eSphere

The Protocol-Centric Approach

to

Healthcare Information Technology

A New Paradigm

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Executive Summary

Protocols drive everything that occurs on behalf of a patient. The protocol centric approach allows the organization to plan to provide care, to provide the care, to monitor care, and to improve processes so that better care is provided in the future. It does this by reorganizing the work of the staff and employees to focus on protocols.

Protocols have two jobs. The first is to define and coordinate action around the care of current patients. The second is to serve as a knowledge base for improving the care for future patients.

In this white paper the following topics will be addressed:

- The foundation for the Protocol Centric Approach
- The need for the Protocol Centric Approach in today's healthcare milieu
- Modeling the healthcare process
- Practical facts about protocols
- Benefits of using protocols
- Implications of protocols on future practice

Defining the Protocol Centric Approach

The protocol centric approach extends the use of the concepts and methods of science-based protocols that are the foundation of modern medicine. A protocol centric approach builds on five long-standing healthcare practices:

#1 Using Protocols to Provide Current Clinical Care

Protocols are the fundamental unit of patient care. The idea of basing clinical practices on defined clinical protocols dates back at least to the rise of modern medicine, when sterile technique protocols were first defined to improve surgical outcomes. The lesson was that health care is provided best when practices and techniques are science based, well defined and used repeatedly. This is what a protocol enables.

#2 Monitoring and Review

The protocol centric approach attaches each task performed for a patient to both a patient and a protocol. Real-time and post hoc monitoring and review of protocols are used to evaluate processes of care for outcome effectiveness and resource efficiency. *Monitoring MUST be performed in real-time to identify issues as they occur so that they can be immediately addressed. Protocols allow the construction of automatic process monitors that identify conflicts among orders for care, and can provide alerts and warnings based on assessments, measurements, and outcomes.* Protocol driven monitoring and review, more readily identifies defects and improvements in the underlying processes of care. There is a difference between monitoring and evaluating *patient data*, and monitoring and evaluating *protocol data*. Patient data analysis assumes that outcome is independently correlated with each action and resource.

Protocol data analysis assumes that outcome is correlated with protocols, and that it does not make sense to look at individual interventions outside of the context of the protocol.

For example, patient data analysis might ask why a patient required three chest x-rays. Protocol data analysis would determine if three chest x-rays are on the ordered protocol, and if not, what indications were present that necessitated variations from the protocol.

#3 Using Protocols to Build New Knowledge

The protocol centric approach uses the scientific method as the basis of knowledge for defining protocols. Medical research using the scientific method is constantly being performed to fill in gaps in medical knowledge, and forge improvements in current protocols. Hypotheses are formulated about the outcome, effectiveness or efficiency of a protocol. Science-based medical research provides data for accepting or rejecting the hypotheses. Studies can be performed that provide post hoc analysis of data. The protocol centric organization involves all disciplines and all of the activities performed on behalf of patients as part of formally defined protocols. With so many disciplines involved, how is the care managed and coordinated? Coordination among all disciplines, and over the disease process, occurs using protocols. Diagnosis changes over the process of caring. The work is coordinated using protocols. Protocols include not just physician practices, but also all workflow related to the intervention. In the protocol centric organization, these "behind the scenes" activities are defined in formal protocols, and are documented and monitored just like the clinical interventions.

For example, the patient presents with chest pain; chest pain is diagnosed as coronary artery disease; the coronary artery disease is treated with a coronary artery bypass graft; after surgery the patient is then "diagnosed as a post CABG patient. The surgeon manages the surgical intervention, but assumes someone else is managing the patient.

For example if a patient's protocol calls for a mammogram test, there are "behind the scenes" administrative protocols that assure that the mammogram test is performed, and that the results are reported to the physician.

#4 Planning

Protocol centric planning is a three-step process: Step 1 is to estimate the patient volume. Step 2 is to derive the service volumes required to serve the patients by applying the protocols against the patient volume. Step 3 is to estimate the resources needed to provide the identified services. The protocol centric approach focuses on estimating the volume of services that will be provided. Protocols have been applied to well defined and repeatable medical interventions, such as surgery. The Protocol centric planning approach extends the use of protocols from the well-defined procedural area to other areas of medical intervention.

