The Center of Excellence:

Justifying eHealthcare

Perseid Software Limited
Needham, Massachusetts

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1 Executive Summary

How do you justify, start and most importantly, how do you fund a complex new technology and service such as eHealthcare?

The pressure to automate the entire value chain of services in healthcare; to make more timely and cost effective clinical decisions and improve patient safety; to reach and educate consumers, providers and patients and to do so profitably and reliably has resulted in the development of a complex mix of information technology and systems that can extend literally from a patient at home or researcher in a lab to a national or international insurer or self-insured, encompassing numerous sites and facilities. These capabilities require expensive, reliable, easy-to-use information systems and services integrated to ensure they are easily audited, secure and non-stop.

This white paper provides a foundation both for understanding the anticipated evolution of real-time eHealthcare services and a method to fund eHealthcare—The Center of Excellence. It will define the Center of Excellence as a healthcare implementation of continuous quality improvement and suggest a model information systems architecture for eHealthcare. It will also suggest an organizational plan that facilitates the development of integrated clinical, administrative and financial systems, some real-time, that support an eHealthcare Center of Excellence on a par with those already operating in the manufacturing sector of the economy.

For the financial executive, this white paper provides a means of viewing the value chain in the eHealthcare as a series of integrated business and insurance processes—supporting an increasing sophisticated and complex series of Centers of Excellence—with a return on investment in mind.

The Center of Excellence is the key to successful eHealthcare funding and evolution because it creates a path to success using incremental development, demands well defined metrics for success, a focus on excellence and a maximization of a return on investment that is expected to fund the future evolution of real-time healthcare.

2 Solutions Using eHealthcare

2.1 Introduction—Creating and Measuring Value in eHealthcare

The IT infrastructure supporting an eHealthcare product throughout its life-cycle is very complex and expensive. Developing a new eHealthcare project requires complex technology and partnerships and is based on an important but rare set of experiences in commercial insurance and/or provider relationships─direct and continuous interaction with patients and their family on a seven by 24 hour basis. The information systems supporting these processes must support insurance, patient care, communications, order entry and healthcare services creation; research; development; disease management and clinical trials to be effective and useful.

For example, a new eHealthcare program within the domain of internal medicine requires patient registration, collecting in the office and in the home vital signs, unique patient-centered variables (attributes) such as conditions; creation of eHealthcare services, order entry, remote variable collection on the patient, secure communications for medical "forums" and social networks.

All data generated by these processes must be validated and entered into core databases for insurance, forming a comprehensive Clinical Data Repository (CDR) and Patient Health Record (PHR).[1] [2]

Other requirements beyond the basics of clinical and insurance data collection include the requirements for data analysis supporting clinical research, possibly the creation and maintenance of patient clinical trial data and, most importantly—the sharing data among clinical and insurance partners specialized patient-specific data, analytical results and more general research and clinical treatment discoveries and observations useful to new disease and wellness program development.

[1] The CDR is a database repository of validated patient-specific information created by licensed providers that certify ("attest") to the accuracy and ownership of clinical data. The Personal Health Record is a database of non-provider, patient-created observation that have been entered by the patient or family.

[2] Combined with other clinical data, these data sources are the foundation of a Virtual Electronic Medical Record (vEMR).

Because of these functional and technical requirements, the IT infrastructure shared among partners for eHealthcare applications will be expensive to design and build, complex in operation and it will be geographically and functionally dispersed among many parties.

Computing platforms can literally range from cell phones or Apple iPhones and tablet computers[3] to very large datacenter servers holding the core databases and transaction processing systems, resulting in complex storage and computing systems that require 24-hour non-stop operation. In a typical eHealthcare network, thousands of patients and hundreds of administrative and clinical users at dozens of locations would be expected to simultaneously generate and consume substantial amounts of critical business process, clinical, financial and research data, some in real-time if medical devices are supported in the eHealthcare applications.

Finally, the data and image storage management and administration requirements in eHealthcare have become daunting. Multiple storage types—files, records, databases, images, documents, etc. must be supported. Multi-vendor operating systems must be supported. Multiple computing platforms must be integrated and managed. Disparate storage systems, including network attached (NAS), storage area network (SAN), and enterprise must be integrated. Data systems and structures from simple files to complex relational databases must be supported within these storage architectures, non-stop and in real-time.

This white paper will examine the complexity associated with multiple partner organizations and real-time healthcare application development support in eHealthcare and it will propose a business and clinical organizational model to support the justification and payment for the business processes, software and hardware supporting an integrated architecture for clinical treatment, application development and production in eHealthcare.

The focus will be on developing a model organization─The Center of Excellence─and the technology architecture required to support clinical services, Business Process Management (BPM) and enterprise-scale IT architectures that will operate the integrated complex of applications and services within the Center of Excellence─thus supporting the chain of clinical and financial value justifying eHealthcare.

An emphasis will be placed on the value of integration of clinical services and their data and how Web 2.0 software and telecommunications services can dramatically improve the management processes and reduce the complexity of systems integration in eHealthcare when Centers of Excellence are deployed. [4]

2.2 Methods of Funding eHealthcare

There are several methods for funding eHealthcare projects. Each has advantages and disadvantages but few could be considered "pre-funded," that is, the method has an inherent return on investment that is highly predicted to recover the substantial investments required for eHealthcare.

The traditional methods are:

1. Traditional research and development
2. Shared partnership(s) with business partners
3. Project Financing

2.2.1 Traditional R&D Funding

Most information technology projects are funded on a cost plus basis internally in an enterprise and amortized across all the entities in an organization. Occasionally in healthcare organizations, R&D projects must meet or exceed some "hurdle" value, that is, an estimated increase in productivity and/or efficiency of one or more internal or external processes or business functions or an internal rate of return on capital (IRR). For the non-profit, there is usually a requirement for cash flow that is at least break-even for a new technology, rarely there is a requirement for an internal rate of return.

2.2.2 Shared Partnership or Joint Venture

The Shared Partnership or Joint Venture business model assumes a shared capital investment by two or more business partners, for example, a hospital and one or more medical groups. This is

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[3] iPad for the office or home and iPhones for the patient or family members.
[4] Web 2.0 Internet services are defines as Internet web applications that depend on reliable, very high-speed telecommunications services, some in excess of 10 million bits per second for teleconferencing. Although no

usually done through a contract for services between the partners and an agreement to return capital as a result of the success of the R&D effort to the partnership to cover the development and operating costs of the eHealthcare project or to share the technology produced.

2.2.3 Project Financing

Project Financing can be a variation of a Shared Partnership wherein the partner participates in the development and financing of a project or Project Financing can be a self-contained project of a single organization. It has certain characteristics that distinguish it from traditional R&D and partnerships:

- It is project focused as opposed to technology focused and produces a product or service for sale
- Precise clinical and financial goals are defined and must be met
- The project is expected to recover its costs from meeting a financial metric
- The project may use external capital from the capital markets, e.g., debt or equity financing
- The project may generate "soft" returns, that is, the estimated value of intangible returns, but the total project financing costs must be returned by "hard," that is, actual capital in the form of debt repayment, surplus (for a non-profit) or profit for a for-profit.

2.2.4 The Procter and Gamble Example

P&G developed in the 1990s a series of integrated healthcare and case management programs using Project Financing to fund the reductions in healthcare expenditures expected by senior management and to initially reduce deaths and injury from Asthma, Diabetes, Behavioral Health and Occupational Health and Safety.

