entered with demographics, case detail and a specimen list. The program generates test orders via EXPERT 1 automatically based on several variables. Figure 3 is the data entry screen for [LAB]. Duplicate case identification numbers are disallowed, and two different cases cannot have the same autopsy number. Extensive checking for data validity is done. Newly accessioned cases are internally identified as "pending." Each case entry is journaled in real time to provide an audit trail of this activity.

[CHK] permits supervisors to alter any data item in a database master record and to change automated orders. All changes/additions done with this program are journaled.

The [WKL] program assembles a bench-by-bench worklist of all cases which have pending work. It alerts the technologist to cases which are older than an interval programmed in by the supervisor. This program is run automatically by the system at predetermined times of the day and rescheduled automatically.

[BRS] is the main result entry and modification program which also contains a large expert system, EXPERT 2. Technologists can select the individual case result entry mode or permit the program to scan for cases which need results. The cases are presented in

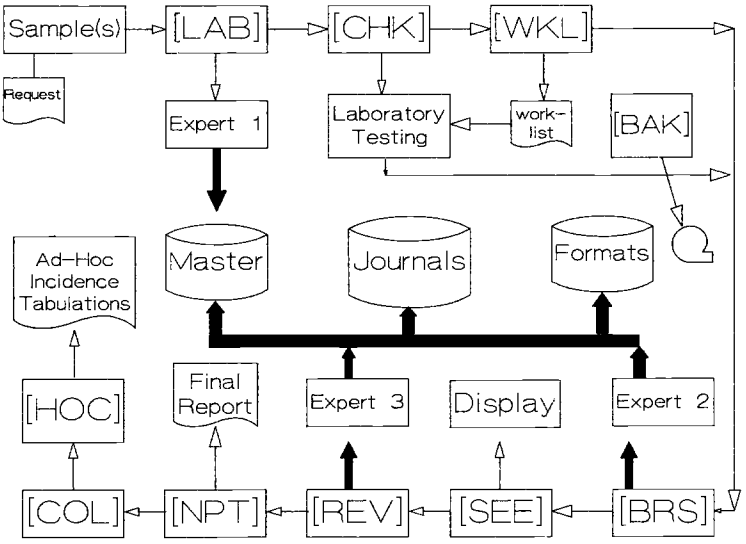

FIG. 2—*Laboratory programs: additional information will be found in the text. Note designations: files (cross-sectional cylinders), programs (rectangles), usual workflow sequence (thin solid lines) and data flow paths (heavy lines), and file links (heavy arrowed lines).*

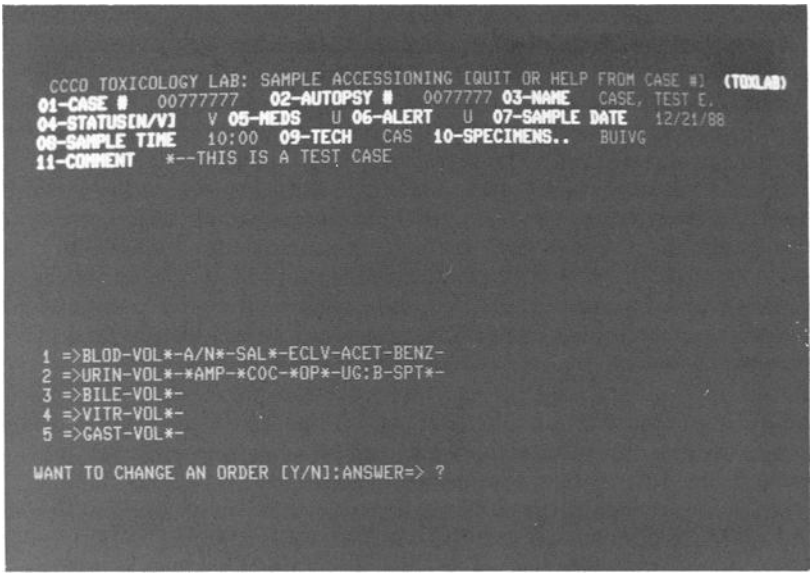

FIG. 3—*TOXLAB, accession screen: a typical case accession, where demographics generate a comprehensive toxicologic evaluation.*

the same order as the worklists, by sample type when appropriate, which facilitates result entry. Negative findings are logged with a single key stroke. Results (qualitative and quantitative) may be changed or even deleted provided the case has not yet been reviewed and approved by the supervisor. The appearance of certain sample specific results causes this program's expert EXPERT 2 to create automatically new test orders for the same or other samples. When all non-negative results have been entered, the technologist declares the case to be "ready" for supervisor's review. Every result is journaled in real time to provide an audit trail of this activity. Figure 4 is the data entry/display screen for [BRS].

