St. Vincent Mercy Medical Center
Ohio Department of Public Safety HB 138 Special Project #6
Final Report: June 30, 2003
Grant # C23972

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I. Introduction

St. Vincent Mercy Medical Center (SVMMC) received a grant to study the feasibility of recording and reporting information to the state trauma registry by means of portable electronic devices. This project was undertaken by the SVMMC Trauma Department in cooperation with the SVMMC Information Services Department.

Nationally the April, 2002 Trauma Registry User Survey by Bishop and Associates found that none of the 39 Trauma resource Network members who responded used "hand-helds" to record trauma data. In most cases, data was recorded manually by nurses, registrars and/or other personnel and then entered into a database on a desktop computer. This multi-step/multi-format method of data collection is costly and may be prone to inaccuracy and missing data. Reducing the number of times that the same data is abstracted and recorded would optimize cost efficiency. The accuracy of trauma data collection would be improved by collecting the data as directly from the patient and family while the patient is in the hospital receiving care.

SVMMC proposed to study the feasibility of implementing a trauma data collection system based on portable electronic device hardware, specifically Palm Pilot devices. The portability of the Palm Pilot would allow the SVMMC Trauma Department to address the collection and documentation issues described above. We proposed that registrars would enter data directly into the Palm Pilot, eliminating the cost, duplication and potential errors associated with the multi-step/multi-format method.

II. Executive Summary

The purpose of this Special Project was to study the feasibility of recording and reporting information to the state trauma registry with portable electronic devices, specifically Palm Pilots. In recent years, handheld electronic devices have become widely used offering mobility, increased efficiency, and decreased cost. The new system would reduce costs and inaccuracies associated with the multi-step/multi-format method of data collection in place in most hospitals.

At the time this study was being developed, Clinical Data Management, the developer of the TraumaBase software used by SVMMC and the Northwest Ohio Regional Trauma Registry, was in the process of developing Palm Pilot capabilities for TraumaBase. CDM committed to working with SVMMC as a beta test site for this new software.

Following several weeks of team orientation, equipment installation, and communication with CDM, the Palm software was installed at SVMMC, and testing began in January 2003. Numerous problems arose, most rooted in the problem of the Palm's limited data capacity in comparison to the data requirements of SVMMC and the state trauma registry. After many attempts to resolve these problems in collaboration with the software developer, the project team concluded that portable handheld devices are not feasible at this time for recording and reporting information to the state trauma agency. The study was therefore terminated on April 30, 2003.

The project team also concluded that the use of wireless laptop computers would be the best approach to collecting concurrent data in a cost efficient and accurate manner. SVMMC is proceeding with implementation and evaluation of the proposed data collection system with wireless laptop computers. Results of this evaluation will be forwarded to the Ohio Department of Public Safety.

A chart of key project events by date is included in Attachment A to this report.

III. Information/Qualifications

Institution: *St. Vincent Mercy Medical Center* was founded in 1855 as Toledo's first hospital. Today, St. Vincent stands on its original site in the center of the city and provides services to local residents as well as the broader northwest Ohio and southeast Michigan region. St. Vincent is a subsidiary of Mercy Health Partners, the largest, most comprehensive and geographically accessible health system in northwest Ohio. SVMMC serves thousands of adult and pediatric trauma patients each year and is verified by the American College of Surgeons as a Level I trauma center with Pediatric Commitment.

Principal and Co-Investigators: The Principal Investigator, *F. Barry Knotts, M.D., Ph.D.* is a trauma surgeon and Medical Director of Trauma Services at SVMMC. In his roles as Chairman of the Ohio EMS Board Trauma Registry Committee and Chairman of the Board of Directors of the Northwest Ohio Trauma Registry, he was in an excellent position to ensure coordination of this project and its outcomes with the Ohio Trauma Registry. The Co-Investigator, originally *Rachael White, R.N., M.S.N.* the Trauma Program Director (Adult and Pediatric) at SVMMC resigned from her position with the institution in January 2003. Cheryl Black, R.N., B.S.N., C.C.R.C. the research associate on the study, accepted the role. Ms. Black is a SVMMC Clinical Research Nurse with Critical Care Specialty. She is certified in research coordination by the Association of Clinical Research Professionals and has experience coordinating multi-center clinical trials.