The base principles were to:

- Use formal engineering design and total quality management principles to build the programs
- Progressively build centers of excellence, each one building on the clinical and financial success of previous centers
- Use integrated group health, occupational health, workers' compensation and disability data to form a comprehensive "picture" of an employee and their family
- Globalize the solutions
- Use statistical and predictive methods to control clinical risk, current and future costs
- Use incremental design and funding to grow the programs

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solution proposed herein requires web 2.0 services *per se*, they are expected to evolve rapidly into web 2.0 service speeds as telecommunications companies deploy "3G" and "4G" mobile telecommunications up to 10 mbps.

By the end of the program, P&G had developed care and case management programs supporting 16 Centers of Excellence using the methods and practices of a "High Performance Organization" (HPO) outlined in Figure 2-1 and Center of Excellence processes in Figure 2-2.

Table 2-1 P&G Centers of Excellence

Program	*Description*
Amputations	**Amputations from Diabetes and occupational accidents**
Brain Injury	**Brain injury from occupational accidents**
AIDS	**Comprehensive AIDS treatment**
Burns	**Burns from all occupational sources**
Cancer	**Comprehensive Cancer Care**
High Risk Newborns	**High risk Neonatal care**
High Risk Pregnancy	**High risk pregnancy care**
Home Health Assessment	**Programs for risk assessment and home healthcare**
Low Birth-Rate / Ill infant	**High risk newborns**
Medical Case Management	**Integrated care and case management**
Psychiatric Care	**Psychiatric care to reduce hospital admissions, adverse drug events and suicides**
Transfer Procedures	**Patient transfer programs among medical treatment and disability facilities**
Transplants	**National transplant program**
Spinal Cord Injury	**Spinal cord injuries from medical and occupational events**
Stroke	**Avoidance and treatment of stroke**
Trauma	**Shock-Trauma care and standards combined with *Transfer Procedures***

The success of the entire P&G Center of Excellence program was determined by the initial success of the Behavioral Health program. To conserve costs for technology, the initial program was defined around the clinical and financial success of the Behavioral Health/Psychiatric Care program alongside the Medical Case Management program. The program was so successful that

it funded many of the following programs, and the greatest success both clinically and financially was the general healthcare Medical Case Management program among a dozen or so hospitals in the Cincinnati area and P&G.

2.2.4.1 Measures of Success and Metrics

The measures of success of the program and goals and objectives for the Behavioral Health program were:

- Avoid adverse drug events and hospitalizations
- Improve compliance for medications
- Avoid suicides and improve interventions
- Involve the patient and the family

By focusing on a project-oriented financing approach and ensuring that the first few Centers were at least self-sustaining, the master program was able to generate more than $10 million in capital for additional project financing and, most importantly, measurably improve outcomes and employee/family satisfaction.[5]

2.2.5 Getting Started With a Center of Excellence

The premise of this whitepaper is that the Center of Excellence is the appropriate method and means to enable eHealthcare solutions and certainly to begin the process of funding eHealthcare projects from the cash flow resulting from their success.

In the following section, we define the Center of Excellence, provide some additional recent examples of success and begin the process of defining the complex information systems architecture: processes, hardware and software required to support the design, development and operation of multiple Centers of Excellence; even those requiring real-time patient and device transaction processing and rule execution.

The eHealthcare information systems architecture and systems will evolve from the progression of measurable successes derived from the development of multiple Centers of Excellence—each adding capital, new motivation and increased sophistication and complexity to an integrated

[5] An external firm was used to develop a statistical methodology to measure employee satisfaction and measures of clinical and financial outcomes. All were statistically significant and practically meaningful.

eHealthcare information systems architecture that evolves over time through incremental design and development—while concomitantly avoiding risk of program and technology failure.

2.3 The Center of Excellence

2.3.1 Defining the Center of Excellence

What is a Center of Excellence?

A Center of Excellence is an organization with a culture of continuous quality improvement that creates and manages a healthcare program to simultaneously and continuously:

- Measurably improve the quality of care provided to patients
- Measurably reduce costs of care
- Measurably improve patient and provider of care satisfaction
- Preferably, also reduce the absolute count of procedures delivered
- Preferably, also reduce reported adverse events from diagnosis and treatment
- Continuously enhance the processes and procedures of the Center of Excellence to improve "speed to market" and productivity of each iteration of the Center of Excellence

The Center of Excellence uses clinical, financial and administrative information systems to accomplish these goals and objectives and implements a process involving the principles of Total Quality Management (TQM) and Continuous Quality Improvement (CQI).[6]

The Center of Excellence is a continuous engineering and scientific process that is *evidence-based* and driven by statistical measures of quality, safety, productivity, efficiency and emphasizes engineering discipline, teamwork, education and planning.

2.3.2 Successful Examples of Centers of Excellence

The concept of the Center of Excellence (CoE) outlined in Figure 2-1 was initially developed by Japanese manufacturers in the 1950s based on the core mathematics and methods created by Dr. W. Edwards Demming to support statistical quality control in manufacturing.[7]

The Center of Excellence is an organization that focuses on continuous quality improvement of well-defined goals and objectives that have measurable outcomes in the form of metrics that can

[6] American Society for Quality, Healthcare, http://asq.org/healthcaresixsigma/
[7] Dr. W. Edward Demming, http://en.wikipedia.org/wiki/W._Edwards_Deming

be measured and modified continuously. Note how the functions and processes in Figure 2-2 create a continuous cycle of design through improvement.

In the healthcare market, the CoE was pioneered by Kaiser Permanente in the HMO medical delivery model and by the University of Maryland in Shock Trauma.[8] [9]

2.3.2.1 *The State of Maryland Shock Trauma Program*

Dr. R Adams Cowley, M.D. pioneered the application of multi-specialty surgical, nursing and technology teams to trauma care and the use of what is now know as CQI in the development of the highly successful patient treatment programs for shock-trauma which began in the 1960s and evolved into a free-standing unit, the Maryland Institute for Emergency Medicine in the 1970s.

Computer centers at the University of Maryland were employed to develop predictive clinical and financial models of patient outcomes. Always clinically remarkable in terms of patient outcomes, effectively reversing the death rate from shock and trauma from 80% deaths in a 48 hour period after admission to 20%, the financial burden of the trauma cases on the University of Maryland led to a re-examination of the cost sharing of the *successful* outcomes and to the creation of the free-standing Maryland Institute for Emergency Medicine, an entity created outside the University to share the financial burden of success across the entire State of Maryland.

In effect, the University of Maryland—because the patients now lived as a result of the success of the program—could no longer afford the cost of care for the surviving patients. The University was placed by the very success of the program in an untenable financial situation, thus emphasizing the importance of always monitoring Centers of Excellence on three dimensions: administrative, financial and clinical.

Dr. Cowley is generally regarded as the "father" of modern inter-disciplinary surgical teams and shock/trauma in the civilian sector and, unknowingly at the time, one of the earliest innovators in TQM and CQI in healthcare.[9] [10]

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[8] Kaiser Permanente, http://xnet.kp.org/newscenter/aboutkp/historyofkp.html
[9] R Adams Cowley Shock Trauma Center, Research, http://www.umm.edu/shocktrauma/research/index.htm
[10] R Adams Cowley Shock Trauma Center, History, http://www.umm.edu/shocktrauma/about_us/history.htm

In the commercial sector, the self-insured corporation pioneered the CoE in manufacturing and business services.

Two recent small and moderate examples of a successful center of excellence are (1) Geisenger's program to reduce inpatient hospital care costs at its primary facilities for its insured patients and (2) a unique physician's program in New Jersey.

2.3.2.2 The Geisenger Program

The Geisenger program is an example of a successful inpatient Center of Excellence designed to avoid deaths from inpatient surgery. [11] [12] [13]

The Geisenger system serves more than 2.6 million residents throughout 42 counties in central and northeastern Pennsylvania. This novel program of hospital system redesign focuses on real-time outcomes improvement accomplished through a multidisciplinary team approach to dynamic risk stratification of every patient, coupled with real-time risk mitigation. By demonstrating that this program reduces hospital deaths and at the same time minimizing cost, the results contribute to a growing body of knowledge that says that higher healthcare spending does not correlate with higher quality of care.

