Abstract
A Medical Information System must be current if it is to be a viable adjunct to patient care within a hospital setting. Hospital-based customization provides a means of achieving this timeliness with maximum user satisfaction. It, however, requires a major commitment in personnel time as well as additional software and training expenses. The enhanced control of system modifications and overall flexibility in planning the change process result in enthusiastic support of this approach by many hospitals. The key factors for success include careful selection of local personnel with adequate vendor support, extensive QA control, thorough auditing/validation and direct user involvement.

Introduction
A computerized information system within a hospital setting that is not updated on a regular basis is a system that will gradually wither and die.(1) A dynamic hospital setting creates an inherent need for a continually maintained system which can keep pace with its rapidly changing environment.(2) The recent history of computerization within hospital settings has seen a concentration on product decision-making and subsequent implementation-training issues. With the introduction to computerization now well established in many hospitals, it is an appropriate time to examine the process by which such systems can be modified in adaptation to the changing needs of an institution.

Astute hospital administrators have characterized locally addressed system customization issues with various vendors during initial product decision-making activities. It became readily apparent to most decision-makers that vendors employ a variety of approaches to customization. Issues arise such as vendor versus client updating, volume of update data permissible, timing of turn-around systems, technical versus non-technical staff involvement, training requirements, ease of updating, etc. Without further data upon which to base a decision, administrators most often were impressed by customization approaches which tended to be flexible yet reliable with a maximum number of changes in the shortest turn-around time while requiring minimal technical staff and a significant degree of "user" involvement.

As always, experience has proven to be a valuable teacher. Not only have administrative decision-makers become more knowledgeable in asking the "right" questions regarding customization features, vendors have also benefited from field experience. In some instances, vendors have modified their approach to customization as a means of providing optimal client support. As an example, one vendor initially provided clients with a centralized customization feature wherein site-collected data were compiled and forwarded to the vendor support staff who actually incorporated the modification into an updated system. This experience demonstrated that a centralized approach provided a high degree of consistency and reliability while in some instances sacrificed flexibility and timeliness. Consequently, this vendor has recently offered a hospital-based customization capability as an option for existing as well as new clients. The decentralized feature allows hospitals to modify applications software such as the system library, the environmental data subsystem and fixed video displays. The remainder of this paper will discuss the preparatory activities which must occur prior to "building" a system on-site and an overview of the actual process.

Project Planning
Frederick P. Brooks, Jr., the "Father of the IBM System/360," used his extensive project management experience to establish the following "rule of thumb" for scheduling a software project: (3)

1/3 Planning
1/6 Coding
1/4 Component test and early system test
1/4 System test, all components in hand

It is useful to consider these recommendations in initial project planning meetings. As is readily apparent in Dr. Brook's "rule of thumb," 2/3 of the entire project schedule is devoted to planning and system testing. Conventional scheduling typically allot considerably less time to these two activities, particularly to the testing component. This approach often results in schedule delays as system discrepancies are corrected or results in lengthy down time during installation attempts of an incompletely validated system. Dr. Brook's experience has indicated that, in reality, most projects do indeed require the indicated proportion of time for system testing. Reflection of this requirement in the initial schedule results in a more realistic project plan.

To date, our system customization experience at various hospitals tends to support the need to emphasize planning and testing/validation activities in the overall schedule. This experience has shown that the greatest variability in predicting time requirements for task completion occurs in the testing/validation stage. A realistic schedule should reflect this variance and base the time estimates on a probabilistic approach. Experience has also indicated that minimization of the planning phase results in later schedule delays as unplanned events disrupt actual activities.

The Critical Path Method (CPM) or Project Evaluation and Review Technique (PERT) are frequently espoused as the appropriate methods for use in project planning. (4) Both techniques have merit and are used by several hospitals involved in
customization effort. Regardless of the method used, a schedule of tasks to be performed as well as an indication of task interdependencies is crucial to the timely completion of a customized system.