Data System Specialist/Lead Registrar: *Martha Davis,B.S., RHIT* interfaced with SVMMC information services and CDM on setting up and redefining fields, and on testing the integrity of the new system. Ms. Davis coordinated and facilitated the concurrent collection of data as well as the synchronization of the Palm Pilots with the Trauma Registry software.

Information Systems Personnel: The SVMMC Information Systems (IS) department purchased the necessary hardware and installed the software required by CDM. *Joanne Kuenzer Mosson, R.N., B.S.N.* is a Clinical Analyst with the IS department for Mercy Health Partners. Ms. Kuenzer Mosson was the contact person in the IS department who assisted with the coordination of this project. She was an integral team member in the coordination of the system between the trauma department data systems specialist and CDM.

Project Team: The project team was comprised of the individuals as mentioned above. The Administration of SVMMC supported the project with assistance from *Barbara Dianda-Martin, R.N., B.S.N.*, Vice President of Nursing Services. The team provided oversight on the project, ensuring that all involved departments had input into the implementation and conclusions of the project. It was decided in the group forum to conclude the project due to the limitations of the Palm database capabilities with all members contributing to the decision.

IV. Review of Literature/Historical Perspectives

Handheld computers arrived on the market nearly ten years ago. When the personal computers first came out, they were shunned by healthcare institutions that were entrenched in mainframe-based computing.[1] Only recently have become more widely used. Palm's first mainstream unit was the Palm 1000, which was released in 1996.[2] Current models offer better speed in processing, more memory and infrared technologies.

Handheld computers are lightweight, portable and can be programmed to meet the individual needs of the user. They are small enough to fit into a coat pocket and can have full size keypads that can be folded and fit into the pocket as well. This allows for easy use of Word with the Palmtop. The handheld computer offers mobility, increased efficiency and decreased cost.[2]

Lal et al[2] in 2000 published a study looking at the accuracy and cost effectiveness of using a hand-held computer for data entry in the collection of burn data. Identical data were retrieved twice from 110 charts 48 hours apart and then used to create an Excel spreadsheet. The method of retrieval was alternated between Palm system and handwritten every 10 charts. Their results found the total time for the Palm method of data collection and downloading to a personal computer was 23% faster than the handwritten method with computer entry. They also found 58% fewer errors were generated with the Palm method.

Trauma registries offer a comprehensive method for ongoing evaluation of an institutional trauma care program and trauma system. The accuracy of the data entry is vital to the use and meaningfulness of the registry data itself. Currently the manual method of data collection requires transcription to occur twice. The use of the Palm system for data entry minimizes the handling of data, therefore reducing the number of errors in the data that arise from coding and data entry.[3] With data entry at or near the point of care, efficiency in the collection process will assist with an increase in timely reporting of quality indicators. Maintenance of an accurate active registry must be viewed as important as the medical care rendered.[4]

Technology is changing rapidly and trauma professionals need to keep up with the latest technology that will help decrease their workload.[5] The time efficient non-duplicative data entry will assist in reducing errors while reducing the workload of the registrars. Concurrent data will be available for use in trauma program and overall quality evaluation.

References

1. Shah M. Grassroots computing: Palmtops in health care. *JAMA*. 2001;285(13):1768.
2. Lal S., Smith F., Davis J., Castro H., Smith D., Chinkes D., and Barrow R. Palm computer demonstrates a fast and accurate means of burn data collection. *J Burn Care and Rehab.* Nov./Dec. 2000;21(6):559-561.
3. Weber B., Roberts B. Data collection using handheld computers. *Nursing Research*. May/June 2000;49(3):173-175.
4. Gillott A., Thomas J., and Forrester C. Development of a statewide trauma registry. *J Trauma.* Dec.1989;29(12) :1667-1672.
5. Eastes L. Use of the personal digital assistant for point-of-care trauma documentation. *J Emergency Nursing.* Oct. 2001;27(5):516-518.

V. Financial Issues and considerations

Because this study was terminated prior to full implementation of the planned Palm Pilot data collection protocol, cost efficiencies of the new system could not be analyzed. SVMMC does plan to conduct this analysis with a system based on wireless laptop computers.

The primary start-up costs for the Palm-based system included staff, equipment, and consultation. The SVMMC Trauma Department's lead registrar dedicated 171 hours, actually less than originally anticipated, to implementing, testing, and troubleshooting the new system, and communicating with Clinical Data Management support services and SVMMC information services personnel. SVMMC information services personnel dedicated 188.5 hours to the project, significantly more than anticipated. This time was necessary for identification and coordination of necessary upgrades to computer equipment and troubleshooting the new system.