The Geisenger study, published in the September 2010 issue of the *Annals of Surgery*, followed more than 100,000 patients prospectively over nine years in three hospital systems. Initially piloted and validated for post-surgical patients, the workflow redesign program was recently implemented across all hospitalized patients at one of Geisenger hospitals. Based on an 18%-25% reduction in hospital mortality observed consistently after implementation of this program in prior and current studies, Dr. Thanjavur S. Ravikumar, the Geisenger team leader and Director of Surgical Innovation estimates that it has the potential to save up to 95,000 lives a year if adopted nationally. While there will be a small incremental cost in staffing, this is

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[11] Ravikumar, T., et al., "A Validated Value-Based Model to Improve Hospital-Wide Perioperative Outcomes: Adaptability to Combined Medical/Surgical Inpatient Cohorts", *Annals of Surgery*, September 2010 - Volume 252 - Issue 3, pp 486-498, http://journals.lww.com/annalsofsurgery/pages/default.aspx

[12] http://journals.lww.com/annalsofsurgery/Abstract/2010/09000/A_Validated_Value_Based_Model_to_Improve.9.aspx

[13] http://www.perseidsoftware.com/documents.html,

overshadowed by financial savings in length of stay reduction, optimization of resource utilization and averting complications.

The program named descriptively "Continuum of Care," and led by co-author Cordelia Sharma, MD, involves redesigning the workflow and delivery of hospital-based care to maximize clinical effectiveness.

Similar to the "patient-centered advanced medical home" model, the program emphasizes timely comprehensive and coordinated care that is personalized to the patient's needs and makes use of Geisenger's advanced electronic clinical information system. "The components include patient assignment to risk 'cohorts,' unit-based team building, multidisciplinary team rounds structured for quality, actively managing risk-prone patients by acuity-stratified rounding (Hawk rounds) and safety net creation outside of the ICU's," notes Dr. Ravikumar.[14]

2.3.2.3 The Camden, New Jersey Program

The New Jersey program involved, initially, a single physician who believed that the poorest members of the Camden, New Jersey community deserved higher quality of care. [15] [16] [17]

Dr. Jeffrey Brenner did not know at the time he would go on to prove that providing every member of the community a higher quality of care would both reduce costs and also improve outcomes.

His program was based on the center of excellence policing concept that he learned about from the former New York City police commissioner, William Bratton, and the Compstat approach to policing that he had championed in the nineties, which centered on mapping crime and focusing resources on the hot spots. [18] In effect, the Compstat program is a center of excellence for public safety.

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[14] https://webapps.geisinger.org/ghsnews/articles/Geisingerstudyshowshospital6986.html
[15] Gawande, Atul, "Can we lower medical costs by giving the neediest patients better care?", Medical Report, *The New Yorker*, January 24, 2011
[16] http://www.newyorker.com/reporting/2011/01/24/110124fa_fact_gawande
[17] http://www.perseidsoftware.com/documents.html
[18] Weisburd, D. *et. al.,* "The Growth of Compstat in American Policing," *Police Foundation Reports*, April, 2004, http://www.policefoundation.org/pdf/growthofcompstat.pdf

He found that between January of 2002 and June of 2008 nine hundred people in only *two* buildings in Camden accounted for more than 4,000 hospital visits and about *two hundred million dollars* in health-care bills.

One patient had three hundred and twenty-four admissions in five years. The most expensive patient cost insurers $3.5 million. After the program was operational, The Camden Coalition has been able to measure its long-term effect on its first thirty-six super-users. They averaged sixty-two hospital and E.R. visits per month before joining the program and thirty-seven visits after—a 40% reduction. Their hospital bills averaged $1.2 million per month before and just over half a million after—a fifty-six-per-cent reduction.[11]

2.3.2.4 The Procter and Gamble Program

For a larger program, The Procter and Gamble Company (P&G) in the 2000s developed more than a dozen Centers of Excellence to improve the quality of care, costs and outcomes and employee satisfaction for about one million covered lives. For more than seven years at P&G, for example, healthcare costs remained stable, the number of procedures dropped each year and outcomes were measurably better and employee satisfaction improved each year.[19]

Most importantly at P&G, deaths from certain conditions, including asthma, diabetes and suicide were lower and significantly improved.[20]

[19] This was validated by Corporate Health Systems who was retained by P&G and which later became Ingenix. The program was operated by James M. Palmer (retired).
[20] This was validated by Corporate Health Systems who was retained by P&G and which later became Ingenix.

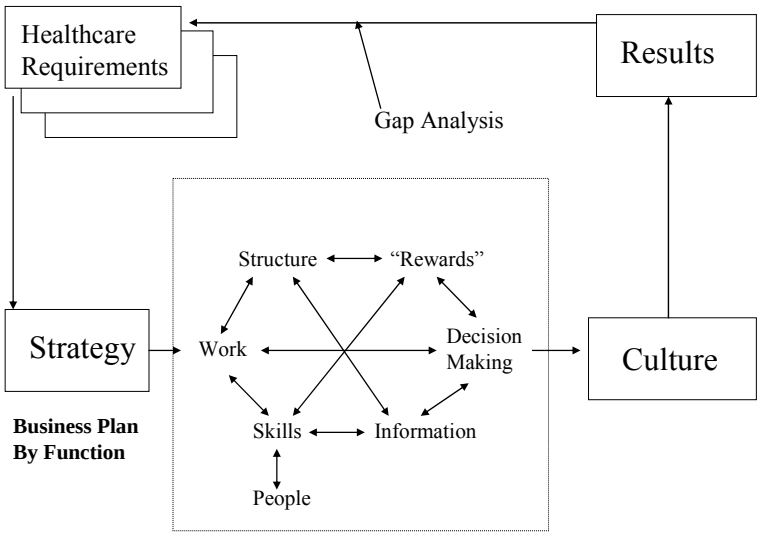

Figure 2-1 The Center of Excellence High Performance Organization[21]

2.3.3 Principles of the Center of Excellence

The CoE is characterized by a set of interlocking and cooperating business processes and attitudes that drive the continuous quality improvement processes in a High Performance Organization (HPO) as shown in Figure 2-1.[21]

The Center of Excellence has:

- A Mission
- A culture and a high performance organization to implement that culture
- A set of requirements to define and meet
- Specific goals and objectives to meet
- Methods and business processes defined for success
- A definition of success and failure
- Metrics for measuring success
- Feedback processes to acquire new knowledge of requirements and processes
- Continuous quality improvement processes for rapid improvement of service delivery processes
- A dedicated team of members
- A Champion within the host organization

[21] Courtesy of Mr. James M. Palmer, The Procter and Gamble Company (retired)

2.3.4 Functions of the Successful Center of Excellence

To design, test, deploy and manage a center of excellence; data and clinical, financial and administrative processes must be integrated, managed and deployed to serve multiple simultaneous purposes.

To manage in real-time requires the integration of a wide variety of complex enterprise, personal, occupational and family information:

- Validation — Strategic planning data on the goals, objectives and requirements for success
- Administrative — Healthcare claims, membership, diagnostic and treatment data
- Financial — All encounter information and utilization and benefit information
- Research — Cohort (group) studies of what is working and why and what is not
- Clinical — Dictionary, CDR/PHR,[22] side effect, outcomes and services and orders
- Biological — Proteomic, genomic and other biological and chemical information on patients
- Mobile — Information on clinical device and remote observation data from facilities and homes
- Service — Medical and insurance services for patients and programs for providers and members
- Metadata — Information about what is contained in the these databases

Figure 2-2 defines the continuous quality improvement processes within the CoE for eHealthcare.

