Laboratory Computing—Process and Information Management Supporting High-Quality, Cost-Effective Healthcare

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One currently observes many healthcare institutions rushing to reengineer and install information systems with the expectation of achieving enhanced efficiency, competitiveness, and, it is hoped, higher patient satisfaction resulting from timely, high-quality care. Unfortunately, information system concepts, design, and implementation have not yet addressed the complexity of representing and managing clinical processes. As a result, much of the synergy one might expect to derive from understanding and designing clinical processes to gain efficiency and quality while maintaining humanness is not readily achievable by implementing traditional information systems. In this presentation, with laboratory services as an example, we describe a conceptually different information systems model, which we believe would aid care-givers in their efforts to deliver compassionate, quality care while addressing the highly competitive nature of market-driven healthcare.

Indexing Terms: workflow/clinical process reengineering/laboratory information system/process management

The economic metamorphosis occurring in the healthcare industry will produce substantial changes in the delivery of medical and diagnostic services by the end of this decade. The primary economic force behind these changes is a market-driven rush to managed care with negotiated fee schedules and eventually capitation of reimbursement for each covered life. The majority of institutions engaged in the business of healthcare lack detailed knowledge of the actual cost and institutional processes required for its delivery and, in addition, possess ineffective mechanisms for controlling costs because of the traditional separation of the healthcare delivery system and the medical practitioners who define resource utilization for the healthcare processes.

A parallel technological revolution in communications and computing will significantly expand and presumably improve our ability to respond to the challenges posed by the precipitous restructuring of the healthcare delivery system. The use of information technology would ideally address, among other things, our need to dynamically manage process and leverage the value of information at all points in the delivery process, regardless of where it is obtained. Taking a page from the business world, we might call this “information in time.” Timing and the accessibility of information are crucial, given that the predominant value of diagnostic services is informing, and thus enhancing, medical decisions. However, in addition to the traditional goals of data capture and distribution and presentation of information, future information systems must be capable of process or workflow representation and management. Dynamic process management is essential for optimal resource utilization and quality-monitoring systems, especially in a complex healthcare network.

To achieve an improvement in healthcare delivery, one must have a thorough understanding of clinical processes and of the information technology and systems required to support dynamic execution and maintenance of these critical processes. A problem or diagnosis is typically associated with resource requirements and a set of services including nursing services, clinic visits, medication administration schedules, and diagnostic studies, some or all of which must be completed to bring closure to an encounter or a problem or to manage the care of a patient with a given diagnosis. If we assume that clinical practice guidelines (PGs) will provide the canonical or, at least, the consensus version of the resources and processes required to manage a given problem or diagnosis, then these high-level descriptions define and, when invoked, initiate a complex set of interdependent tasks, referred to here as Clinical Processes.

For the healthcare domain, a Clinical Process is defined as a set of processes that support the medical care necessary for the treatment and (or) management of an acute or chronic disease, and the defined policies (aspects of practice guidelines) required to achieve specific clinical objectives—including both manual processes and (or) workflow processes. Workflow may be defined as activities involving the coordinated execution of multiple tasks by persons or systems (computers, robots, etc.). Workflow description requires specification of the individual tasks, but just as importantly, the relationships between tasks—sometimes referred to as routes, rules, and roles—must be maintained for the successful completion of the process. We will distinguish here between workflow (the computerized facilitation or automated component of a process) and manual processes (the manual or person-dependent process steps required for the completion of a process).

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² Nonstandard abbreviations: PG, practice guidelines; LIS, laboratory information system; GPMS, global process management system; EIA, enzyme immunoassay; and RSV, respiratory syncytial virus.
For Clinical Processes we can define the primary or patient–provider processes, and an additional hierarchy of subprocesses that are integral to the completion of the overall Clinical Process, e.g., diagnostic testing, treatments, education. Other subprocesses or independent processes are related to an encounter or episode of care (e.g., food services, financial), but are not necessarily required for completion of a Clinical Process. The supporting or subprocesses required for completion of a Clinical Process may be prerequisite, sequential, step-limiting, or postencounter processes, depending on the policies and clinical variables defined by the Clinical Process.