[SEE] permits users and supervisors to view all records from cases in order to quickly answer inquiries. It displays all requests made for a specific case and specimen and the results presently available on these specimens. Figure 5 is the display screen for [SEE].

[REV] permits the supervisor to find and review all cases in which all ordered results have been completed. If the supervisor approves the case, it is internally identified as "approved" and it is ready for printing. This event is journaled in real time to provide the desired audit trail. This system contains another expert system, EXPERT 3, which checks all samples and all results for pharmacological consistency.

[NPT] prints final reports of those cases which have been previously approved by the supervisor. The reports cannot be changed in any way except by a supervisor, who must use the [CHK] program. All printed cases are journaled. Figure 6 is a typical report.

As noted earlier, any action which alters data, including EXPERT ordering, is journaled into a file based on the kind of activity. The program [COL] assembles journal records from these files into a single body of data and then sorts it to create a chronological history of a specimen. Data fields are described in the legends of Fig. 7. Line 1 is an accession record which capsulizes key data associated with entry of a case into the system. Records 2 through 45 are transaction detail records. For example, Line 2 shows that, on 12/21/88 at exactly 11:24:25 and 23/60ths of a second, the operator CAS entered a result

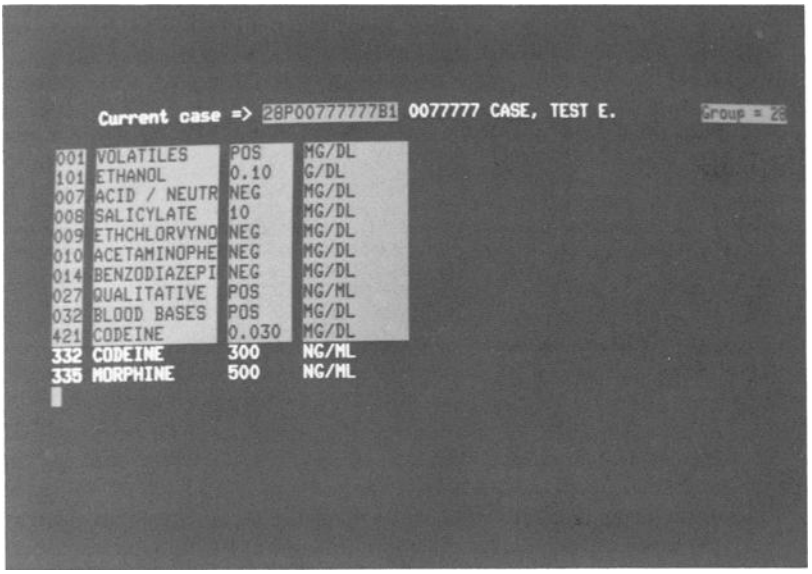

FIG. 4—*Individual result entry: example of [BRS] non-negative result entry for Group 28 (Opiates). User sees all results for the case (reverse video-bright) but cannot change these results. Only Group 28 results (standard video) can be entered/changed. (Code 322 CODEINE 300 ng/mL and 335 MORPHINE 500 ng/mL).*