The High Performance Organization creates, defines and operates the CoE. An enterprise "Champion" guides the CoE through the organizational politics and conflict resolution─creating a path for success of the CoE in the enterprise and also ensuring that the senior management is in support of the CoE.

Goals and objectives are defined for the CoE and these generate a set of requirements for clinical, administrative, systems and financial success and also define metrics for continuous measurement and improvement.

In cooperation with the CoE partners and patients, the CoE executes clinical and financial programs using services to deliver treatments and diagnoses to improve one or more measurable states of health and care in one or more patient cohorts or "watch groups."

[22] Clinical Data Repository/Personal Health Record.

A CoE may or may not execute a formal clinical trial, but essentially, the processes of the CoE mimic a clinical trial in that metrics must be defined, measured and compared against some baseline behavior or set of metrics to determine success or failure of *each* continuous improvement cycle of the CoE.

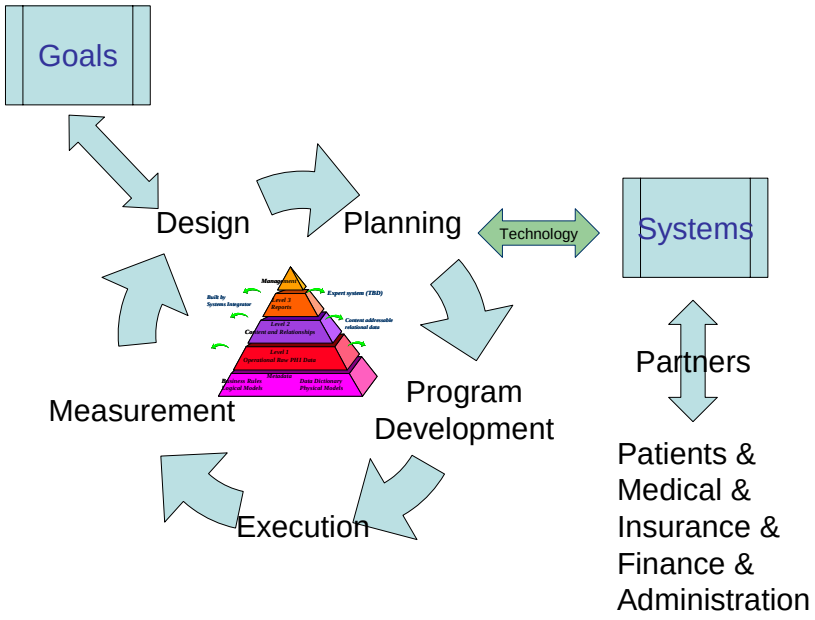

Figure 2-2 The Continuous Quality Improvement Process

The continuous quality improvement process executed by the high performance organization within the Center of Excellence is just that, it is a continuous process, not an event.

Thus, the Center of Excellence implements a cycle of continuous quality improvement in steps:

- Define the partners of the Center of Excellence
- Fund the prototype CoE and establish the return on investment criteria
- Establishing clinical, financial and administrative goals for the center
- Designing the operational goals, objectives and requirements
- Planning the operational task and building the patient cohorts and staff
- Developing the clinical program and financial and clinical metrics for success
- Executing the clinical program with the diagnostic and treatment program
- Measuring patient outcomes, clinical, administrative and financial metrics
- Establishing lessons learned and then continuing the improvement process

At the core of the Center of Excellence process and systems are integrated health and insurance databases supporting the information management needs of the CoE. We will discuss the integrated information systems required to support the CoE in the next section.

3 Information Management in eHealthcare

The Center of Excellence, once commissioned, must support its success through validation of its core metrics for success and return sufficient capital to justify its continued use and growth, preferably into additional means and methods for excellence and new programs for care. Most of the funds allocated to the CoE are going to be spent defining and building the technology in support of the CoE and in training of the staff, participating patients and their family and partner organizations.

eHealthcare is a useful pseudonym for the technology and new business, medical and clinical processes in support of the Center of Excellence because timely development of the CoE and speed to market are determined by the flexibility and comprehensiveness of the underlying technology of the CoE.

Note that eHealthcare technology supports the Center of Excellence; the Center of Excellence does not support eHealthcare. The distinction is important because most information systems that fail, and many do, fail because they lack clear purpose and well defined requirements. The formation of the Center of Excellence provides, *a priori*, the reason and the mission for any deployed eHealthcare technology and it can not operate without clearly defined requirements.

Sequencing the strategy and tactics, so that technology follows need ensures a secure intellectual foundation for the Center of Excellence and also provides concrete justification for the expense of the associated eHealthcare technology.

3.1 Information Model for the eHealthcare and the Center of Excellence

At the core of any eHealthcare architecture are the information models for healthcare and insurance lines of business to be supported and the fully integrated databases underlying the eHealthcare applications including each Center of Excellence. It is unclear how the creation of a Center of Excellence beyond the trivial is possible without centralized integrated databases and information systems as noted by PricewaterhouseCoopers in two research articles on employer healthcare program needs and mobile healthcare business models supporting eHealthcare.[23] [24]

3.1.1 Core Information Model

The central information model supporting the Center of Excellence is composed of a set of entities with relationships and other core data and metadata, examples are:

- Requirements, Goals and Objectives
- Uniquely identified persons
- Persons who are providers of care
- Facilities
- Transactions
  - Claims
  - Encounters
  - Diagnostic
  - Treatment
  - CDR/PHR data
- Metrics
- Patient and Facility classifications
- Research data
- Summarizations
- Documents and Images and Media
- Any other uniquely defined entity in insurance, disability, occupational health, safety and worker's compensation

Figure 3-1 describes the logical data pyramid (model) for the integration of information across the value chain of the eHealthcare enterprise that is based on a uniform set of integrated databases and one that encourages the definition and sharing of data within the enterprise and among partners and patients. This model also supports each Center of Excellence and aggregates

[23] PwC, "Healthcare unwired: New business models delivering care anywhere," 2010, http://www.pwc.com/us/en/health-industries/publications/healthcare-unwired.jhtml
[24] PwC, "What employers want from health insurers – now", 2010

into an enterprise information system, thus creating a central information foundation for a centralized Enterprise Resource Planning (ERP) system to support all present and future centers of excellence.

3.1.2 Core Data Model

Two views of data are articulated in Figure 3-1 with sources of data on the left hand side of the pyramid and the technology to deploy the uses and data on the right.

The tiers of data are divided into progressively summarized data, from raw to highly summarized, from these sources:

- **Biological and Clinical** — The data and information supporting the definition of clinical services, treatments and variables (attributes) associated with direct patient care
- **Administrative and Financial** — The data and information supporting the processes of approval, scheduling, treatment, payment, patient surveillance and program validation through total quality management.

3.2 An Integrated View of Information in eHealthcare

Each step in building the value chain in eHealthcare, from conception through return on investment, *requires* integration. Rapid application development of new solutions and applications is about having the right information at the right time for the right person in the development and production processes. One of the past difficulties in deploying Centers of Excellence has been the inability to integrate all lines of insurance business and clinical information into a common architecture for rapid deployment and use. This causes the CoE CQI "wheel of processes" in Figure 2-2 to cycle so slowly the CoE is ineffective or simply runs out of time to produce a meaningful financial or clinical return on investment. On the other hand, the integrated architecture enables and executes speed to market and thus creates an opportunity for timely success.

Moreover, it is imperative that the core foundation software functions of the eHealthcare enterprise have extensive security, audit and control software available to apply to any entity in

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http://www.pwc.com/us/en/healthcare/publications/what-employers-want-from-health-insurers-now.jhtml

the integrated databases. Thus, many partners can share, *selectively*, data. Treatment partners need access to internal systems of the insurance company. Research partners may need to use current and past clinical data. Regulators may need access to a variety of clinical and financial data in a confidential manner for an extended period of time and in multiple facilities.