A Clinical Process description is more detailed than the PG it describes. A PG will define the temporal sequence (grossly), clinical care variables, diagnostic testing, education, and so forth for a given problem or diagnosis. Clinical Processes are based on PG, and, in addition, refine the temporal relations, roles, and responsibilities; dependencies between tasks, events, and processes (primary or subprocesses); existing and new information required; and the relationship and priority of the independent processes described above. Clinical Processes descriptions then are the specific implementation of a PG in a specific enterprise, clinic, or hospital setting.

Subprocesses required to complete an encounter must be monitored and coordinated, and management interventions must occur in a timely manner to provide efficient, high-quality healthcare delivery systems for the patient and cost-effective resource and services utilization for the provider. Each supporting information system—defined here as systems typically designed to support production environments, e.g., laboratory information system (LIS), pharmacy, diagnostic imaging, respiratory therapy, nursing—must also be capable of coordinating internal processes in light of the primary process defined by a PG. Management of the complex, interdependent hierarchy of processes in this environment (enterprise-wide process management) is analogous to the challenge and design considerations described for traditional workflow-management system models developed for industrial and business support (1–6). The pharmaceutical, banking, and insurance industries, among others, already utilize document management systems capable of coordinating and expediting business processes. A recent report discusses the theoretical advantages of using such a system for managing patients’ charts in a hospital setting (7).

To support the complex and interdependent processes associated with even a simple encounter requires Global Process Management Systems (GPMS) capable of actively managing patient encounters—actively, meaning negotiation of service provision; status checks based on defined time dependencies; notifications of delays either before occurrence, based on limited resources, or at the time of occurrence; scheduling of future visits or services, etc.—through communication and coordination with departmental information systems or human agents. Although vendors now market enterprise-wide scheduling systems, those applications are relatively primitive and do not begin to address the complex process management issues required to achieve the goals discussed here. Supporting departmental information systems must be developed to manage processes and be made capable of patient- or clinic-specific process status analysis and reporting both for service-specific alerts and for negotiation and synchronization with globally managed process pathways. For example, essential elements of both a GPMS and the supporting departmental information systems would incorporate process modeling and simulation tools for dynamic planning and modification of process models and production systems.

For the purposes of this presentation, we will focus on the description of an LIS architecture to meet the process management paradigm. LIS redesign is presented in relation to an enterprise system architecture. Aspects of several scenarios are provided to illustrate the application of such a system.

Diagnostic Service Delivery: Laboratory Testing

Consider the following scenario: A patient is referred to a pediatric endocrine specialist on the basis of clinical observations and initial laboratory testing performed by a pediatrician, both of which indicate a high probability of incipient diabetes, type 1. The pediatrician is a member of a primary-care clinic associated with a tertiary-care facility, both of which are integral components of a healthcare network.

Our assumptions underlying the management depicted in this scenario include the following: All information, including the referral request and results from prior laboratory testing collected at the remote clinic, are accessible to the pediatric endocrine specialist, diabetic nurse educator, dietitian, and admitting staff of the specialty clinics associated with the hospital. These data, appropriately coded, are sufficient to specify a PG and the necessary resources and services for the pending visit. Moreover, it is desirable to accomplish all activities necessary to complete the encounter with the patient during a single clinic visit, including provision of adequate and appropriate time for patient–physician interaction.

This particular goal is desirable if one can achieve economy in time, for both the provider and the patient, without reducing the quality of the encounter, e.g., attention to detail and completion of all the necessary aspects of the visit, including necessary education, personal communication with the patient, and so on. Given the goal for this scenario, it is clear that the laboratory findings should be available before or during the time the physician sees the patient. For the appropriate laboratory results to be available "in time," collection and diagnostic testing must be scheduled in conjunction with the clinic appointment, a predefined testing algorithm must be available to direct the testing process, test results must be immediately communicated directly to the physician, and immediate com-
munication of new test orders as part of a discharge plan must be a coordinated and dynamically managed to make this scenario feasible. An additional benefit derived from achieving this goal is minimization of the resources required to complete an encounter after the patient leaves the clinic. The information requirements alluded to above stress the value of PGs for planning and implementing effective and efficient clinical processes.

A high-level process map for this scenario (Fig. 1) illustrates that certain services are required for completion of the encounter and must be coordinated with the clinical process if the goal of completing the encounter in a single visit and minimizing follow-up is to be attained. The intradepartmental processes represented by the laboratory testing element of the map have traditionally been organized and managed from a departmentally oriented prospective, as opposed to a Clinical Process orientation. Realignment of departmental workflow in concert with Clinical Processes represents an appropriate but complex management problem that will be difficult to implement on an enterprise scale without information systems designed to facilitate communications and coordination of roles, rules, and resources.