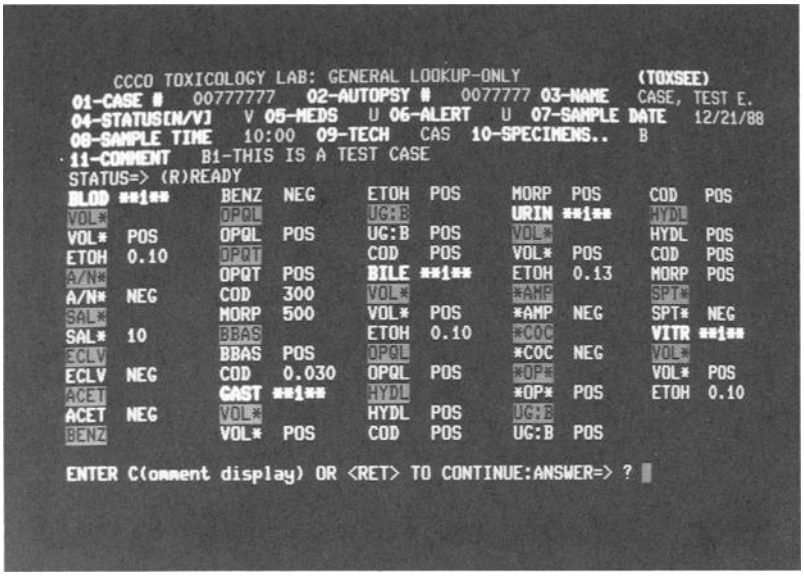

FIG. 5—*TOXSEE, general lookup screen: a typical case in which all orders are now complete, some orders being derived from the EXPERT subroutines.*

value of 0.10 for Test Group 01 (volatiles), Test Code 101 (ethanol) which was for the first blood specimen (B1), on Case No. 00777777. Entries of "EXPERT" mean that the expert placed an order for the test code noted and "APPROVED" means that the supervisor approved the case for final disposition. Other status words are "CHANGED," "DELETED," and "ADDED." Record 46 is the print control record showing key data regarding final printing.

[HOC] is a program which operates on either the online master file or the archive file to do ad-hoc retrieval of cases. These inquiries can be used to find cases with specific demographic characteristics or results, or ranges of results, within any time span. They also create files which are used to produce incidence statistics.

[BAK] is a program which automatically performs a system backup once per day. It also runs periodically during the day to make copies of any file which was changed since the last backup was made.

WP Software—The WP software (DECMATE III) is totally packaged and cannot be changed by the user. It does include a complete set of text manipulation instructions, a very powerful list processing feature which permits creation of form letters, labels, etc. As noted earlier, the WP software unit communicates bidirectionally with the main computer.

User Interface Screens and Experts—The user interacts with each program, illustrated in Fig. 2, via three to eight cathode ray tube (CRT) screens or menus per program. For clarity of presentation, extensive use is made of video terminal attributes (bold, blinking, reverse video, or half intensity).

Using Figs. 3 through 7, we now tie all of the program descriptions together into one practical example of how a case is processed from beginning to end. A sample set comprised of blood, urine, bile, vitreous humor, and gastric contents (B, U, I, V, G), derived from an autopsied individual who succumbed to a violent death is accessioned with [LAB]. The system, [EXPERT 1], orders Volatiles (VOL*), Acid/Neutrals (A/N*), Salicylate (SAL*), Ethchlorvynol (ECLV), Acetaminophen (ACET), and Benzodiaze-

CORONER'S OFFICE, CUYAHOGA COUNTY, OHIO PG- 1

2121 Adelbert Road, Cleveland Ohio 44106

REPORT OF TOXICOLOGY LABORATORY FINDINGS

THE STATE OF OHIO ss
CUYAHOGA COUNTY

NAME :
DATE RECEIVED : 21-Dec-88

CASE NUMBER : 00777777

AUTOPSY NUMBER : 0077777
DATE REPORTED : 21-Dec-88

CONCENTRATIONS IN mg/dL UNLESS OTHERWISE NOTED

SAMPLES ==========>	BLOOD 1	URINE 1	BILE 1	VITR 1	GASTRIC 1
DATES ==========>	12/21/88	12/21/88	12/21/88	12/21/88	12/21/88
-01-VOLATILES	POS	POS	POS	POS	POS
-01-ETHANOL-G/DL	0.10	0.13	0.10	0.10	POS
-07-ACID / NEUTRALS	ND				
-08-SALICYLATE	10				
-09-ETHCHLORVYNOL	ND				
-10-ACETAMINOPHEN	ND				
-14-BENZODIAZEPINES	ND				
-17-U:EMIT AMPHETAMINES		ND			
-20-U:EMIT COCAINE MTB		ND			
-23-U:EMIT OPIATES		POS			
-27-QUALITATIVE OPIATES	POS		POS		
-28-QUANTITATIVE OPIATES	POS				
-28-CODEINE-NG/ML	300				
-28-MORPHINE-NG/ML	500				
-31-URINE/GASTRIC BASES		POS			POS
-31-CODEINE		POS			POS
-32-BLOOD BASES	POS				
-32-CODEINE	0.030				
-42-UR HYDROLYSIS [OP]		POS	POS		
-42-CODEINE		POS	POS		
-42-MORPHINE		POS	POS		
-43-URINE SPOTS I		ND			