The Need for a Protocol Centric Approach

Whether the focus is research, education, or clinical service, the ultimate mission of a healthcare institution is to relieve suffering and return to health. Today's modern healthcare organizations have increasingly turned to protocols to help to provide a road map for care and consistently carry out processes. The use of protocols is becoming increasingly prominent throughout healthcare organizations because protocols address several fundamental problems faced by the healthcare organization:

Accountability

The healthcare organization entrusts responsibility to hundreds, if not thousands of employees to ensure the quality and accuracy of the care provided. Currently, healthcare organizations manage accountability by placing trust in staff who are recruited and trained within functional disciplines, e.g., medical staff, nursing, etc. Privileges and permissions are granted to individual staff within each functional area to perform specific tasks and procedures.

In the protocol centric organization, the problem of accountability is addressed by:

- Granting Permission to Order Based on Protocols - Permissions are granted to the protocols that define processes of care instead of basing permissions strictly within functional areas. Exception privileges are granted to certain staff to handle patients who fall off of the protocol. In addition, the protocols may be ordered to address co-morbid conditions, e.g., if the patient is also diabetic the physician can order the "diabetes protocol". Patient care is ordered using protocols. The physicians order may include protocols that permit some staff to perform functions that they were previously not allowed to order.

  For example, for a 42 year old male referred for chest pain, the physician can order the "chest pain protocol" to order all tasks typically performed for chest pain patients. The physician's ordering of the chest pain protocol then triggers activity in the respective nursing and ancillary areas. The physician's order include an insulin protocol, that allows the nurse to measure patient glucose, and based on the result of the glucose test, decide the dosage of insulin.

- Patient Intervention Permissions Remain Unchanged - Protocols radically alter the way that orders are entered for patients, but the tasks that are performed on behalf of patients remain unchanged. The individual task is still the fundamental unit of work. Although these tasks are ordered according to protocols, and evaluated in the context of protocols, the individual task is a learned competency that staff are trained and licensed to perform.

- Shared Responsibility for Definition, Approval, and Improvement of Protocols - Everyone in the protocol centric organization has two jobs. One job is to carry out medical interventions based on the defined protocols. The second job is to define and improve the protocols. Protocols are best defined through a mixture of knowledge from the scientists who are aware of current research in the subject area addressed by the protocol and by the people who use the protocol in their day-to-day work for clinical intervention.

Documentation

The actions of healthcare organizations are subject to scrutiny by government review agencies, medical societies, payers, and legal lawsuits. This outside party scrutiny and the internal desire to fulfill the mission to render quality patient care drive the organization to require staff to document and monitor patient care. The protocol centric organization uses protocols to simplify the documentation of patient care. Documentation can be performed real-time because current patient care activities can be documented by exception against the protocol ordered for the patient.

Data Organization and Management

Organizations realize that they need to capture and provide data about clinical activity, but are less able to say why the data is needed. Because healthcare is not an exacting science, the

major role of clinical data management is to bring the correct data to the right person at the right time. Protocols solve the problem of why and how to organize data to best support the mission of the healthcare organization. The protocol centric organization is data driven. Data must be identified, mechanisms to capture the data must be created, the data must be stored, and the data must be made available when required based on attachment to a protocol. Protocol oriented data administration places data within the context of a protocol.

For example, a chest x-ray is traditionally associated with a specific patient and a specific ancillary area. Protocol centric data management relates the chest x-ray to a specific protocol. The protocol provides information about the clinical justification for ordering the x-ray, and provides the clinical context for interpreting results.

Modeling the healthcare process

Protocols define the patient care process. Protocols enhance the ability of the organization to support the following aspects of clinical care:

- Timing of Decisions - The timing of the clinical care decisions is critical and requires relevant communication. Protocols define the sequence and timing of clinical care processes. Protocols allow the organization to evaluate if diagnostic tests and medical interventions meet the criteria of "timely". There is no context for evaluating timeliness without protocols. Delays in providing information can be identified and resolved using protocol centric data,

- Deliver the Right Data to the Right Person - Healthcare is not an exact science. Scientists review data, draw conclusions, and implement plans. This requires that the right data is available to the right person to assist in the process of interpretation, and intuition. Protocols relate actions and data to the clinician in the context of the clinical process.

- Disseminate Clinical Knowledge - The practice of medicine is continually changing and advancing. This means that there is an ongoing need for a learning process that disseminates the new knowledge as it becomes available. Protocols are constantly updated to ensure that all clinicians have access to the latest practice guidelines.

- Rapid Response - Clinical practice is contingent upon the day-to-day and minute-to-minute situation. The "if-then" logic of science is used to reflect dependencies and to trigger clinical care events. Protocols allow clinicians to rapidly respond to changes in the patient condition.