Equipment costs, in addition to the Palm Pilots, primarily involved the purchase of new computer work stations and a new server necessary to support the Palm Pilots and software needed for this study.

Consultation costs were fees to Clinical Data Management (CDM), the software developer. At the time this proposal, CDM was in the process of developing Palm Pilot capabilities for TraumaBase and agreed that St. Vincent Mercy Medical Center would serve as a beta testing site. Fees to CDM covered general support, Palm support, and customization of the software (the largest portion). Customization was necessary as we attempted to modify the initial capabilities of the Palm software to the requirements of our local and state trauma database.

Total project costs are outlined below:

DESCRIPTION	Palm Pilot	Palm Synch Station	Palm Soft-ware	Computer Stations	Palm Pilot Server	CDM Support Fees	Subtotal Expenses	Research Associate	IS Staff	Lead Registrar	Subtotal Personnel	TOTAL
	1750.00	**240.00**	**180.00**	**12,858.00**	**0**	**17,600.00**	**32,628.00**	**6414.00**	**2000.00**	**20400.00**	**28814.00**	**61,442.00**
IBM/Sarcom – M515 & HanDBase for pocket PC	2040.00		144.00				**2184.00**					**2184.00**
1 computer workstation – IBM-M42 Intel Pentium Desktop ($800) and Flat Panel Monitor (775)				1575.00			**1575.00**					**1575.00**
5 computer workstations (as above)				7500.00			**7500.00**					**7500.00**
Clinical Data Mgt–support/services						2000.00	**2000.00**					**2000.00**
Sarcom – Palm portable keyboard				420.00			**420.00**					**420.00**
Clinical Data Mgt-support/services						9490.00	**9490.00**					**9490.00**
Sarcom – Palm Pilot Server					5408.00		**5408.00**					**5408.00**
Joanne Kuenzer-Mosson, RN, BSN									7257.93		**7257.93**	**7257.93**
Cheryl Black, RN, BSN, CCRC								1028.35			**1028.35**	**1028.35**
Martha Davis, RHIT										3585.20	**3585.20**	**3585.20**
TOTAL	**2040.00**	**0.00**	**144.00**	**9495.00**	**5408.00**	**11490.00**	**28577.00**	**1028.35**	**7257.93**	**3585.20**	**11871.48**	**40448.48**
Funds available	-290.00	240.00	36.00	3363.00	-5408.00	6110.00	**4051.00**	5385.65	-5257.93	16814.80	**16942.52**	**20993.52**

VI. Education and Training Issues and Considerations

Additional formal training was not an issue in implementing the project. We believe that the reason was the high level of experience of the lead registrar and the strong support to the project from the SVMMC information services (IS) department. The need for this level of IS support was not anticipated when the project was being proposed, and a budget adjustment was necessary to cover their additional time. The lead registrar, Mardi Davis B.S., RHIT, is very proficient with TraumaBase and was able to train herself on use of the Palm Pilot. Had the project continued, she would have been responsible for training the additional registrars and nurses.

VII. Data and Information Issues and Considerations

The initial TraumaBase Palm Pilot data collection software provided by CDM was rigorously tested by our lead registrar and found to have several deficits. These deficits included several features that did not work. Often when CDM provided fixes for these features, they resulted in additional problems.

The most significant deficit was the very limited set of data elements that CDM had programmed. The initial data fields proposed and programmed by CDM conformed to standards of the National Trauma Database with approximately 50 data items. However, the Palm could not support the amount of data that is collected for the SVMMC and Ohio databases. The Ohio database requires over 70 fields. The SVMMC trauma abstract contains over 400 data items. Because there were not enough data fields on the Palm, we had to resort to a “dual” system, collecting a portion of the information on the Palm and a portion on paper. SVMMC provided CDM with a prioritized list of data fields (see Attachment B), with the possibility that the highest priority fields would be added to the Palm. However, this system clearly defeated the purpose of

moving to a Palm system. We also found in working with CDM, that the Palm could not support text information or drop-down fields.

The best Palm Pilot commercially available has 16 MB of memory. The TraumaBase application *without patient data* is 54 MB, far exceeding the capacity of the Palm Pilot. As the time this study was proposed, CDM representatives were optimistic that any field could be put on the system and that we could collect any data that we want. However as the system was implemented, we found that we could not have all of the data fields available at the *same time*. For the system to meet our needs for efficiency and accuracy, we needed to have all data fields available for data entry at the patient's bedside.

