Clinical Research Protocol Mapping: A Description of a Pilot

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Abstract

Clinical and research activities are focused around protocols. A protocol map is a descriptive, visual tool that outlines all the care events that occur during multiple encounters for a patient over the life of a protocol. The map, which is similar to a clinical pathway, also defines specific interdisciplinary standards of practice and key interventions required to facilitate research and patient outcomes. The inability to aggregate data, retrieve information or generate reports prompted the need to computerize the mapping process. The objectives of the protocol-mapping project were (1) to test the concept of whether research protocol information mapped into a pathway could be automated using pilot software and (2) to determine if an automated protocol map could be used to generate information to project resource utilization volumes. The project was divided into two phases. The implementation of the latter phase of the pilot study incorporated the activities of software development, definition and mapping of pathways for research, collection of clinical data and the generation of reports. Evaluation of the pilot was based on the accomplishment of the project goals and objectives. The Protocol Map Pilot was successful in developing a robust tool for capturing protocol information and generating resource utilization data. The findings from this pilot will be used in developing requirements for a new clinical research information system that will integrate clinical and research information needs.

1. Introduction

The mission and operation of the Clinical Center at the National Institutes of Health is to conduct biomedical research. Clinical and research activities are focused around protocols that reflect plans for implementing approved clinical studies. The term “protocol-centric” refers to the functional implementation of clinical care and administrative processes that are required to support the clinical research investigations. A protocol map is a descriptive, visual tool that outlines all the care events that occur during multiple encounters for a patient over the life of a protocol. The map also defines specific interdisciplinary standards of practice and key interventions required to facilitate research and patient outcomes. The protocol map can include assessment needs, interventions, consults, diagnostic and lab tests as well as other anticipated supportive care events. Tracking protocols by mapping out the details of a patient’s expected course of stay is critical to monitoring progress, assessing variation and evaluating clinical and financial impact.
2. Description of the project

2.1 Project goals

The use of protocol maps began in 1985 as an educational tool for clinicians. The use of maps expanded in 1996 to include projecting resource utilization volumes and cost. Initially this was a "manual" process with flowcharting and paper graphs. This proved to be very cumbersome and time-consuming to manage. The inability to aggregate data, retrieve information or generate reports prompted the need to computerize the mapping process. The current automated medical information system (MIS) was limited in its capacity to support clinical research and the need to create a future information system for research maps was identified. The challenge was to find a tool that could capture the complexity of research protocols and provide for management and reporting of data. The decision to pilot this capability in an automated format prompted the search for software to test this concept. Following a review and selection process, software was purchased in 1999 to accomplish this goal.

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2.2 Software selection

The software selected was unique in its object-oriented approach to clinical data collection. It provided an intuitive drag-and-drop interface for protocol map authoring, as well as a more traditional care plan matrix for documentation. Written in Smalltalk, the mapping software lends itself to rapid customization. Java script and HTML were used to create templates and tools for the user. The focus was on pathway development that can be presented in a hierarchical structure. The original design provided for the development of items and care modules that would ultimately become part of a protocol pathway and could be reused in a variety of protocol pathways. Partnership with the vendor was necessary to modify the clinical documentation product to meet the complex needs for protocol development, documentation, and reporting.

2.3 Protocol map pilot study

Phase I of the protocol map project focused on the first objective, which was to establish proof of concept. The pilot explored different models for mapping the protocols in order to determine software flexibility and robustness. Nine protocols from seven different Institutes were mapped in the software and populated with clinical and research data. Each protocol had varying degrees of complexity and reflected clinical trials, natural history, screening and education studies. Over the course of the pilot, 187 patients were registered and data collected on 255 encounters. The result of this phase of the pilot yielded favorable responses from clinicians and researchers and was deemed successful in testing the concept of computerized protocol maps.

Phase II of the protocol-mapping project focused on implementing and assessing the capacity for the protocol mapping software to generate information to project resource utilization volumes. This expansion of the pilot, which was implemented over a nine month
period, focused on testing the concept of protocol centric data collection and developing reporting tools for financial and resource utilization needs. Unlike Phase I that included multiple research institutes, the strategy used during this phase was to partner with one research Institute to decrease variability and focus implementation resources. Clinicians, researchers, physicians and nurses were involved. This aspect of the pilot attempted 1) to evaluate the current data structure and identify redesign needs; 2) to collect data against the identified protocols; and 3) to identify and develop reports.