- Provide Right Resources at the Right Time - Clinical practice is not an isolated process. Multiple disciplines affect different parts of the clinical process. The right resources must be provided at the right time. This requires coordination between various health care providers. Protocols relate the anticipated patient volume to resource requirements.

Practical facts about protocols

A protocol is a definition and sequencing of healthcare related actions (assessment, decision making, intervention). Protocols define both the healthcare worker actions and the appropriate medical technology. In working with protocols, the following "facts" have been uncovered:

Protocols are Not Uniform Because Patients are Different and React Differently to Interventions

The core problem in using protocols is that every patient is different. Patients respond to medical intervention differently from one another because of three factors:

- ✓ How the intervention interacts with the problem the patient brings with them (e.g., CHF)
- ✓ How the patient interacts with the induced effects related to the intervention (e.g., surgery paralyzes lung and bowel)
- ✓ The other effects that occur because of the interaction between human and intervention. (i.e., it is never known with 100% certainty what side effects will occur when a specific patient is operated on)

In aggregate, these three factors make each patient unique, and make it difficult to define a single protocol that applies to all patients.

The Smaller the Process, the More Consistently it Can Be Defined Using Protocols

A process consists of the totality of patient care for a given patient with a given condition. A protocol describes how the process is clinically managed. The smaller the process, the less chance there is for variation in the process, and the more consistently a protocol can be defined and applied. A patient's care process is managed by a plan of care that is the sum of its multiple protocols:

Patient's Care Process ⇒ Managed by a Plan of Care = Σ multiple protocols

Smaller protocols allow care for the patient to be customized. Care is customized by ordering and merging different protocols, or protocols that take different paths. Protocols are defined at multiple levels of specificity. Smaller protocols have fewer activities, and less opportunity for random variations in patient response that result in "variance".

For example, if a patient has a fever, then the fever protocol may call for the temperature assessed every 4 hours, and if fever is present, to give 500 mg of Tylenol. The same small fever protocol might be used as part of larger protocols such as a protocol for a hospitalized cardiac surgery patient, a protocol for an outpatient receiving chemotherapy for cancer, or a protocol for a person at home in bed with the flu. In each of these examples, the smaller fever protocol can be applied consistently between patients, and the larger protocol will show more variation between patients.

Protocols Can be Used to Define All Medical and Administrative Work

The introduction of scientific standards in medicine (e.g., the use of sterile technique in the OR) has provided a dramatic gain in effective use of staff time and improved patient outcome. What has become apparent more recently in medicine is that even protocols not based in science can have similar magnitudes of improved effectiveness in the use of staff time and outcomes achieved for the patient. Inclusion of non-scientific techniques into the patient care process involves the inclusion of the people who do the work. In the protocol centric

healthcare organization, people from all disciplines contribute their guidelines into the tasks performed for each patient based on specific indications.

Every Action is Associated with a Protocol and a Patient

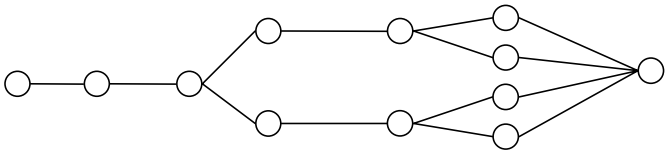
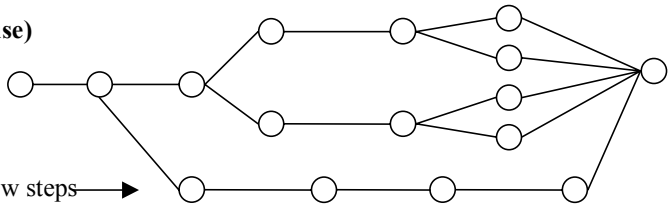
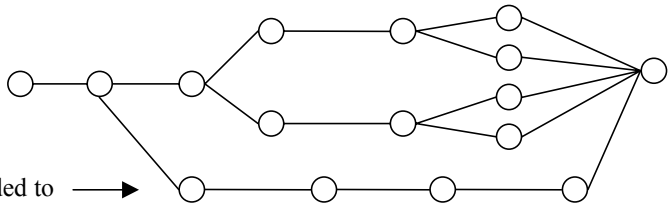
Physicians, nurses and other healthcare workers document the individual actions of assessment, decision-making, and interventions to meet the requirements of the medical and legal traditions. Every activity performed on behalf of a patient is associated with a protocol as well with a patient. The phrase "patient-centric" captures the meaning that the patient is the recipient of the actions of the healthcare team. The phrase "protocol centric" captures the meaning that healthcare actions take place within the framework of a protocol. The irony is that protocols are one of the last areas to benefit from advances in information technologies even though protocols are the core fabric of every organization.