Intra-laboratory Process

The sequence of events pictured in Fig. 2 includes those activities occurring just before the request for laboratory services and workflow internal to the laboratory that are relevant to this scenario and to internal laboratory operations. The boundary between the clinical domain and the laboratory separates what might be classified as people-oriented workflow management systems from a domain that is traditionally production-oriented, e.g., efficiency of scale is achieved through batch analysis, automation of handling and testing, and, in some larger operations, use of robotic systems for sample preparation, distribution, and ultimately the testing process. To meet the goal set for this scenario, one may need to balance the internal efficiency of laboratory operation against the needs of the high-level clinical processes. In practice, this level of coordination would be difficult, if not impossible, without workflow management systems integrated with traditional LIS modules and a GPMS.

![Flow diagram depicting the primary and dependent pathways related to referral of a patient from a primary-care provider to an endocrine specialist.](image-url)

Fig. 1. Flow diagram depicting the primary and dependent pathways related to referral of a patient from a primary-care provider to an endocrine specialist.
Selective process, separating automation for primary system. Process is replete with constraints and critical points, several independent domains exist and are tightly linked. In a traditional hospital environment processes and priorities in these domains are not tightly linked.

Laboratory Workflow Management Systems

In the example at hand, laboratory studies constitute a subprocess that must be completed within known temporal constraints defined by the goal(s) of the primary or clinical process. The proposed components or modules of an LIS capable of managing processes are discussed below. The basic functional issues are not unique to an LIS; however, design constraints would necessarily be distinct for that system.

Process Mapping and Simulation Modeling

Dynamic management of a process, that is, definition, implementation, monitoring, and dynamic revision, is an essential capability for a replete workflow system. Independent system-simulation modeling tools for process optimization are becoming available and should provide the ability to test and refine laboratory operations via simulation, obviating the need to rely solely on pilot projects that consume time and resources (8). Optimally, this tool, and others required to automate process management, would be provided as an integrated component of the suite of modules making up an LIS. The tool should provide for process mapping and simulation, allowing high-level displays as well as definition of complex interdependencies for separate tasks, variables for each task, goals for a process, etc. Once created, the simulation would be available for ad hoc “what if” testing on the basis of changing input (e.g., number of samples per shift), resources available for a given task, and so forth. Selective monitoring of processes, including component tasks, would not only provide for a more efficient and effective management review of operations, but also provide statistical information derived from the data to dynamically update the values assigned to variables associated with a given task or process. Monitoring and data acquisition could be established for a batch or a single specimen.

In the current scenario, we are interested in the time required to complete the entire algorithm defined by the PG and not a single test. A typical algorithm for this PG might specify measurement of fasting glucose and urine and (or) blood ketones. If the results of one or more of these tests were positive, then measurement of glycohemoglobin would be performed.

Control Mechanisms and Scheduling and Monitoring Systems

Today’s LIS provide rule-based systems for automating some aspects of process management. Obviously, the degree of automation described for process management above is heavily dependent on some form of decision-support system. Although rules may serve in some instances, neural nets and genetic algorithms may be more appropriate for other aspects of process analysis and optimization. For example, a genetic algorithm would be preferred for task coordination where a combinatorial problem must be solved for a maximal or minimal result. Logical combination of these control mechanisms would provide the highest degree of efficiency when designing and evolving complex process models. Limited functionality addressing these issues has been described by a group in the Netherlands (9). Their application focuses on internal laboratory capacity planning. Ultimately, the rules or logic defining decisions, nodes, and alternative pathways should be imbedded in the semantics and workflow model supported by the system.

The GPMS would require date, time, and capacity estimates provided by the LIS and other systems so as to negotiate an appropriate patient itinerary. The LIS would require that a specific PG or order set be submitted by the GPMS for each service request, which, in turn, would define the time required for completion of this set of subprocesses. Periodic monitoring of the testing process would allow prediction or detection of delays before the event. Monitoring and appropriate intervention or notification provided to individuals who must manage downstream processes may ameliorate the untoward effects of delays in the patient service areas.