A project oversight committee was formed that included administrative and clinical representatives from the research Institute, nursing, information services, finance, senior management of the Clinical Center and the clinicians who developed and implemented the maps (the mapping project team). The mapping project team included a full time project manager and three clinical research nurses. Only one of these individuals had worked with the mapping software during the Phase I pilot. The software that was piloted evolved over time in response to the required enhancements dictated by the new and different types of research studies. Therefore, training for the involved staff was an ongoing initiative. The implementation of this phase of the pilot study incorporated several subtasks or activities, which included software development, protocol mapping development, data collection and generation of reports.

3. Implementation

3.1 Software development

The initial task was to evaluate the current data structure of the software and identify needs for re-design. Existing data dictionaries were reviewed and streamlined for consistency and comprehensiveness. Over the next several months, four major releases and approximately 75 interim releases to the software, based on identified design specifications, were implemented. These updates provided enhancements that allowed for remodeling of protocols to include triggers, alternate charting templates, on-line form generation, improved flow of data entry and reporting capabilities.

3.2 Protocol map development

Following software development, a procedure and process to author protocol maps in a structured format was needed. This authoring activity included all stages of the systems development life cycle: analysis, design, development and implementation. This process also included training the mapping staff on how to “author” or map protocols using the mapping software. Authoring activity varied depending on the complexity of the protocol consuming a range of one to 39 hours per protocol with a median and mean time of 14 hours. Total hours spent on authoring activity during this phase was 529 hours to develop 36 protocols. Other activities included user training, system support, data collection and administrative tasks.

3.3 Data collection

Focused implementation of this second phase of the pilot included a variety of types of research studies (clinical trials, natural history, screening and training). Over 60 clinical care nurses were trained to collect protocol data using the mapping software. Nurses, Principal Investigators (PI) and research support assistants began collecting data on the first eleven
computerized protocols in July 2000. Data collection on the remaining protocols began in September 2000. Data collected on all active protocols for Phase II of this project included 778 patients registered, 849 patient encounters and 34,000 chart items.

3.4 Report development

Report requirements were identified, categorized and prototypes were developed. These included administrative, research, clinical, regulatory, education, authoring, and patient specific reports. On-line report "views" provided a vehicle for accessing real-time patient or protocol specific data. Administrative reports included resource utilization data such as subject and data counts by protocol, care modules, milestones, items, outcomes or data elements, which are easily retrieved by the user. Real time patient counts per study, patient lists, patient accrual ceiling and cohort designations for individual or groups of studies, and subject demographic information were also available. Prototype reports on eligibility criteria for participants in a research study, clinical outcomes and protocol map variances were also developed.

In response to Principle Investigator requests, additional report capabilities are in development and these include the ability to retrieve non-standard, non-routine reports on an ad hoc basis and the ability to extract data for research analysis and reporting. In addition, the capability to filter the data, extract and download this data to another program such as spreadsheet or a statistical package, for analysis are targeted features for the next software release.

4. Evaluation

Evaluation was based on accomplishment of the project goals and objectives. Proof of concept was established in that an automated protocol map could be used to create and track research protocols. Reports were developed and generated related to administrative and financial requirements. Beyond the initial goals, this project also provided reports and innovative functionality for clinical and research needs. Overall feedback on the project addressed the following areas: stakeholder involvement, interaction with software, data collection and training.

4.1 Stakeholder involvement

Involvement of the Principle Investigator (PI) was critical. A weekly or biweekly time commitment assisted to sort out and identify eligibility criteria, triggers, protocol workflow, data collection needs and report requirements for each research study. This time also provided an opportunity to determine if software modifications would be required to automate the protocol. The more involved the Principal Investigator was, the more reflective the protocol map became of the clinical and research process. In order to encourage Principal Investigator involvement, the strategy to initially focus on the development of research reporting over financial reporting needs was used.

4.2 Interaction with software

There were few limits on how much we would customize the software for an individual protocol. This was purposely done during this phase to push the limits of protocol map development. As a result many software revisions occurred throughout the project. This gave
the mappers new tools for creating protocols but also made it difficult to develop standards when the software was constantly changing. Often there would be numerous items or modules with similar names but minor content differences. This level of customization decreased the reusability of items and modules between multiple protocols. The system was very flexible but this same flexibility also made it difficult to manage report needs and maintain dictionaries. As more protocols are automated the need to establish standards is more evident and critical to the success of future development.