The need for "selective transparency"[25] of information systems first proposed by W. Roy Dunbar, CIO of Eli Lilly drives the need for integration of systems and data. Selective transparency allows an employee, research partner, provider, insurer, patient or regulator, or any authorized entity or person access to aggregate data or the ability to execute a transaction, program or report—based on role and security, access and control criteria.

The key to selective transparency is having:

1. An integrated information systems architecture that allows for and encourages real-time access to real-time information and raw data.
2. Secure, timely and selected access to integrated data that can be controlled by business processes
3. The ability to access data and processes anywhere, anytime
4. The ability to introduce software to control business process management and improve workflow and to reduce the costs associated with business process execution
5. Simple and effective enterprise application interfaces to enable application integration
6. The ability to see audit trials of use at all times

Integrated and shared security architectures facilitate business and operational integration within the Centers of Excellence by encouraging employees, patients, providers, research partners and others to quickly register, store and share data. When in place, this architecture facilitates sharing data with patients and clinical and administrative partners who are outside the literal boundaries of the clinical facilities, thus creating the virtual eHealthcare enterprise.

Given that eHealthcare applications are going to become widely dispersed geographically as patients and providers constantly move and research may be a national or even a global exercise, the need for fully integrating and registering data and sharing it effectively is profound—both in terms of costs and managerial value.

[25] Mark D. Euhling, "The Pharma Prophets", Bio-IT World, April 7, 2002. http://www.bio-itworld.com/archive/040702/boston_it_pharma.html

In fact, one could argue that the Center of Excellence in the communications environment of the post 20th century can not function effectively with so many parties constantly on the move without full data integration and 7x24 access to critical administrative and clinical data.[26]

3.2.1 Logical Data Model for eHealthcare

Having said this, the Center of Excellence does not require *at first* real-time healthcare data in most circumstances to start the CoE, unless the CoE supports aggressive home healthcare applications that involve data acquisition from real-time devices like pulse oximeters and oxygen concentration devices or direct patient entry of clinical attributes.[27] But, it is preferred that the core information systems support real-time data acquisition and that they also support high-volume secure and audited transaction processing such as we would expect from a financial services company.

As an example, The Cochrane Institute reports a significant reduction in the illness burden, deaths and costs of care for anti-coagulation treatment by patients in their own homes, showing that even relatively complex medical procedures can be done safely and effectively in the eHealthcare realm of home healthcare.[28]

In Figure 3-1 data is "denser" and more detailed in the lower tiers of raw data and as the information flows "upward" in the pyramid of functions and data, it is more and more highly aggregated and summarized. By design, a complex Center of Excellence would have real-time patient and claims data flowing into the "bottom" of the system and less data intensive, but computationally more complex executive "dashboards" at the top of the model.

A practical example of this information model would be a Center of Excellence for asthma or behavioral health to reduce hospital admissions and E.R. visits. Requirements would exist for mobile and home healthcare data acquisition of clinical attributes and remote patient access with

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[26] *ibid*, PwC [23]
[27] Harvard Sensor Labs CodeBlue Network, http://fiji.eecs.harvard.edu/CodeBlue
[28] Garcia-Alamino JM,, *et. al.*, "Self-monitoring and self-management of oral anticoagulation (Review)," *Cochrane Database of Systematic Reviews*, 2010, http://www.cochranejournalclub.com/self-monitoring-and-self-management-oral-anticoagulation-clinical/pdf/CD003839_full.pdf

associated clinical rules and analytics to create and manage cohorts of low, medium and high risk patients.

The goals and objectives would define requirements such as:

- Avoidance of death and disability
- Reduction in hospital and emergency room admissions
- Reductions in adverse events
- Reductions in absolute numbers of procedures
- Reductions in costs of care
- Increases in patient and family satisfactions and
- Increases in metrics related to quality of care.

To get aggressive control of adverse events and avoid hospitalizations one can imagine the importance of reaching out to the patient in all aspects of the patient's life though mobile health protocols and technology that when coupled with clinical and financial rules, guide the patient and the patient's care manager(s) through a variety of episodes of care maximizing the results of clinical and financial metrics for success.

3.2.2 Information Systems Architecture

The dual "stacks" of enterprise information in Figure 3-3 provide a comparative view of the critical management functions and the security, access and control foundation of an eHealthcare information system for the Center of Excellence. These functions include the financial, administrative, clinical and validation processes associated with developing a Center of Excellence and its eHealthcare applications: the operational and research data required once the CoE "product" enters the target patient population.

Note that the foundation architecture for selective transparency is implemented as a core systems integration function. Data is registered by form and type (as metadata) and then security, access and control constraints are applied to the data to register its presence in the enterprise and to provide selective access to interested and approved parties. A key aspect of effective registration and distribution is to register a data asset (for example, a person) only *once* as a unique resource. This is a primary requirement of the software architecture. The software architecture of the Center of Excellence should avoid the proliferation of multiple versions of records, files and

databases which is a classic means of destroying effective data integration in an enterprise as shown in Figure 3-2.

The premier goal and requirement of the core systems architecture is avoidance of loss of control of clinical and financial data and associated audit trails. All insurers and most providers have comprehensive social and legal requirements equivalent to large corporate enterprises designed to ensure that data only reaches authorized parties and applications. Each application and transaction in an application must implement the appropriate audit chain of control of all clinical and financial data entered and presented, particularly when mobile healthcare applications are deployed over the Internet. A simple example would be the ability to secure each mobile device and user by TCP/IP address to minimize the possibility of inappropriate access to the CoE information systems and databases.