ND = NONE DETECTED NTDN=NOT DONE POS=ANALYTE(S) DETECTED
QNS= QUANTITY NOT SUFFICIENT UNS =UNSATISFACTORY SAMPLE

Craig A. Cechner, Ph.D.
CHIEF TOXICOLOGIST

Elizabeth K. Balogi M.D.
CORONER

- REFER TO REVERSE SIDE FOR ANALYTE LEGEND -

FIG. 6—*Lab report: a typical report showing the culmination of all work in an explicit report.*

```
*  |_a__|_b_|c|__d___|_e_|_____f_____|__g__|__h__|__i___|_j_|_____k_____|
1-881221l122#00777777 CAS CASE,TEST E. 881221BUIVG 890127 CAS STD DISPOSAL POLICY

*  |_A__|_B_|C|__D___|E_|__F__|___G__|_____H____|_I_|___J___|
2-8812211124P00777777Bl CAS* 881221  11242523   B011010.10
  8812211124P00777777Bl CAS* 881221  11243321   B01001POS
  8812211124P00777777Gl CAS* 881221  11244332   G01101POS
  8812211124R00777777Gl CAS* 881221  11245223   G01001POS
  8812211125P0077777711 CAS* 881221  11250537   I011010.10
  8812211125R0077777711 CAS* 881221  11251418   I01001POS
  8812211125P00777777Ul CAS* 881221  11252320   U011010.13
  8812211125R00777777Ul CAS* 881221  11252804   U01001POS
  8812211125P00777777Vl CAS* 881221  11254115   V011010.10
  8812211125R00777777Vl CAS* 881221  11255018   V01001POS
  8812211126P00777777Bl CAS* 881221  11262843   B07007NEG
  8812211127P00777777Bl CAS* 881221  11271338   B0800810
  8812211128P00777777Bl CAS* 881221  11280453   B09009NEG
  8812211128P00777777Bl CAS* 881221  11283923   B10010NEG
  8812211129P00777777Bl CAS* 881221  11291416   B14014NEG
  8812211131P00777777Ul CAS* 881221  11313111   U17017NEG
  8812211131P00777777Ul CAS* 881221  11315936   U20020NEG
  8812211132P00777777Ul CAS* 881221  11323143   U43043NEG
  8812211133P00777777Ul CAS* 881221  11330419   U23023POS
  8812211133R0077777711 CAS* 881221  11331231   I27027EXPERT
  8812211133R00777777Il CAS* 881221  11331440   I42042EXPERT
  8812211133R00777777Bl CAS* 881221  11331742   B32032EXPERT
  8812211133R00777777Bl CAS* 881221  11331951   B27027EXPERT
  8812211133R00777777Bl CAS* 881221  11332200   B28028EXPERT
  8812211133P00777777Ul CAS* 881221  11332502   U42042EXPERT
  8812211133R00777777Gl CAS* 881221  11332734   G31031EXPERT
  8812211134P00777777Il CAS* 881221  11340511   I27027POS
  8812211134P00777777Bl CAS* 881221  11344205   B27027POS
  8812211135P00777777Ul CAS* 881221  11343101   U31353POS
  8812211135P00777777Ul CAS* 881221  11343950   U31031POS
  8812211135P00777777Gl CAS* 881221  11355909   G31353POS
  8812211136R00777777Gl CAS* 881221  11360945   G31031POS
  8812211136P00777777Bl CAS* 881221  11365405   B324210.030
  8812211137P00777777Bl CAS* 881221  11370813   B32032POS
  8812211137P00777777Ul CAS* 881221  11374422   U42510POS
  8812211137P00777777Ul CAS* 881221  11375204   U42513POS
  8812211138R00777777Ul CAS* 881221  11380126   U42042POS
  8812211138P00777777Il CAS* 881221  11382012   I42510POS
  8812211138P00777777Il CAS* 881221  11382652   I42513POS
  8812211138R00777777Il CAS* 881221  11383948   I42042POS
  8812211145P00777777Bl CAS* 881221  11454007   B283323POS
  8812211145P00777777Bl CAS* 881221  11454724   B283355POS
  8812211148R00777777Bl CAS* 881221  11480417   B28028POS
45-8812211152?00777777   CAS* 881221  11520114   APPROVED

*  |_1__|_2_|3|__4___|5_|__6___|___7___|__8____|_____9_____|
46-8812219999S00777777Gl00777772l-DEC-8821-DEC-88CASE, TEST E.
```