In this scenario, orders and appointments submitted to the LIS would rely on process (diabetes algorithm) capacity estimates derived from simulation modeling and prospective workload estimates. Alternative dates and (or) times may be proposed by the workflow system, depending on capacity. Once a date and time are confirmed by both systems, personnel scheduling would have to remain consistent with workload projections for that time period. This being the case, scheduling programs must have workload data estimates if they are to post optimal staffing plans. Scheduling of patient visits, which depend on a variety of resources, require both general and specific knowledge of processes. Although the intersystem negotiation may need to be monitored by humans to manage exceptions, well-designed control strategies should be capable of handling a high percentage of such tasks.

The tools discussed above would have to be inte-
grated and capable of processing data from actual events related to task initiation and completion, e.g., specimen arrival verification, initiation of analysis, receipt of initial result, and verification of results. Failure of quality-control testing in a given batch may be included as a factor that increases the probability of delay and thus would require methodologies for revising the event and process map connections, in addition to the process tasks and interrelationships.

**LIS Architecture**

Extensions of the traditional LIS suite of modules based on the prior discussion are shown in Fig. 3. This presentation is not intended to address design issues related to the traditional functional modules, although the LIS database is represented here as two compartments with different data models. The component systems shown in Fig. 3 would be required to implement automated workflow or process management. Data developed by the process simulation model would be stored and accessible for workload capacity planning and ultimately for personnel scheduling. The control systems would use capacity estimates and guidelines to schedule patient testing over the GPMS. In addition, if a clinical process management plan included home healthcare visits, where specimens are collected and returned for testing within the laboratory, notification of expected work and estimated time of arrival could be sent to the LIS control system via the GPMS. We assume here that asynchronous wireless communications are supported between the home healthcare provider and the GPMS for a given institution.

Historical data, such as epidemiological information, discharge diagnosis, etc., could be retrieved from the LIS database or other enterprise systems and analyzed for the purposes of workload capacity planning. This would be particularly useful for workload that varies on a seasonal basis, e.g., viral culture, rapid viral tests, and microbiological cultures for evaluation and treatment of lower respiratory disease during the winter months.

**Clinic Practice Guideline: Process Revision**

The following scenario describes the revision of laboratory processes secondary to the implementation and subsequent revision of a practice guideline for bronchiolitis. The laboratory work specified in the PG includes an enzyme immunoassay (EIA) and tissue culture for respiratory syncytial virus (RSV) on day one of admission.

A review of clinical practice patterns has demonstrated that if the use of antiviral drugs (ribavirin) are limited to only high-risk patients with positive laboratory findings for RSV, the average cost per case with respect to this therapeutic option could be substantially reduced. The decision model developed for the study specifies that RSV EIA results must be available within 2 h of initiation of the encounter.

Under prior PG specification, no temporal constraints were made on availability of laboratory findings. With the intended revision, tissue culture is excluded and a dependency for testing is added, and the testing is temporally linked to a clinical process.

Before the recommended change, the laboratory made RSV EIA and tissue culture available as a routine service. Requests for stat EIA testing outside of normal business hours were handled on a case-by-case basis. Because of the change in service required to acquire laboratory results in time for making a medical decision, the laboratory will have to revise test availability and establish an algorithm, or set of rules, linked to the PG for bronchiolitis:

**IF** PG = BRONCHIOITIS, THEN ORDER RSV EIA, TIME-OUT = 2.0 HOURS POSTCOLLECTION, PRIORITY = HIGHEST;

**IF** RSV EIA POS, THEN NOTIFY = PHYSICIAN, STOP;

**WHEN** RESULTED, NOTIFY = PHYSICIAN, GPMS.

**IF** DELAYED, NOTIFY = PATHOLOGIST, GPMS, PATH-LOG.

The rule set for test processes associated with the PG for bronchiolitis would be created and managed by the LIS control system (see Fig. 2). A new process would be modeled and simulation testing would be done with use of performance parameters for the individual tests and prior workload associated with RSV EIA. In this example, data would have to be evaluated for each month, given the extreme variation in prevalence of this virus. Staffing requirements would be estimated on the basis of the results of the simulation. These data would be passed to the Workload Capacity Planning and Sched-
uling modules for evaluation and revision of staff scheduling and allocation of staff between laboratory workstations. In this example, advanced planning for clinic appointments in light of laboratory and other ancillary service capacity is not a requirement. It is, however, essential that the laboratory compare the proposed process changes against historical data such as admissions for bronchiolitis and prevalence of RSV for two or more seasons in planning for appropriate staffing and to project costs associated with the planned increase in service. Data from the simulation model would be used to generate proposed updates to LIS system parameters, e.g., addition of tests to specific worklists, for review and approval by the LIS administrator. Once in play, the new processes would be monitored (LIS Monitoring System), and failures, such as delays, would be noted. Managerial review of process, staffing, and other measures could be invoked on the basis of the failure rate exceeding a specified threshold.