VIII. Findings/Conclusions

After several attempts to resolve the problems described above, the project team concluded that portable handheld devices are not feasible at this time for the recording and reporting of information to the state trauma registry. Palm Pilots, at their current stage of development, are not able to support the amount of data necessary to meet our local needs and state reporting requirements. One alternative would be the "pocket PC" which does have more memory. The standard for HP iPaq is 48 MB SDRAM, 16 MB NAND Flash, but even this would be hard pressed to meet our needs. CDM presently has no plans to develop software for the pocket PC.

The project team concluded that the use of wireless laptop computers would be the best approach to continue to collect concurrent data in an accurate and cost-efficient manner. This would allow for the registrars to have access to all fields in the database. It was the conclusion of the project team to purchase the necessary equipment for wireless laptops and continue to collect

registrars' time data until 3 months of laptop entry was complete. Administrative support was received and approved for the purchase of wireless equipment.

IX. Recommendation and Future Plan

For the reasons described above, personal handheld devices, specifically Palm Pilots, proved to be unfeasible for the collection of trauma registry data. We do believe however, that our initial premise that collection of registry data as directly as possible from the patient and family with concurrent entry into electronic format will have significant benefits both in cost savings and accuracy. SVMMC therefore is proceeding with implementation and evaluation of the proposed data collection system with wireless laptop computers. A description of our data analysis plan follows. Since a value was identified for the collection of concurrent data we anticipate a similar benefit to data collection with the laptop computers. Results of this evaluation will be forwarded to the Ohio Department of Public Safety.

Objective #1 To identify the costs and cost-benefit of the current system compared to the Wireless Laptop System

1.1. Identify and measure start-up costs of the Wireless Laptop System, such as

Palm pilots (change to laptop)
Software
Software / maintenance license
Other hardware or software required
Internal IS time and personnel cost
Training time and personnel cost

1.2. Identify staffing and processes (i.e., flow chart) for collecting patient data under the current system and under the wireless laptop system, and qualitatively compare the two methods. Show and discuss the steps that are eliminated under the laptop-based system and staff responsibilities that can be shifted.

1.3 Measure and compare staff time and staff costs required to abstract patient data, from admission of the patient to final completion of the record in the Registry.

To accomplish this, a daily log will accompany each registrar. For each patient entered, the registrar will record the following:

Patient's trauma number
Type of work:
Abstracting data while patient is hospitalized
Abstracting data after discharge
Manually transferring data from abstract form to Registry
Electronically transferring data from Palm to Registry
Method of Abstraction
Hand writing data onto current abstract forms
Palm entry of data
Not doing abstraction; doing transfer
Other _____
Time started working (hh:mm military time)
Time ended working (hh:mm military time)

Registrar data entry information will be collected until 3 months of laptop data is complete. Average cost per patient will be calculated using the time spent and staff salary, and compared between groups. Salary information is available from the manager and/or Human Resources.

1.4 Measure and compare concurrency of the database.

By concurrency, we mean the lag time between when a patient is discharged and the date the patient's information is completed in registry. Concurrency data will be obtained from the registry for the 60 (30 per group) patients used for aim 1.4 above. It will include their discharge date and the date their data were completed in the registry.

It must be recognized that there are many factors that influence concurrency of the registry, including staffing, patient census, and seasonal factors. For the purpose of this feasibility study, the proposed method of concurrency will suffice.

Statistical Analysis Considerations for Objective #1: Data from daily logs will be entered into an EXCEL spreadsheet or an ACCESS database, and analyzed using SAS. Patient's trauma number will be changed to an arbitrary ID number in the database.

Time and cost differences between the two methods will be assessed using descriptive statistics (mean, standard deviation, median, confidence intervals) and Student T-tests or nonparametric Wilcoxon-Mann-Whitney tests.

Results for aim 1.4 will be presented combining all registrars, ignoring between-registrar variability; that is, individual registrars will not be compared. However, if there are significant differences among registrars, then other statistical methods may need to be used to account for variability among registrars (e.g., analysis of variance or mixed models). But individual registrars will not be identified in any statistical reports.

Sample Size Considerations: Prior data on time and costs are not available to aid in the sample size estimation calculations. Therefore, we use a general effect size (difference in means/ standard deviation) for calculations. A sample size of 30 patients per method was chosen in order to detect a "large" effect size (Reference Cohen, ES = 0.8) between groups, with 5% type I error and 80% power.