FIG. 7—*TOXCOL, case journal: lines identified by an asterisk (*) are used to provide a frame of reference for this journal and* do not *appear in the actual journal. There are three groups of records, accession (Line 1), transaction detail (2–45), and final printing (46). The data in each field are as follows: Line 1:* a = *date,* b = *approximate time,* c = *classification,* d = *case number,* e = *operator security code,* f = *patient name,* g = *repeated date,* h = *samples received,* i = *disposal date,* j = *person disposing sample(s),* k = *how sample was disposed of. Lines 2–45:* A = *date,* B = *approximate time,* C = *status,* D = *case number,* E = *specimen and sequence number,* F = *operator code,* G = *date (repeated),* H = *time to the "tick" (1/60th s),* I = *specimen(BUIGVO)-group code (00 to 99) and test code (000 to 999),* J = *test result. Line 46:* 1 = *date,* 2 = *9999 (always),* 3 = *status (*S *always),* 4 = *case number,* 5 = *specimen and sequence,* 6 = *case number,* 7 = *accession date,* 8 = *print date,* 9 = *name.*

pines (BENZ) on blood. It orders VOL*, Colorimetric SPOT Screening Tests (SPT*), EMIT Assays for Amphetamines (*AMP), Cocaine Metabolite (*COC) and Opiates (*OP*), and a screen for Organic Bases (UG : B) on urine and VOL* on the bile, vitreous, and gastric specimens [*1,2*]. The result of this ordering strategy is illustrated in Fig. 3. Figure 4 shows the entry of data for individual non-negative results ([BRS]). In this example case, EXPERT 2 detects a positive *OP* in the urine and automatically orders Opiate screens, qualitative (OPQL), and quantitations (OPQT), along with a screen for other bases (BBAS) on the blood specimen, an opiate hydrolysis (HYDL) on the urine, a screen for bases in the gastric contents (UG:B), and a qualitative screen (OPQL) and

hydrolysis (HYDL) for opiates in the bile. The results of this action and other subsequent actions resulting from other positive or numeric results are illustrated in Fig. 5 (the screen of [SEE]) and journaled in appropriate files, which can be collected and viewed using the collect program [COL] shown in Fig. 7. All results are entered and ultimately approved by the lab director or supervisor(s) and subjected to pharmacologic consistency checks [EXPERT 3] and passed to the printing program [NPT], the output of which is illustrated in Fig. 6.

As noted above, we have developed a series of rule-based decision systems [EXPERTS] which guide test selection, confirmation, and interpretation. The senior staff in the laboratory generated a series of rules governing the initial ordering of tests on samples under a variety of case-specific circumstances. In addition, the program rule base contains specific conditions which define how additional test orders should be added as results begin to appear. Here the expert system uses the knowledge that the professional staff developed over many years to decide what additional tests to order on specific specimens if specific analytes or combinations of analytes are found to be positive or specimens are not available or suitable. This procedure sometimes reveals an important fact in a poisoning, enhances diagnostic acumen, and reduces the chance of not performing the proper tests if the experienced professional is not in the laboratory at the time the specimens are being processed. Computerized experts make the human expert available at all times, and others [*13*] have demonstrated additional virtues of artificial intelligence.

Finally, the performance of TOXLAB relative to our existing manual system is presented in tabular fashion in Table 1. These evaluations are based upon the actual time and changes seen by our staff over the 30 months that the system has been operational.

Discussion

While reviewing large turn-key clinical laboratory systems for applicability in our environment, we were impressed by recurring comments on the relative "weakness" and complexity of microbiology modules relative to similar chemistry, and hematology modules [*12*]. The toxicology laboratory provides a situation with the complexity of the microbiology laboratory with the need for the rigor of the chemistry laboratory.