**Information: A Requirement for Process-Focused Computing**

In both of the scenarios provided above, clearly information related to the overall process (e.g., the diagnosis and treatment of diabetes and bronchiolitis), specific details with regard to subprocesses (e.g., laboratory testing), and historical data covering workload and epidemiology are absolutely essential to the successful use of workflow-enabled systems in the medical domain.

We may broadly classify clinical events as follows:

**Scheduled**
- Known pattern and acuity, e.g., specialty clinic using practice guidelines
- Unknown acuity, e.g., exploratory surgical procedure

**Unscheduled**
- Predictable pattern and acuity, variable volume, e.g., seasonal infectious disease
- Unpredictable pattern and acuity, variable volume, e.g., diabetic acidosis

The two scenarios described here represent scheduled and unscheduled event types of known pattern and acuity, at least from a laboratory service perspective. To proactively plan and manage both the clinical and the support services required for unscheduled variable volume clinical events, substantially greater detail and delineation of information will be essential. Accumulation of risk factors and outcomes for diagnoses, such as bronchiolitis, should make it feasible to make population-based estimates of admissions rates to an intensive care unit, length of stay, requirement for mechanical ventilation, etc., where comorbidities are known. At the moment, neither physicians' groups, hospitals, nor managed-care organizations have demographic data that include the comorbidity data required for modeling and forecasting resource utilization and the associated cost for a given population of covered lives, despite the fact that, in some cases, risk factors and outcomes data are already in the medical literature.

For the outpatient visit, laboratory processes and related resource allocation are dependent on, and constrained by, the number of planned patient encounters, patient acuity, and the time frame in which the diagnostic test results are needed. The potential impact of a future clinic session on laboratory operations is variable and requires dynamic assessment. The capacity of support services, such as the laboratory, to enhance clinical operational efficiency depends on the availability of this information.

Although all the information mentioned above is already available, albeit not always accessible, the missing link is the PG. PGs, of course, are under development on a national level and within individual institutions and will be invaluable for analysis, design, and implementation of clinical processes and effective and efficient use of resources.

With regard to unplanned encounters, such as a patient seen in the Emergency Center for acute bronchiolitis, historical data that define the prevalence of a given organism or disease and the admitting and discharge diagnosis along with acuity information can be used to gauge the service capacity required to address the needs of these patients.

**Advantages of Process-Focused Management and Information Systems in Healthcare**

As is often the case with the unplanned, unanticipated changes, the transformation of healthcare delivery will probably produce both desirable and undesirable outcomes. The reorientation of our focus from a fee-for-service, function-oriented business to a commodity, process-directed business has the potential to produce several benefits, including:

1) Increased patient satisfaction through reduced waiting time and duration of encounter, and completion of the encounter, including consultation and education, on the basis of all pertinent findings during a single visit (laboratory and other diagnostic service results).

2) Improved continuity and quality of care through availability of information in advance or in time for medical decisions relating to therapy, consultations with other specialties, etc.

3) Decreased cost of care through a reduction in the number of visits, phone calls, letters, etc., now required to complete the management of a problem(s) or an encounter; reduced duplication of orders or of necessary testing that might be done "just in case" because of lack of availability of results at time of encounter.

These benefits can be realized as a consequence of realigning institutional and departmental resources in light of optimized Clinical Processes. The proposed conceptual change in management strategy is predicated on information systems designed to facilitate its execution. Manual methods of communication and process coordination would severely limit the scale in
which one might successfully implement this approach (i.e., realize the expected benefits).

Vendors of information systems that market to the healthcare industry have not yet publicly indicated that they are addressing or will address the issue of process management in future systems development. Given the typical time required to complete the development cycle for new products in this industry, one cannot help but wonder how long it will be before information systems capable of addressing the changing business needs of healthcare providers are available.

References