Key issues to be addressed in developing this project plan include:

1) System size versus frequency of updates

An obvious trade-off exists between the volume of change data to be incorporated into a system and the frequency of generalizing new system updates. In other words, the greater the magnitude of change, the longer it will take to produce an updated system. This system size decision is inherently dependent upon the needs and goals of a specific institution. Small, frequent updates are typically planned by hospitals who wish to provide timely response to frequent changes in patient billable items. A larger system production effort which spans several months may be preferred by a hospital planning to implement a Medical Information System (MIS) in a large department.

2) System Contents

An orderly schedule of modifications for future system updates should be developed in the customization planning effort. Priorities for system content changes must be evaluated as part of the long-range planning. Several approaches to determining priorities have been used. For example, each ancillary department may be assigned a production slot to update the MIS with all appropriate changes for that department. Alternatively, departments may be allowed to submit changes for each new system and a review committee rates the degree of criticality for each request based on an established criteria.

3) Task Definition & Interdependencies

Subsequent to development of the general contents of future system updates, definition of individual tasks and subtasks must be undertaken. The MIS customization project is a cyclical process with similar system tasks performed for each update produced. This cyclical process is described in a later section. Further subtasks specific to a given update system must be identified and reflected in the project plan. Identification of interdependencies between tasks is critical to development of an accurate project plan.

4) Time Estimates for Task Completion

One of the most difficult activities in project planning is forming accurate estimates of completion times. It has been stated that "all programmers are optimists." Likewise, customization planning is an activity to shop optimistic time tables for task completion. Priorities expressed by hospital administrators and user groups reinforce this pattern of reflecting the time required "if all goes well." Although there is little sound data upon which to rely, the project manager must resist pressures to produce a "desirable" schedule and instead develop a "realistic" schedule based on personal knowledge and experience with consideration of resources available.

5) Status Review Meetings

A schedule for regular status review meetings must be developed during preparatory planning. These meetings typically include all MIS custom staff as well as appropriate hospital administrators. Deviation from the project plan must be reviewed with consideration given to provision of additional resources as necessary. Updating the schedule with revised time estimates is critical for overall project control.

6) Customization Staff

Staffing is a key issue in initiating a decentralized approach to system customization. MIS vendors suggest various staffing support options for hospital-based customization efforts. One vendor recommends options varying from a full-time, on-site vendor support team to minimal part-time vendor support in association with maximum client involvement. To date, the trend appears to be towards the latter option, and experience is indicating the success of this approach. This trend follows discussions in recent publications which stress the need to avoid over dependence upon vendor support. However, an optimizing user-vendor relationship is an important goal in customizing issues. The ideal user-vendor relationship should produce a mutual appreciation and trust that maximize the system's efficiency by drawing together all of both parties' expertise in their individual fields. In addition to the user-vendor staffing decision, the specific staffing must be addressed. Many vendors of MIS applications software provide customization by means of "programmerless" programming. Consequently, the type of personnel typically involved in the project reflect this non-technical approach. An individual with a medically related background, some familiarization with computers, good communication skills, and a "mind for details" is an ideal candidate for this part-time, current-facility function. In the related computer equipment results in availability of an ample resource pool. Although various staffing mixes assigned to MIS support, the main issue is the situation might be a project manager, a vendor-provided system configuration specialist, a coding/data entry personnel and a computer support specialist. All may be involved at various times depending upon the volume and rapidity of updates. Hospital computer operation resources are also required as well as periodic support from vendor-provided software engineers and computer specialists.

The timing of the customization effort must also be considered in evaluating staffing needs. Hospitals who are actively involved in implementation of an MIS will likely require additional implementation staff to work in conjunction with the customization personnel. Although the implementation staff could readily be trained to perform customization tasks, the capability of maintaining concurrent implementation and production and activities would be compromised.