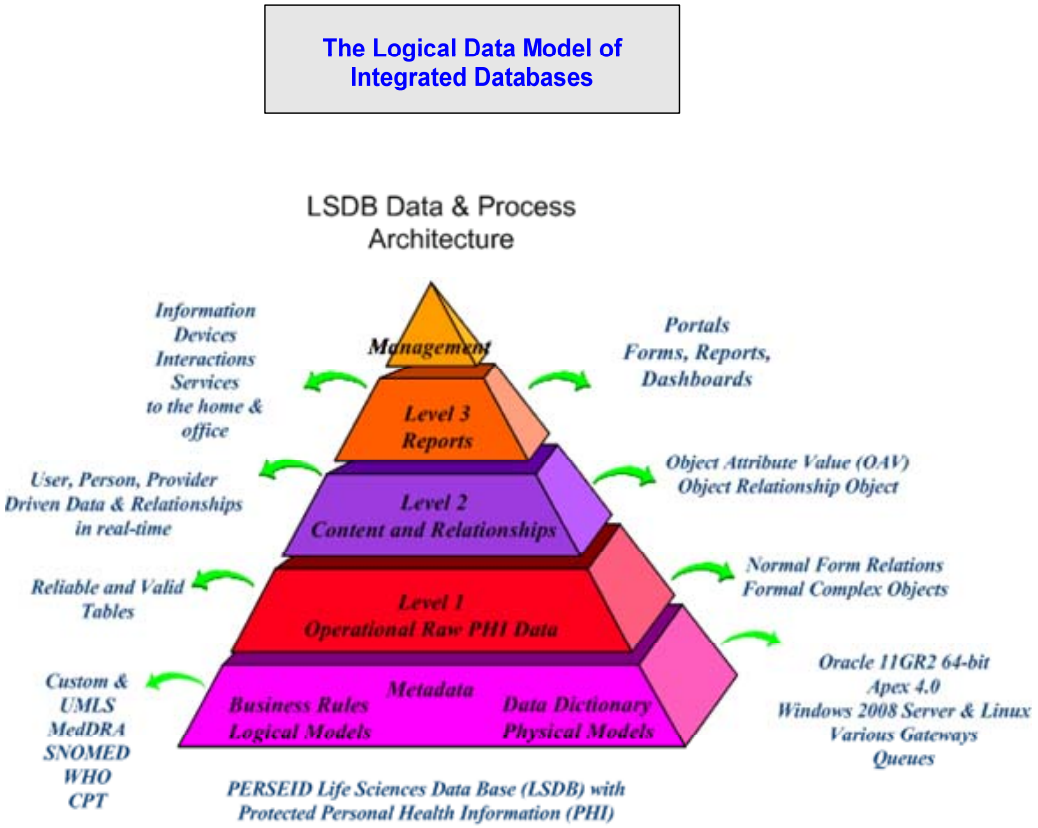

Figure 3-1 eHealthcare Enterprises Generate Tiers of Complex Data

The metadata at tier one of Figure 3-1 identifies who has access to data and the circumstances and means by which the data may be accessed and viewed, preferably to the level of a person at a place and time. Thus, access and use of the higher levels of data become a process controlled at each level of the information model by appropriate security, access and control needs of users and software, particularly real-time mobile software. An example would be control of each data element and clinical attribute in the clinical repository related to personal genetic data.[29]

The foundation of the data integration architecture is one based on security, access, control and metadata resources that facilitate the overall enterprise systems integration processes. New systems and data are registered in the enterprise and data access is provided through controls that allow departments, partners and others selective access to the data depending on their validated needs and rights. Data is secured, integrated and available for re-use at all times in a single *logical* repository.

Thus, data integration encourages Internet-based systems and application integration. The complexity arises from the fact that the data is made mobile through the use of home computers, tablets and cell phones. This requires that a full audit trail of access and use be maintained and that security, access and control rules operate on a 7x24 basis.

It is extremely unlikely that traditional line of business and departmental applications in most insurers and providers can support such an integrated set of requirements.

3.3 Traditional Computer and Data Architectures Lack Integration

Figure 3-2 highlights the "traditional" systems architecture of healthcare and insurance information systems. The lines of business are not integrated and each tends towards duplication of data and systems resources. Each information system utilizes its own processing resources and storage architecture. The duplication of the resources is expensive and encourages a lack of data and rule integration in the enterprise and poor shared security, access and control processes. An example would be a lack of integration of group and personal health, worker's compensation,

employee-assistance, occupational health and reinsurance data on a group or person—to say nothing about the usual lack of integration of clinical and financial data beyond claims.

In the traditional enterprise systems model, business process management is performed by individuals, not software. Communications among applications is accomplished through database extracts and transfers and "hard-coded" custom protocols among applications programming interfaces (APIs). On average this model involves expenses for simple application or module integration of between $60,000 and $1,000,000 *per* interface.[30] [31] The resulting enterprise application and systems integration methods are complex, unique to the enterprise and very expensive to manage, and validate.

It is easy to see how unlikely it is that traditional information systems architectures can evolve into supporting Internet based real-time foundations for eHealthcare and any Center of Excellence requiring mobile- or patient-centered care requiring a response time less than the cycle time of claims processing.

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[29] Control over viewing individual clinical, administrative and financial attributes of a patient by a user based on the user's access rights and roles.

[30] John Hagel III, "Edging into Web Services", *McKinsey Quarterly*, 2002, Number 4, Technology http://www.mckinseyquarterly.com/article_abstract.asp?ar=1245&L2=21&L3=37&srid=21&gp=1

[31] These expenses are larger than those in the article to account for validation and verification expenses in the life sciences.

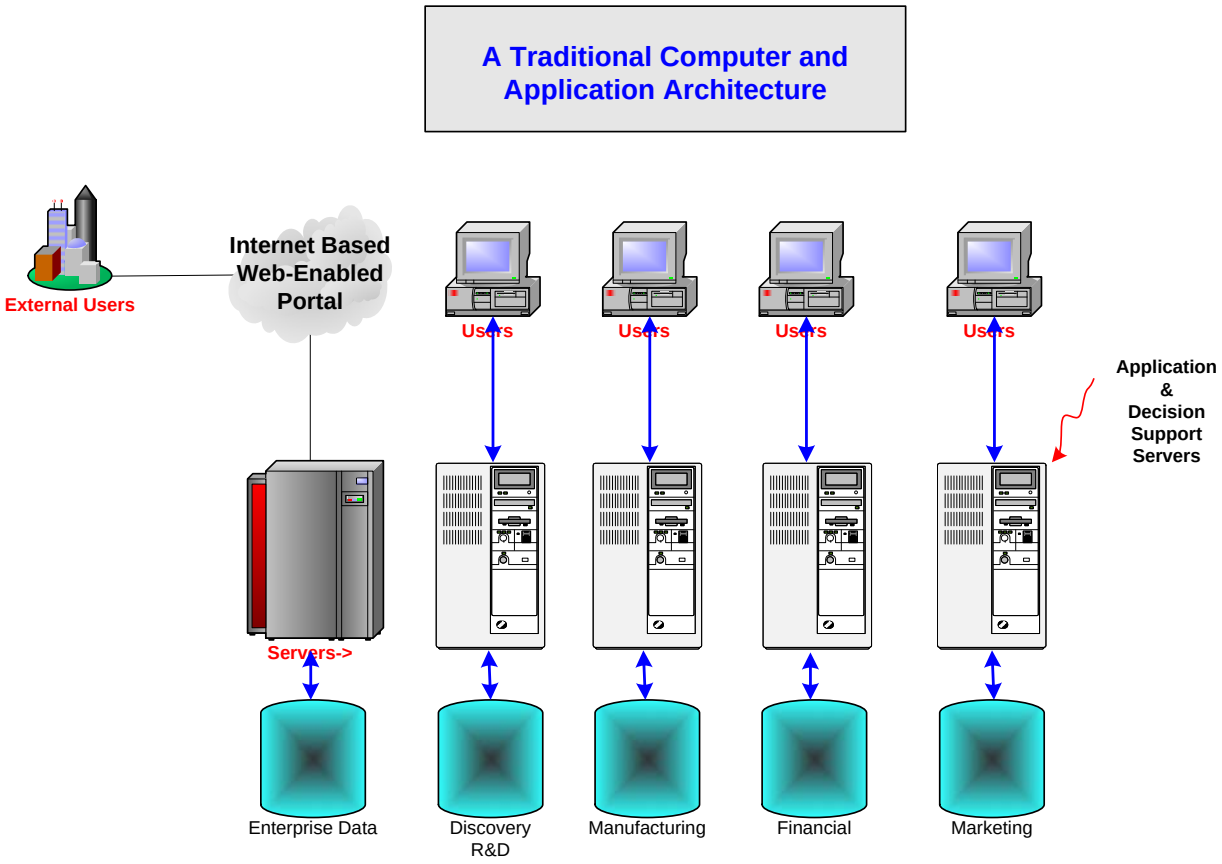

Figure 3-2 A Traditional Architecture Lacking Integration

3.3.1 Moving Towards a Center of Excellence Systems Model

Figure 3-3 presents an evolving view of systems and data integration, focusing on using integrated central databases of administrative, financial, research, clinical data and documents/media. The data and documents are stored *uniquely and once* to support a uniform view of the eHealthcare enterprise and the product development processes supporting each Center of Excellence from a uniform "data space" of information.

Computer-aided design and requirements information are included in the core databases to enable the rapid application development required for contiguous quality improvement and total quality management and to aid in managing the rapid cycles of improvement required to enable the CoE.