Protocols Help Create New Knowledge

Differences between patients as to how each individual patient responds to interventions complicates the research process of predicting the outcome associated with a particular protocol. Overall guideline doesn't really exist. The ultimate larger guideline is the aggregate of all the smaller protocols, and is customized to each patient. The ability to learn from smaller processes and to correct them is the goal of the protocol centric organization. Tomorrow's knowledge can be found in today's documentation (see Exhibit 2).

Exhibit 2: Learning from Protocols

Protocols are continuously improved, either from lessons learned from clinical experience or from new findings from medical research.

	Protocol
Original Protocol: When ordered for a patient, the steps in the protocol are pre-defined and "fixed".	**Version 1** 
Ordered Protocol: In practice, a new steps might be tried to achieve the desired patient outcome.	**Version 1 (in use)** 
New Version: Upon acceptance, the protocol is "unlocked", the new steps are added to it, and the protocol is "relocked". The new version of the protocol provides a new choice for treatment.	**Version 2** 

Protocols Distribute Knowledge

Protocols are the mechanism used to distribute the knowledge needed to apply medical science to patient care. A protocol includes knowledge about what actions to perform and what medical technology to use when certain indications are present. If there were no protocols, then every time a healthcare professional encountered a patient, they would need to reinvent what actions to take and how to perform those actions. Physicians, nurses, and other healthcare workers can perform the actions which, based on past research and clinical experience, have the greatest likelihood of benefiting the patient because there are protocols.

Benefits of using protocols today

Protocols change both the planning process for providing patient care, and the process for providing care.

Use of Smaller Protocols to Construct Larger Protocols

The clinical process consists of measurements, diagnostics, tests, observations, experience and interpretation. The center of this process is the patient and the scientists/ clinician that are empowered to deliver this care. In providing care, protocols are used to ensure consistency. The interventions, their sequence and their timing are fixed and consistently applied. Interventions are customized to each patient, although if you look at smaller protocols, the smaller the protocol the more consistently it applies.

Deciding Care

Behind every intervention, there is a complex of "hidden" activity. The decision of who should perform each specific task in the protocol is decided in defining the protocol. Clearly there is a two part answer to the question of "who decides care":

1. Whoever decides the content of the protocol decides care.
2. Whoever orders the protocol decides care.

The answer to "who decides care" is similar to industry. The engineers and production workers in a manufacturing company decide how a product is made. Orders for the product initiate the work. Healthcare runs parallel to industry because defining the work to be done is separate from initiating a process. The protocol defines the whole process. Each functional area (e.g., Nursing, Clinical Laboratory, Radiology, Pharmacy, etc.) either individually or together defines the protocol. The clinician evaluates the patient, and decides which protocols to initiate.

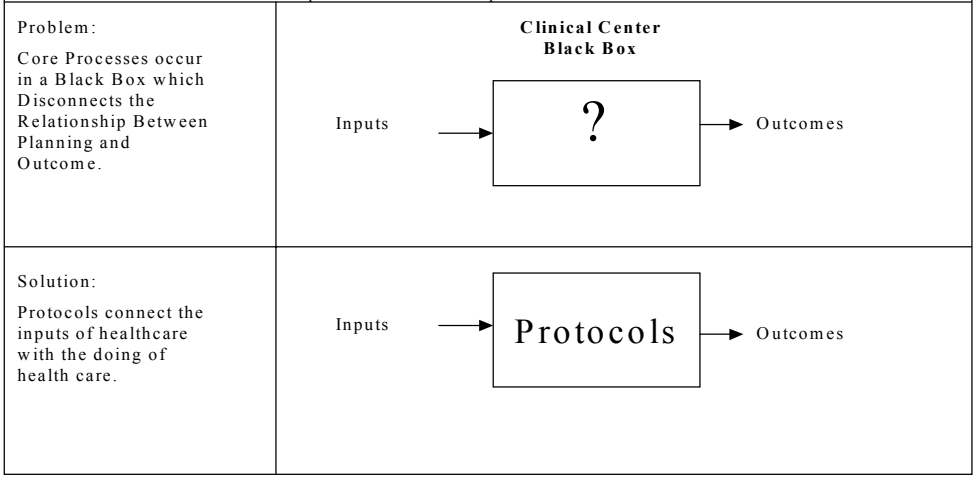
For example, if a clinician orders a laboratory test, a sequence of activity occurs. The specimen must be obtained, delivered to the testing equipment, and then processed. And, the result must be reported. The clinician did not specify all of these actions required to obtain the test result, but did trigger their occurrence. In effect, when a physician orders a clinical laboratory test, they are initiating a protocol to perform the test.