7) Training

Training of personnel who will be involved in the customization effort should be addressed during initial contract discussions. Although hospital personnel assigned to the project may be vendor-trained. Vendors typically provide training programs on a "customized" basis for the particular hospital's requirements. Reference manuals must be provided and should be updated by the vendor when necessary. Computer operators and ancillary department staff requiring the customization effort and also must be provided with a training program at the initiation of a project. Hospital personnel assigned at a later date to assist with customization activities may also attend a vendor-provided course. However, many hospitals who have become "expert" system producers prefer to train additional staff using in-house personnel.

8) Hardware/Software Requirements

Hardware and software configurations supporting customization efforts vary among vendors. One system, the Spectra MIS, uses the on-line back-up CPU for the customization activities. Although a few hardware modifications are required at the onset to support production, the capability of switching on-line productivity activities to an alternate CPU's is maintained. The customization software and supporting documentation is provided by the Spectra vendor.

The Customization Cycle

The dynamic nature of an MIS environment, continual MIS modifications and enhancements are required. If legal, environmental, or regulatory
requirements are not the cause for change then enhancements are demanded due to growth and learning.(12) The process modifying the MIS becomes a cycle whereby the customization steps - data collection, data entry, validation, conversion, and documentation - begin again after each new system is installed.

As an illustration of the customization cycle, the process employed by the users of the Spectra MIS will be presented. These subsystems of the Spectra MIS may be modified by accessing Spectra software programs. This capability provides individual hospitals with significant flexibility in tailoring the system to their changing needs. There are some restrictions in the modification process which ensure maintenance of the "conceptual integrity" (13) of the MIS. For example, a hospital cannot create a personal time-keeping system on the MIS. This module was not initially designed into the system since the vendor felt that it was not an integral part of a patient care system. Therefore, it is impossible for the hospital to implement this application.

Three Modifiable Subsystems

Customization of the applications software in the Spectra MIS involves modification of three interrelated subsystems as depicted below:

- **Environmental Data Library**: Env (SILIB)
- **Fixed Video Displays**: FVD (SILIB)
- **Data Entry/Auditing**: Auditing

The Standard Item Library is a "data dictionary" of terms or items used in the MIS. As Ross suggests, the data dictionary is the first area to be modified and it ensures adequate documentation for future steps. (14) All items added to the library are assigned a specific item number which facilitates placement on appropriate displays. Any item which is to generate a charge must be added to the library. Frequently used terms are also typically added to the library i.e., medication scheduling modifiers. In addition, attributes of each item exist in the library along side the item, to define color change, charging scheme, etc.

The Fixed Video Display Subsystem includes all those displays which are not dynamic within the system, for example, menu displays for each user or test lists performed by ancillary departments. Standard items from the library may be used or a literal can be "hard-coded" on the display without adding them to the library. This subsystem demands the most extensive planning and design but provides the hospital with the greatest flexibility to meet their needs.

The Environmental Data Subsystem includes all video controlling system operations to a given hospital. For example, specifications are included for terminal devices attached to the MIS, alternate printers, report destinations, time-triggered reports, user classes, and several other environmental checks per system. This subsystem most closely resembles the process of generating an operating system and most hospitals find it tedious and uncreative, but essential to customizing.

Due to the interrelationships between these three subsystems, the data entry effort and the subsequent system build process must follow a prescribed path. A simplified example of the overall process is as follows:

Data collection is the important first step in the customization cycle. In the data entry process, as is evident in the example, SILIB entries must precede FVD data entry while ENV data can be input concurrently. FVD screening is an intermediate check point, which involves, overtyping, modified, displays on a copy of the current system and performing initial validation of spelling, display design, color changes, and display layout. The system build incorporates both FVD and ENV changes into a format that can be loaded down to the current MIS for critical testing and validation and subsequent conversion.