Modeling the protocols were more time consuming than mappers anticipated. This involved reading the protocol information, meeting with the PI's or his/her representatives, collecting other documentation that supported the protocol and understanding the workflow. It was often difficult to map the more complex protocols with multiple triggers and pathways without understanding the workflow from the Principal Investigator perspective. Sometimes it was difficult for the Principal Investigator to articulate their needs versus wants and the mapper would re-work the protocol several times even after it was implemented. Time devoted to authoring maps decreased as the mappers became more familiar with the software.

The software contained separate modules for laboratory and pharmacy items. The laboratory module was populated with terms used by the current Department of Laboratory Medicine. This worked well as long as “standard” terminology was used in the protocol. The pharmacy module needed major changes to meet our needs, especially in the area of drug dosage, administering medications for blind drug trials and IV solutions. An interface with existing external lab and pharmacy systems would enhance this process to ensure the items were standardized. This would also reduce the need to monitor and enter updates to terms and values related to the external systems.

4.3 Data collection

Clinical and research data were collected against all the automated protocols. Staff nurses on select units were trained to enter data for the protocols using the mapping software. Units were often busy which made data collection by the nursing staff difficult as this process was a duplication of the data collected for the current automated medical record. Because nurses do not perform all the clinical activities of a research protocol, often they did not know if certain tests were completed or how to enter assessment information that the Principal Investigator or other physicians collected. However, some nurses found the mapping software helpful in understanding the data requirements and flow of the protocols.

Several of the Principal Investigator’s, or Institute designees, entered data for their own protocols. This proved to be a more efficient and accurate approach to collecting the research information. Principal Investigator’s were also burdened with the duplicate documentation demands that were required. For example, lab results were transcribed from systems and/or forms into the mapping software. Knowledge concerning the software and database structure was an additional benefit for the Principal Investigator’s as it improved their ability to articulate report needs based on their understanding of where and how data was captured.

The mapping staff also contributed a great deal to ensuring data was entered into the computer. It was easier for the mappers to do the registration rather than rely on the nurses, Principal Investigator’s or clerks. Mappers would also gather information from the medical information system (MIS) to do the duplicate documentation in the mapping software. The mapping software was available to users on one designated computer in the clinical area. This was perceived as limited access particularly on busy units with many protocols.
4.4 Training

Constant changes to the software required continuous re-training for the mappers and staff. An initial three-hour class was provided for the nursing staff on how to document against the protocols. Participants completed a written evaluation of the classroom training. Results noted that those with experience using Windows applications had less difficulty using the software than those who had little experience. Most staff found the software easy to use however, labels in the software were new to the organization and caused some confusion to those collecting the data. Seventy-eight percent of the respondents \( (n = 50) \) felt the protocol(s) were representative of the patient population they work with. Only sixty-six percent of respondents \( (n = 50) \) felt ready to start using the protocol mapping system after classroom training. In response to these findings, on-site help was available during implementation as well as providing daily visits to the unit for several months after to identify problems, provide immediate assistance to users and facilitate technical support.

5. Conclusion

The Protocol Map Pilot was successful in developing a robust tool for capturing protocol information and generating resource utilization data. The utility of automating the protocol mapping process should not be underestimated. Although a pen and paper map was quicker to produce, the need to aggregate data, retrieve information and generate timely reports was critical for responding to clinical, research and financial needs. The development of care modules and pathways were central to the management of patient information. This provided a structure for building a protocol map with all the variances and complexities that accompanies the research process. Beyond the scope of projecting resource utilization volumes, this project addressed the clinical and research needs for decision support through triggers, alternate charting templates and a variety of web links to medical information.

Stakeholder involvement and the flexibility of the software were key factors to this success. A variety of clinical, research and financial staff participated in defining the needs for the mapping software. All clinicians found the software easy to use and helpful in understanding the data requirements for the protocols. Access to the software on more computers and additional training were identified as quality improvement measures for the next phase. In addition, providing an interface to the existing Department of Laboratory Medicine's computer system would ease the burden of double entry of information both related to standardization of items and reporting lab values. The findings from this pilot will be used in developing requirements for a new clinical research information system that will integrate clinical and research information needs in a protocol-centric manner.