In the toxicology laboratory, as in microbiology, the types of specimens are essentially broadly defined and there may be many different, sometimes unexpected, specimens from a given patient. Most important perhaps in these similarities is the unpredictability of testing strategies and result production. We, like the microbiologists, are attempting to discover a pattern in a sample or series of correlated samples with no a priori knowledge of the physical resources or time which will be required to solve the puzzle. In addition, we must deal with antemortem and postmortem samples, which substantially complicates the design of the toxicology lab computer system.

The most noteworthy characteristics of the toxicology laboratory which add to design complexity are the requirements for comprehensive "chains of custody" (COC), imposed by the courts and mandated by accrediting bodies, as well as well-defined laboratory standard operating procedures (SOP's), mandated by accrediting bodies. We defined our computer-aided COC to be a set of independent records of activities which indicate when any piece of evidence or patient sample aliquot changes custody within the laboratory. These records are created on the computer in real time when the transaction takes place, or as close to that time as is practical. The implementation of this requirement is referred to on the feature and benefit table (Table 1) as "journaling." The audit trail of a journal establishes the date, time, and responsible person at accession time, sample aliquoting, passing of the aliquot to the testing stations, result entry, result approval, and printing of the final report. In addition, a sample disposal journal has been developed so that the final disposition of the sample is added to the chain.

We defined our computer-aided SOP to be directed by a set of *experts* and *rules* for

TABLE 1—*TOXLAB module feature and benefit table.*

Feature	Systems: Relative Ease of Feature		New System: Relative Benefit to Laboratory			
	Manual	New	Value of Change	Time Saved, H/Week	Ease of Management	Credibility
Contemporal interdepartment multiuser access to data	−/+	+ + + + +	+ + + +	4–6	+ + + +	+ + + + +
Response to inquiry	5 min	<10 s	+ + + +	5–8	+ + +	+ + + +
Completeness of response to inquiry	+ + +	+ + + + +	+ + + + +	N/A[a]	+ + +	+ + + +
Error detection	+ + +	+ + + + +	+ + + + +	2–4	+ + + +	+ + +
Comprehensive sorted work lists	+	+ + + + +	+ + + + +	3–5	+ + + +	+ + + +
Incidence statistics	+	+ + + +	+ + +	1–2	+ + + +	+ + +
Workload statistics	+	+ + + + +	+ + +	5–7	+ + + +	+ + +
Report style and readability	+ + + +	+ + + + +	+ + +	5–10	+	+ + + +
Ability to retrieve and use archival data	−	+ + + +	+ + + + +	NF[b]	+ + + +	+ + + +
Automatic profile ordering with ad-hoc changes	+ + +	+ + + + +	+ + +	4–6	+ + + +	+
Ad-hoc research inquiry	−	+ + + +	+ + + + +	1–3	+ + + +	+ + +
Optimizing staff utilization with management tools	+	+ + + +	+ + + + +	3–6	+ + +	+ + + +
In-process specimen tracking	+	+ + + + +	+ + + +	3–6	+ + + +	+ + + +
Expert judgment for order modification available at all times	+ + +	+ + + + +	+ + + + +	3–5[c]	+ + + +	+ + + +
Automatic reporting after supervisor's review	−	+ + + + +	+ + +	2–4	+ + + +	+ + +
On-line documentation of systems/procedures	+	+ + + + +[d]	+ + +	5–8	+ + +	+ + +
Journaling and chain of custody documentation	−	+ + + + +	+ + + + +	NF	+ + + +	+ + + +
Incremental case number assignment	+ + + + +	+ + + + +[e]	+ + +	NF	+ + +	+ + +

[a]N/A = not applicable.
[b]NF = new function.
[c]Professional's time.
[d]Help mode.
[e]Error free.

these *experts* which aid in sample ordering [EXPERT 1], confirmation testing [EXPERT 2], and result reconciliation [EXPERT 3]. The advent of this simple form of AI in our laboratory has dramatically improved the quantity and consistency of the work which can be accomplished in any unit of time. The most recent and exciting of these experts, EXPERT 3, will hopefully allow us to learn from our results and the results of others, as the data for its rules, pharmacologic and pharmacokinetic parameters pertinent to drugs at both therapeutic and toxic or lethal concentrations, become available.