Planning Service Volumes

Protocols provide a new tool that allows service volumes to be accurately predicted. The predictions of resource use based on protocols allows the organization to set budgets for current operations, and to identify variances. Protocols allow the forecasting of the resources that each

type of patient will likely consume. The focus of planning for current operations is on volume, not cost. Traditionally, errors in volume are worse than errors in unit cost. Protocol centric is a good way of predicting volume. The plan provides the projected volume of internal services, e.g., the number of laboratory tests, the number of medical consults, the amount of medications. Protocol centric organizations will know how to adapt because they will know the volume of internal services needed to meet the expected patient volume.

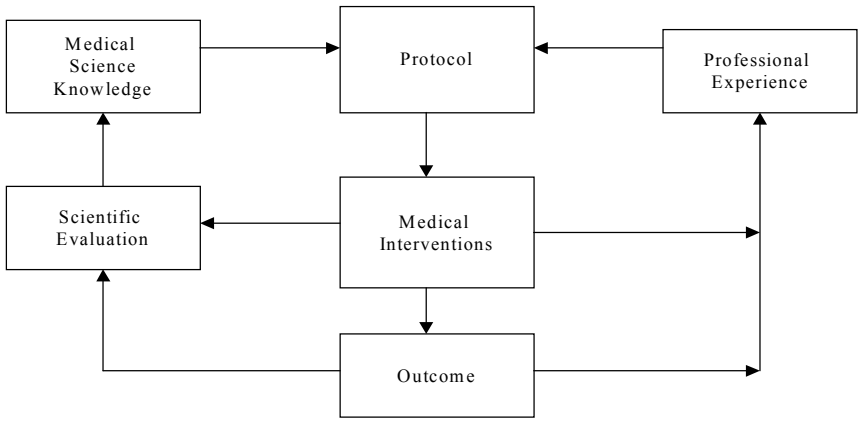
Exhibit 3: Protocols are the Blueprint that Connect Inputs with Outcomes



Implications of protocols on the delivery of care in the future

Medical protocols are an integral part of medical research, education, and clinical care. Medical research requires a protocol. Everyone involved with the research patient needs to follow the rules so that the research variables are controlled. Protocols are the storehouse of medical knowledge that describes the indications, activities, and "if-then" contingencies. Medical protocols are built on basic and clinical research. In the research process, a hypothesis is formulated, data are collected, and the hypothesis is confirmed or rejected using scientific standards. The outcome of the research process is a protocol that describes the actions and

Exhibit 4: Protocols are Part of Medical Science New Knowledge Production



technology to utilize when specific indications are present. Research based protocols are used in medical education to transfer knowledge. Physicians in training and experienced physicians keep abreast of the changing medical field by learning new protocols that describe medical care, or when to use certain drugs, a new surgical technique, or a new diagnostic sequence.

The scientific approach can be applied to every protocol, either clinical or administrative. In day-to-day operations, a protocol is "locked" and work is performed according to the protocol. In the protocol centric approach, clinical data can be used to evaluate the outcome effectiveness and resource efficiency of the protocol. The protocol is then "unlocked" and altered where changes to the protocol can be made to improve the process.

Medical Informatics: Enabling the Protocol Centric Approach

Protocols offer tremendous opportunities to improve current and future patient care. A bottleneck to the protocol centric approach is that protocols have been limited either to paper-based descriptions, or to generalized guidelines. The protocols sit "off-line" and are quickly out of date because constantly evolving work practices make them obsolete. Paper based protocols are too cumbersome to support dynamic, real-time protocol centric work processes.

Why are protocols on paper? Current healthcare information systems are based on the ordering function and financial requirements. The ordering paradigm perpetuates the problem of providing the correct information to the correct person at the right time. Orders and results for any given patient are each handled independently, without any clinical linkage. The ordering paradigm exists because financial activities have been translated into clinical information systems. The goal of today's clinical information system is to get an order through and create a charge. The order paradigm has been forced into use for clinical documentation and results reporting.

The ordering paradigm is the antithesis of protocol centric because it ignores the clinical relationships between data. All of the following are by-products of a protocol: 1) orders, 2) financial charges, 3) work initiation, 4) workflow. These are attributes of a protocol, not the goal of an information system. The goal of a clinical information system should be to provide the correct data to the right person at the right time to provide patient care.