Confidentiality of Data: The database the statistician receives will contain no identifying information, only arbitrary ID numbers, times and dates. Only Ms. Black will have the list that matches ID with trauma number and with registrars. Reports that are distributed to the principal investigator, in-house administrators, and/or for publication will not identify individual registrars or patients, nor will they disclose salary information.

Objective #2 To identify changes in the accuracy of registry data under the current system compared to the Wireless Laptop System

2.1 Quantify the typographical inaccuracy in the registry that arises at the point of manual data entry by a registrar(s) from an abstract form to the registry.

Under the Wireless Laptop system, this type of typographical discrepancies should be eliminated since data are electronically transferred. The overall rate of discrepancies and missing fields will calculated, as well as field-specific rates.

2.2 Quantify and compare the percentage of discrepancies between the medical record and the paper abstract form, the medical record and the Laptop.

Another source of potential error is when the registrars abstract data from the medical record (either on the floor or after discharge) and record it on paper or in the Laptop. Using the 60 patients from objective #1, aim 1.4, Ms. Black will review their medical records following discharge. She will compare information in the hospital chart to the information collected on the abstract form (30 patients) and information collected in the Palm (30 patients).

For each record reviewed, Ms. Black will use a checklist and mark the fields that are discrepant between the medical record and the abstract form or Palm (depending on the study group), and also note which fields were missing information in the abstract or Palm but data were available in the medical record.

The overall rate of discrepancies and missed data will be calculated and compared between groups. We are also interested in looking at field-specific rates, as this may indicate areas for improvement in the Wireless Laptop System or in the abstract form.

Statistical Considerations for Objective #2: Data will be entered into two difference databases, one for each aim, in either EXCEL or ACCESS, and analyzed using SAS. Databases

will not contain patient or registrar identifying information, only arbitrary ID numbers as in Objective #1.

Rates will be presented as the average percentage of fields that agree and the percentage that disagree, and percent missing. Confidence intervals will accompany these rates. The average rates across patients will be compared between groups using Student T-tests or Wilcoxon-Mann-Whitney, depending on their distribution.

Using the same rationale as for objective #1, a sample size of 30 per group will allow us to detect large differences between the two methods.

APPENDICES

A. Key Project Events by Date

B Comparison of CDM Proposed Data Fields and SVMMC Proposed Data Fields with Priority Coding

Appendix A: Key Project Events by Date

9/30/2002	Project management timeline developed for IS department
10/11/2002	IS Kickoff
10/31/2002	Project Team Kickoff
1/3/2003	New TraumaBase server installed, configured and ready for testing.
1/13/2003	New PCs and PC upgrades to be complete – due to a slow down in processing on the new server – **delayed**
1/15/2003	Currently working with CDM support staff and SVMMC IS staff to maximized the processing speed. **Progress report submitted**
1/17/2003	Novell client 483 sp 2 – increase the application speed. Migration of the Trauma Dept will be scheduled based on completion of testing
1/20/2003	Beta Agreement with CDM; specifications clarified; install new desktops
1/21/2003	Server processing speed maximized – Rachael White resigned – Cheryl Black, RN added as Co-Investigator (currently research assistant)
1/24/2003	Desktop installation complete
1/27/2003	Install Palm Pilots & Palm software
1/28/2003	Software installed on Lead Registrar's (LR) palm/computer **Palm testing begins**
2/7/2003	LR providing feedback to CDM – 42 fields priority, some data fields NOT displaying in the database, export process – no way to keep the current list of trauma patients when complete
3/6/2003	Update to CDM with continued problems
3/17/2003	CDM added collection field requested – anticipate going live with the palm pilot after final testing of additional fields
3/24/2003	LR verified updates – during testing LR found several fields were not functioning as expected (they had been functioning prior to the updates)
4/4/2003	**Installation complete** – Palm to go live 4/7/2003
4/7/2003	**Palm live**
4/9/2003	Registrars collecting time data – **time data collection initiated**
4/11/2003	Palm issues – data collection not going well – several issues identified – LR working with CDM to get resolved, as one resolved additional issues arise – went to paper abstract process due to Palm not working
4/22/2003	Progress Report submitted
4/24/2003	**1st patient successfully imported from Palm to TraumaBase** – new problems discovered
4/30/2003	Mike Glenn at ODPS updated on progress and conclusions. Agreement reached to **stop study** at this point