Remembering that our primary operational goal in the Center of Excellence is to "spin" the quality control "wheel" in Figure 2-2 as often as possible, we note that this is much more effective and timely when the information is integrated, merged, validated, secure and available at all times.

Each continuous quality improvement cycle generates another round of results, new discoveries, improved quality, reduced costs and improved patient care and satisfaction; so rapid application development and deployment improving the "speed to market" is a central goal and objective of the eHealthcare information systems architecture.

Clinical research can be conducted at the population level and tracked over a period of years. Integrated clinical, biological, financial, regulatory and efficacy documentation and data are each shared in real-time with external partners.

Because of the substantial size of the central repositories, the databases in Figure 3-3 may be implemented as multiple physical databases.[32] This data architecture makes it easier to reliably merge clinical, financial, administrative and patient/family data into accurate reporting systems in the Center of Excellence.

What is needed to support this form of real-time enterprise information management is the integration of the data into repositories, using shared "metadata."[33] [34] This improves data integration, removes redundancy and encourages regulatory and partnership data sharing.

However, because the business processes are still uncoupled from the software processes, these complex database-driven applications are still managed by people using traditional project management systems and documentation.

The Center of Excellence needs more robust integration of goals, objectives, requirements and precise specifications to precisely define how the Center will be created and operate. The

[32] The core databases of the Perseid Life Sciences product, for example, include 125 Oracle tablespaces (databases) fully integrated into one logical data model.
[33] Bernard P. Wess, Jr., "Enabling the Real-Time Life Sciences Enterprise with an IT Infrastructure," EMC White Paper, Perseid Software, February 2002.
http://www.emc.com/vertical/pdfs/life_sciences/interstitial_data_warehouse.jsp

preferred functional integration supporting the Center of Excellence metadata and processes are shown in Figure 3-3.

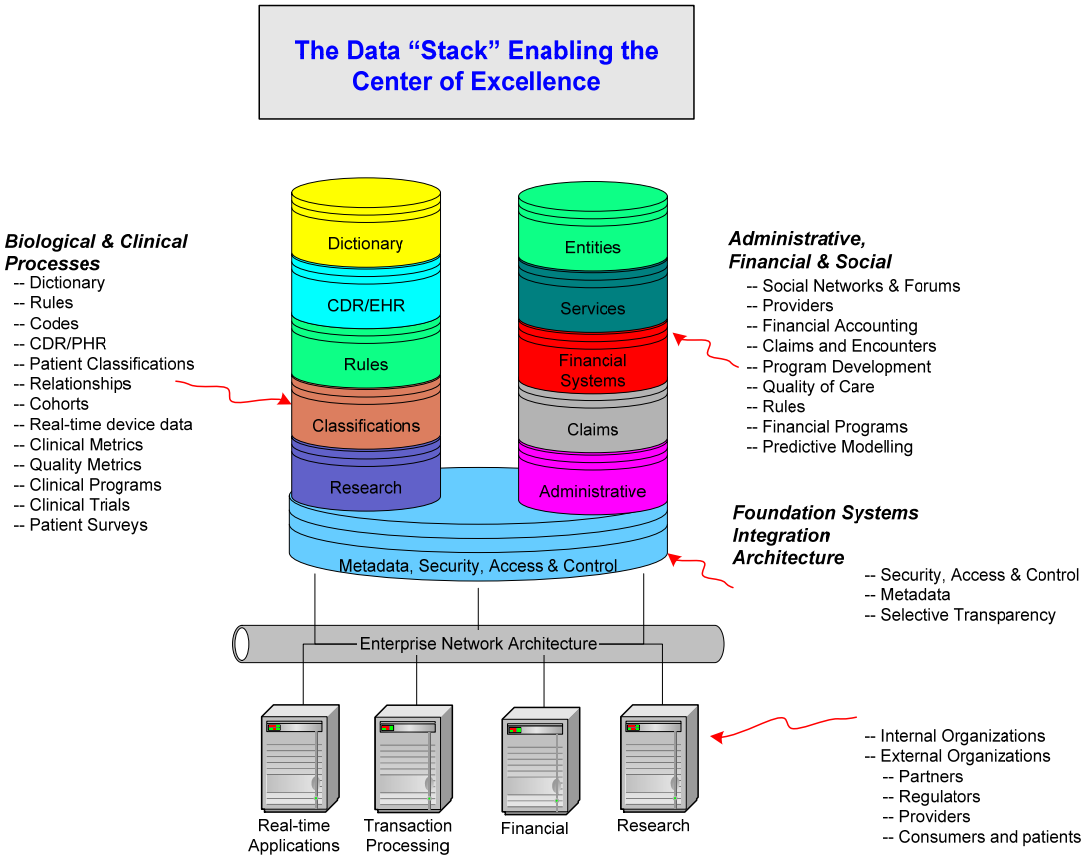

Figure 3-3 An Integrated Database and Process Architecture

[34] "Metadata" is information in the data systems that identifies the contents of the data itself—its fields, tables, reliability and validity, for example.

3.4 A Model for Web 2.0 eHealthcare Systems

Internet (web-) 2.0 applications and systems integration are based on the ability of Internet-enabled applications to exchange in real-time messages using web software services that register applications, software services, security, access and control information as enterprise data in various directories available in a secure manner within the enterprise.

These applications operate now at high-speeds, even to the patient, typically in excess of 1.5 million bits per second (mbps) and connect to servers that are housed in very-large secure data centers and are now offered to eHealthcare customers as information processing commodities, termed cloud computing. [35] [36]

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[35] 1.5 Mbps is the standard T1 communications carrier speed for leased lines, some vendors offer speeds of 4mbps for $50/month to a person.

[36] Cloud Computing is the 21st century reincarnation of time-sharing from the 1970s using the Internet to provide shared access to applications that are Internet-enabled and hosted in large data centers under the operation of a contracted IT services vendor.