Today's clinical information systems are not part of the solution, they are part of the problem because they encourage and perpetuate a stand-alone order process that ignores clinical process. Information technology is needed that integrates the protocol into the clinical care process.

For a new information system, how are these things achieved?

Imagine moving protocols from paper to the computer …

- ✓ Instead of being static and off-line protocols could be used dynamically to customize the work to be performed for each patient.
- ✓ Each time a protocol is used, the outcomes associated with it are recorded, and used to assess the outcome of the work performed.

- ✓ Each time a change to the protocol is approved, it is instantly communicated and used for care of the next patient.
- ✓ Protocols are no longer limited by the general descriptions that are imposed by paper, but that they can include intricate detail and "if-then" logic.

*Imagine how a Protocol Centric computer looks from the perspective of the **Physician***

- ✓ Initiating orders by initiating protocols that have been defined for every patient condition
- ✓ As a physician you come into the hospital or clinic and have a list of your patients, and the tasks required of you immediately available.
- ✓ All new and changed symptoms, measures, and test results are reported to be used in your medical decision-making.
- ✓ You are automatically asked if the care should deviate from protocol because of a change in patient condition, or other event.
- ✓ You can view the complete plan of care that all caregivers are working towards, a plan of care that clearly delineates tasks, time, and responsibility.
- ✓ You can instantly view the patient's complete history, medications, and test results.
- ✓ You can make a change in the diagnosis and treatment approach that is instantly communicated to your colleagues, staff, and support personnel and if appropriate, the change becomes part of a new protocol for providing care.

*Imagine how a Protocol Centric computer looks from the perspective of the **Nurse***

- ✓ All nursing protocols are available in the computer. There is no possibility of misinterpreting a protocol because the action of entering a protocol into a computer requires specific definition of the protocol.
- ✓ The protocol provides the plan of care, with the time and sequence that each assessment or intervention is to be performed.
- ✓ Nurses transferred from other units to address staffing shortages for the shift can easily fit into the unit because their complete routine is specified by the plan of care.
- ✓ The burden of documentation is reduced because documentation is by exception and against the plan of care.
- ✓ A nurse can tell at a glance if laboratory has drawn ordered bloods, and when test results are scheduled to be available.
- ✓ Physicians are immediately informed or paged when the nurses assessment identifies exceptional changes in the patient condition
- ✓ Medication errors are greatly reduced or eliminated because the medication ordering process is streamlined, with improved verification of pharmacy orders.

*Imagine how a Protocol Centric computer looks from the perspective of the **Ancillary Areas***

- ✓ Orders to initiate work are immediately displayed in the ancillary area.
- ✓ Clinicians are empowered to initiate the entire protocol needed to fulfill the order.

- ✓ The ancillary area gets a report that showed what protocols are associated with each order, and with each activity on the ancillary's protocol.
- ✓ Work list are provided that showed responsibility for each task.
- ✓ Time estimates based on the protocol are provided to users of the ancillary service for when the ancillary's service would be completed.
- ✓ Outcomes are recorded for each task performed by the ancillary service, so that each step in the process could be evaluated for improvement.

Evolving to a Protocol Centric organization

The core concepts of the protocol centric health care organizations have evolved over time. Although similar to the lean production techniques of modern high-tech organizations, the protocol centric healthcare organization is uniquely designed to respond to the need to provide customized patient care when the clinical arm of multiple scientific disciplines provides that care. In the protocol centric organization, all productive work is modeled as a sequence of input-process-output. The protocol must be monitored real-time, and, potential problems must be immediately identified and avoided.

One valuable lesson from lean production techniques is that work processes need to rapidly respond to changing technology, changing customer requirements, and to identify and remove process defects. Lean production organizations rely on scientists and managers to identify the need for process changes for strategic and technical reasons, and rely on the people doing the work to accomplish the necessary changes. Protocols allow the division of labor between identifying the need for change and making the change to occur.

Why is it that the protocol centric organization should arise at this particular time in healthcare? It is the confluence of need with new technology. The need is local to each health care organization's mission, tradition and competitive situation. The protocol centric approach focuses the organization and its staff to meet their unique challenges of providing medical research, education and patient care. The reliance on clinical information systems that are based on the financial ordering paradigm is the major technical bottleneck to implementing the protocol centric approach. New information technology concepts and features, as outlined in this brief, are needed to realize the protocol centric potential.