Finally, by careful design and selection of hardware and software, this system can grow within our facility, which achieves our primary goal. The system has been designed to handle the requirements of the statistics gathering section of our office, as well as that of the trace evidence laboratory (Fig. 1). Planning for additional growth into other major areas of the office is underway. In all of these applications, the databases can be tied together by the office case numbers (or case number combined with autopsy number where applicable), which are unique and assigned to each case as it enters the building. In this way, ultimately, all of the data generated within our facility on a given case will be able to be reviewed and compared over time.

Conclusions

The implementation of computerization in the forensic laboratory is a natural extension of the use of this tool in facilitating the tracking of large amounts of information. Because we are a forensic agency, the accuracy of this process relative to a given sample or set of samples is paramount in assuring that the information gathered is reliable, able to be documented, and readily available to those who have a legitimate need to know. The computer is a valuable tool that, when appropriately used and applied, can assure that this process not only occurs in a proper manner, but also that it occurs in a cost-effective, efficient, and documented fashion. The system that we have described accomplishes these goals as a result of a proper matching of computer software and hardware, with well-understood, realistic, and achievable goals. As computer usage develops, improvements in the manner in which the information generated is organized, manipulated, collated, and retrieved will yield epidemiological data which should result in an increased benefit to the general public health.

Acknowledgments

We wish to acknowledge the assistance of Gary Sebrosky, Eric Lavins, Daiva Paliulis, Carl Hazenstab, Irene Hendrix, Tammy Stefan, and Jennifer Morrison, who helped to refine and debug programs and without whose help this effort would have been prolonged. We wish to thank Karen Feldman, who worked diligently on many revisions of this manuscript, and Sue Sutheimer, Gary Sebrosky, and Dr. Irving Sunshine for their review of this work.

References

[*1*] Hepler, B. R., Sutheimer, C. A., and Sunshine, I., "The Role of the Toxicology Laboratory in Emergency Medicine," *Journal of Toxicology and Clinical Toxicology,* Vol. 19, 1982, pp. 353–365.

[*2*] Hepler, B. R., Sutheimer, C. A., and Sunshine, I., "The Role of the Toxicology Laboratory in Emergency Medicine. II: Study of an Integrated Approach," *Journal of Clinical Toxicology,* Vol. 22, No. 6, 1985, pp. 503–528.

[*3*] Hepler, B. R., Sutheimer, C. A., and Sunshine, I., "Role of the Toxicology Laboratory in the Treatment of Acute Poisoning," *Medical Toxicology,* Vol. 1, 1986, pp. 61–75.

[*4*] "Toxicology Laboratory Report," Cuyahoga County Coroner's Statistical Report, Cleveland, OH, 1984, pp. 157–172.

[5] "Superchips Challenge the 386," *Computerworld,* Vol. 21, No. 09A, 1987, p. 13.
[6] Jeffery, B., "Is IBM in the PC Business?" *Computerworld,* Vol. 21, No. 09A, 1987, p. 17.
[7] Howritt, E., "LAN Industry Skyrocketing," *Computerworld,* Vol. 21, No. 7, 16 Feb. 1987, pp. 43–46.
[8] Howritt, E., "Reluctant Support for Network PC," *Computerworld,* Vol. 21, No. 7, 16 Feb. 1987, pp. 1–4.
[9] Wecker, S., *Networking (Technical Notes and Reprints),* Digital Equipment Corp., Educational Services, Bedford, MA, 1984.
[10] Hurst, R., "Minis Reign over PC LANS," *Computerworld,* Vol. 21, No. 18A, 6 May 1987, pp. 55–58.
[11] *Cuyahoga County Coroner's Information Processing System Conceptual Design,* Price Waterhouse & Co., June 1980.
[12] Cechner, R. L., "A Multifunction Network of Computers in a Large Pathology Department: Integration of Word-Processing, Data Base Management and General Purpose Computing Using Network Principles," *American Journal of Clinical Pathology,* Vol. 79, 1983, pp. 472–478.
[13] Spiehler, V., Spiehler, E., and Osselton, M. D., "Application of Expert Systems Analysis to Interpretation of Fatal Cases Involving Amitriptyline," *Journal of Analytical Toxicology,* Vol. 12, 1988, pp. 216–224.

Address requests for reprints or additional information to
Dr. Ronald L. Cechner
Department of Pathology
University Hospitals of Cleveland
Cleveland, OH 44106