Protocol Modeling in a Laboratory Information Management System

Christopher J. Dubay, David Zimmerman, Bradley Popovich

Biomedical Information and Communication Center, and Medical and Molecular Genetics Department, Oregon Health Sciences University, Portland, Oregon.

ABSTRACT

The LabDirector system has been developed at the Oregon Health Sciences University to support the operation of our clinical DNA analysis laboratory. Through an iterative design process which has spanned two years, we have produced a system that is both highly tailored to a clinical genetics production laboratory and flexible in its implementation, to support the rapid growth and change of protocols and methodologies in use in the field. The administrative aspects of the system are integrated with an enterprise schedule management system. The laboratory side of the system is driven by a protocol modeling and execution system. The close integration between these two aspects of the clinical laboratory facilitates smooth operations, and allows management to accurately measure costs and performance. The entire application has been designed and documented to provide utility to a wide range of clinical and research laboratory environments.

DESIGN & IMPLEMENTATION

The demands of a production clinical laboratory are quite stringent in terms of: efficient management of laboratory resources, quality assurance and quality controls (QA/QC) of procedures and results, chain of evidence requirements for legal and forensic analyses, scheduling and prioritization of tests, and the integration of laboratory and administrative functions. We have attempted to address these requirements in our design process.

System design began with a prototype flat file database to capture an exhaustive list of the data elements in the environment. The system was then implemented as an interactive menu driven application using the 4D relational database management system in a client/server configuration on Macintosh computers over our campus Ethernet network. A high level of direct involvement between the laboratory director and the software developer resulted in a functionally organized system, which was intuitive and immediately employable by all the system's users. As the system was adopted by this work group, it was refined by direct interaction between the users and developer, resulting in a very well received and useful application.

To extend the system design for increased support of QA/QC and resource tracking using a protocol model, a structured design review was performed. User interviews were conducted to model the administrative and laboratory work flow. Analysis of the work flow resulted in a high level design that supported the administrative functions and their interaction with the laboratory using an enterprise scheduling system. This was implemented by tight integration of the Now Up-to-Date scheduling software with LabDirector using AppleEvents inter-process communication. This integration was designed to be generic, allowing the use of any enterprise scheduling software supporting AppleEvents.

The design requirements for the laboratory side were somewhat more complex. Changes or variations in protocols, as well as the addition of new protocols, produced a moving target for computerized worksheet design. An environment where protocols could be designed and analyzed (as to cost, complexity, duration, etc.), as well as documented as they were performed (capturing results, batches of reagents used, QA/QC steps, etc.), especially for the variations in the protocol (giving the lab workers maximum flexibility in documentation), was envisioned and described. A protocol modeling and execution environment has been designed to support these requirements, and is being integrated into the LabDirector system.

EVALUATION

The LabDirector system is being evaluated in terms of its impact on laboratory through-put and the resulting changes in cost effectivness. Historical laboratory activity is being captured through the protocol execution feature and will be analized to produce management information reports on actual costs and performance.