**Data Collection Process**

After the general system contents have been determined in the project planning stage, extensive research is required as part of the data collection effort. Appropriate departmental personnel are contacted and their requests are reviewed and clarified. Customization personnel undertake an analysis of request feasibility, extent of changes required, and compatibility with pathway logic. A review committee may be involved in determining the merits of including specific requests.

The Spectra MIS provides the capability of capturing charges for specific items. As part of the data collection process, items intended to pass as charges must receive special attention. It is generally preferable to establish the item description so that it matches precisely the description stated in the financial system's charge description master. The unit of charge must also be evaluated and appropriately indicated with the item description, i.e., Abdominal Pads 6/package.

Following the initial research and approval of a detailed system Table of Contents is prepared which includes all individual change requests as well as an indication of specific displays and tables to be modified. Data are then transcribed onto manual coding forms or display mock-up forms. Appropriate departmental personnel review these final input forms for accuracy and indicate their approval.

**Production Phases**

**Data Entry**. Data entry in the customization cycle is an actual process example SILIB entries must precede FVD entries while ENV changes. The entry is an interactive on-line activity on the back-up CPU to the live MIS. A data entry clerk could be responsible for the task, but as in programming, there is some reduction in error if the person coding the forms enters the data. Paper checking of input is encouraged and vendor supplied programs edit the data for each subsystem. Comprehensive error listings are provided so that corrections can be made early before the validation stage.

**Validation**. The validation of a newly produced system is critical. The quality of testing is directly reflected in the reliability of the
installed system and its acceptance in the hospital environment by the affected department's staff. (15) For this reason audits are encouraged at each step in the customization process; however the final validation is still an extensive effort.

In preparation for this validation, the new system is installed on-line and back-up CPU. Validation protocols are documented and original system change proposals are obtained for reference. Each FVD change is reviewed on-line for spelling accuracy, maintenance of pathway logic, adherence to color conventions, display and aesthetic, etc. Environmental data reports are validated line-item by line-item against original change requests. The charge capture program is also run to verify the accurate passing of new chargeable items. The Table System of Contents is used as reference for completeness of the validation effort. Departmental users are encouraged to participate in this validation process.

Since a thorough audit is undertaken with each step in the customization process, discrepancies detected in the validation phase should be of a minor nature. A review committee typically evaluates any discrepancies detected at this point to determine overall system impact. If system corrections are required, the coding/data entry/system build/validation process is repeated.

Conversion. Upon completion of the validation process, the new customized system is ready to be made available to all users. Typically, a "Spectra Update" publication is distributed to users indicating the changes which have been incorporated into the system and the date/time at which the changes will be made available. This conversion date/time is determined via mutual agreement between the MIS staff, Data Processing and hospital administration. And the cycle begins again.

Documentation. Many authors emphasize the importance of documentation of all enhancements and modifications. (16) This documentation is considered an essential step in the customization cycle. Each system has its own Quality Assurance Manual containing a number of control documents describing the changes in the system, the generation of the system, and the validation process.

In addition to the Table of Contents previously discussed, additional control documents are used in support of actual data input. The documents serve as a means of providing permanent records of the system change process. An example of one control document is the system library update verification indication. For example, a form as data entry is accomplished, files are merged, auditing is completed, tapes are dumped and new library review are requested. Thus, this form provides documentation of all critical steps in the library update process.

The work requests, console logs, and audit sheets from the system generation phases comprise another section of the QA manual. A final section includes documentation of all discrepancies discovered during validation and becomes input to future systems.

Summary
Hospital-based customization of an MIS requires a major commitment in personnel time as well as additional software and training expenses. Hospital-based customized system modifications and overall flexibility in planning the change process result in enthusiastic support of this approach by many hospitals. The key factors for success include careful selection of local personnel with adequate vendor support, extensive QA control, thorough auditing/validation and direct user involvement.

An MIS must be current if it is to be a viable adjunct to patient care within a hospital setting. Hospital-based customization provides a means of achieving this timeliness with a maximum user satisfaction.

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