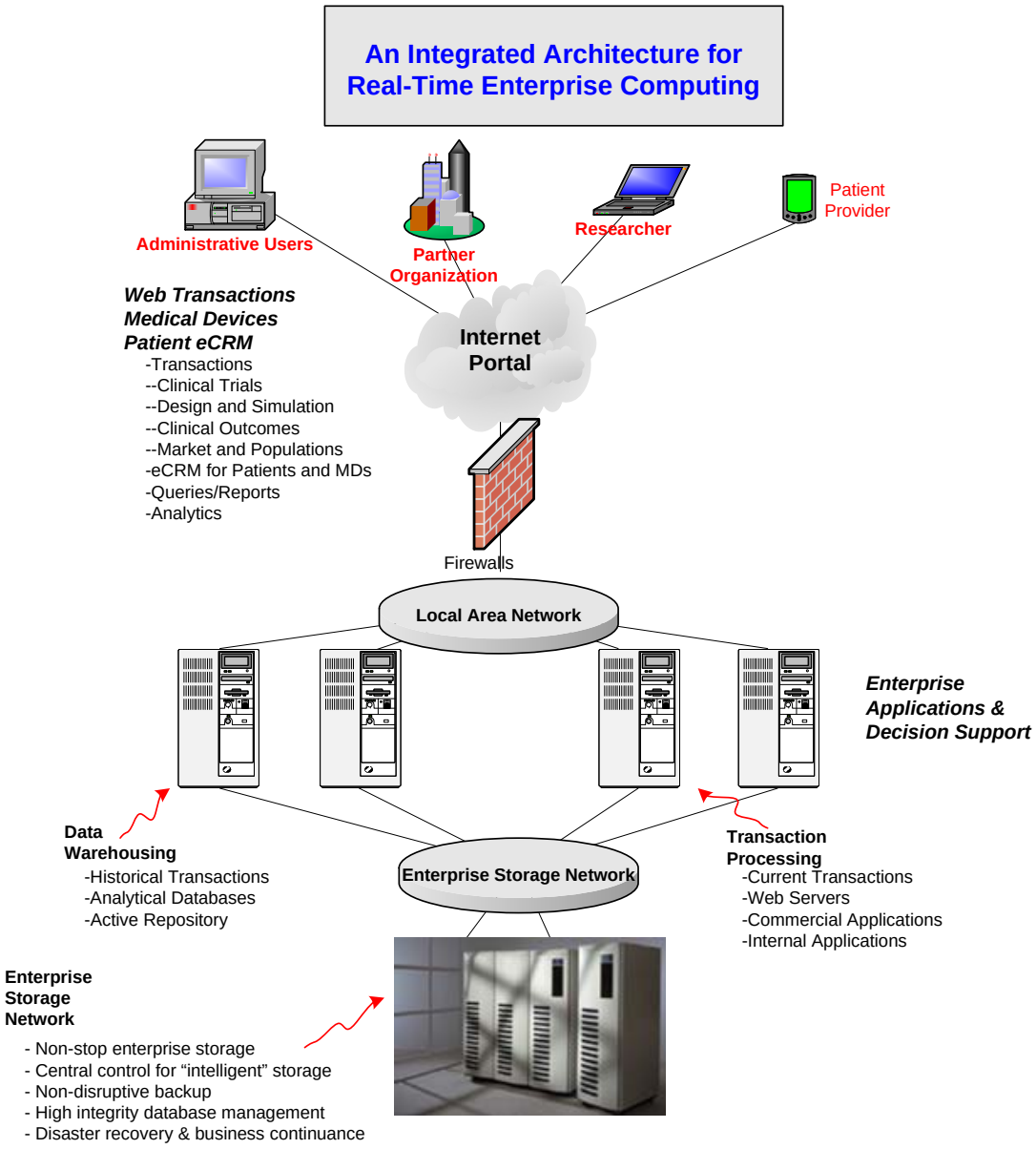

Figure 3-4 A Model Architecture for Integration of Applications in the eHealthcare Enterprise

The final state of a cloud- and Web 2.0-based enterprise network in support of multiple Center of Excellence and eHealthcare is shown in Figure 3-4.

Simple Browser accessed forms and reports, transaction processing, real-time rule engines, applications, analytics, persistent data objects (images, documents) and databases of summary data are divided among production transaction processing and business intelligence servers and

physical databases and most importantly, Center of Excellence departments, external agents, providers, patients and partners.

New data or requests for data arrive from transaction processing systems or web service requests—from patients, providers, partners, research organizations, software "agents" or other systems.

The systems integration architecture is responsible for ensuring that local applications and databases can transfer data to the central enterprise storage network (ESN) in the "cloud" for registration and integration. Using enterprise-level security, access and control solutions merged Centers of Excellence data is integrated in multiple enterprise-scale physical databases into a logical cloud-based server network. This ensures that the data is registered, secured and validated so that it can be accessed by all authorized local and global users through the Web 2.0 cloud architecture. It enables effective regulated data exchange in a secure manner with dramatic reduction in systems integration costs and creates the ability to rapidly design and deploy additional Centers of Excellence through the web-based cloud architecture.

4 Conclusion

The rapid growth in the need for evidence-based healthcare provides a philosophical justification for eHealthcare applications. The financial justification for the investment in eHealthcare is another matter.

To clinically and financially justify eHealthcare one needs a repeatable process and a stable organization to develop the many applications and solutions required to support the substantial economic investment required.

The Center of Excellence provides both an effective organizational model and also defines a clear method for obtaining predictable return on investment─the continuous quality improvement process.

Many healthcare enterprise planning and operational systems possess inherent difficulties in data integration and make rapid return on investment difficult.

Some eHealthcare R&D and production business processes such as clinical trials take years. Moreover, there is a need for security, access and control systems to be implemented across the entire regulatory, contractual and organizational "chains of command" to facilitate sharing the right data with the right party under the right circumstances and at the right time.

Using web services to execute, monitor and manage application, operating and financial systems in eHealthcare, we have developed a model organizational solution and the associated systems integration architecture that integrates business and clinical processes, disparate data and databases and operating platforms into an Enterprise Resource Planning (ERP) architecture. This ERP architecture for healthcare is secure and it enables the design, development and deployment of multiple Centers of Excellence to recover the substantial costs of eHealthcare deployment.

The Center of Excellence can be a standard for designing, creating, managing and effectively sharing eHealthcare applications and their financial risk within the healthcare industry.

Well formed and integrated eHealthcare ERP systems, based on Internet web 2.0 cloud architectures and web services will reduce costs and improve the discovery, development, marketing and production in the pharmaceutical and healthcare markets of new Centers of Excellence by dramatically reducing systems integration and healthcare disease and illness management program development risks.

For more than 1,000 years the construction industry has used *architecture* and *standardized components* to facilitate construction. Given the clinical and economic risks associated with eHealthcare, no less should be done among eHealthcare enterprises, their partners, regulatory agencies and healthcare providers.

The behavioral and technology tools exist, some have been presented in this whitepaper, but the will to use them must also be present.

5 About Perseid Software

Perseid Software is engaged in the design and development of the Life Science Universe™ an ERP healthcare and insurance software product for designing, building and operating clinical, administrative and financial applications.

It is written entirely in Enterprise Oracle 11G using APEX 4.0 and PL/SQL and designed for large-scale enterprise resource planning and development (ERP) applications in healthcare, insurance and the pharmaceutical industry.

Its applications include computer-aided design and engineering tools for design and development; core applications to implement mobile and home healthcare solutions; real-time clinical information systems; Centers of Excellence in insurance, healthcare, disability, occupational health and reinsurance; case and care management; research in healthcare and clinical trials and post-market surveillance in the pharmaceutical industry.

The Life Sciences Universe integrates more than 125 core databases into a single logical information system platform and provides a number of pre-packaged clinical and insurance applications for creating "off-the-shelf" Centers of Excellence. The product includes predictive modeling and rule engines for supporting the design and use of financial and clinical metrics in healthcare and insurance.

For more than 40 years, the principals of Perseid Software have been engaged in the development of mission-critical information systems and in the analysis of healthcare, disability and pharmaceutical data. Perseid's clients include or have included some of the largest and most progressive computer, healthcare and manufacturing companies in the world.

Bernie Wess has more than 35 years of experience in strategy, business development, healthcare, clinical medicine, regulated information systems, applied statistics, and commercial product development, insurance and clinical/bio-informatics. His expertise is focused on the development of state-of-the-art healthcare enterprises based on innovative financial and technical architectures. These businesses are based on the integration of clinical, financial and technology

solutions in insurance and healthcare. His clients or partners have included several governments or agencies, Lilly, PwC, Northrop Grumman Healthcare, Wellpoint Health Networks, ACS Healthcare, EMC Life Sciences, Ford Motor Company, various Blue Cross/Blue Shields, EDS Healthcare, The Procter & Gamble Company, Lotus Development Corporation, Tufts Health Plans and other life science and technology firms.

He has substantial R&D expertise having participated in patent, solution, product and enterprise development for or with UOM Shock Trauma, Sperry Rand (Univac), IBM, Lotus (IBM), MIT, Tufts Health Plans, TRW and Harvard University. He has been a founder in ProtonCare, Perseid Software Inc., InfoMedtrics, Information Architects, Grand Alliance Insurance and Mentor Communications. He is a new technology judge in the Life Sciences for the CHI Bio-IT World Conference.

For more information contact the company or access the website below:

Bernard P. Wess, Jr., President
Perseid Software Limited
Needham, MA
Direct Dial:+1(617)517-6314
bwess@perseidsoftware.com
www.perseidsoftware.com