

**From Bench to Bedside:
What is the Role of Information Technology
in this Transition?**

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From Bench to Bedside: What is the Role of Information Technology in this Transition?



- Trends in clinical care and in research are bringing the “bench” closer to the “bedside”;
- Information technology investments supporting research and clinical care have important differences;
- Information technology has clear challenges in facilitating the transition of results from the “bench” to the “bedside”;

Are we ready?????

Three trends in clinical care are bringing the “bench” and the “bedside” closer together.



- Evidence-based Medicine
- Protocol-driven Medicine
- Personalized Medicine

Evidence-based Medicine (EBM)¹ brings new focus to how medicine is practiced.



- EBM focuses on the "conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine requires the integration of individual clinical expertise with the best available external clinical evidence from systematic research and our patient's unique values and circumstances".²
- The process that underlies evidence-based medicine:
 - Develop a focused clinical question concerning the patient's problem(s);
 - Search secondary databases and the primary literature for relevant articles;
 - Assess the validity and usefulness of those articles;
 - Judge the relevance to the individual patient;
 - Implement the findings in patient care.
- Familiarity with the precepts and tools available for practicing evidence-based medical care makes it possible to bring an enormous literature under control, and, as databases improve, to answer clinical questions at the point of care in real time.³

¹ From Evidence Based Medicine Resource Center at <http://www.ebmny.org/> , accessed October 10, 2004

² From Glossary section of Evidence Based Medicine Resource Center at <http://www.ebmny.org/> , accessed October 10, 2004
[emphasis added]

³ From Evidence Based Medicine Resource Center at <http://www.ebmny.org/> , accessed October 10, 2004

Protocol-driven Medicine builds bridges between research and clinical practice.



- Historically, protocols have been one of the most important mechanisms to bring the results of research to the bedside;
- Participating in a clinical trial on a disease-specific protocol has become much more acceptable to patients;
- Clinical trials are currently the only legal basis for the FDA to conclude that a new drug has shown “substantial evidence of effectiveness, as well as relative safety in terms of the risk-to-benefit ratio for the disease that is to be treated.”¹
- Challenges:
 - Keeping protocols up to date
 - Efficiently communicating findings on best practices
 - Finding patients appropriate for specific protocols
- "Many see the development of protocol-based medicine as the essential cultural change in clinical practice that will permit the design of truly useful clinical information systems."²

¹ Testing Drugs in People, <http://www.fda.gov/fdac/special/newdrug/testing.html>, accessed on October 10, 2004.

² Coiera, Enrico, *Guide to Medical Informatics, the Internet and Telemedicine* (Chapman & Hall, May 1997).

- **Basic Challenge:** providing the right treatment in the right format to the right individual at the right time;
- **Extension of historical clinical data to include:**
 - Genotypic data;
 - Medical images;
 - Environmental data;
 - Genetic profiles;
 - Molecular and genetic research efforts;
 - Targeted pharmaceuticals
- **Personalized Medicine may also lead to fundamental changes in the “historical pharma economic model”:**
 - “blockbuster” drug model may not be sustainable;
 - If personalized medicine leads to personalized diagnoses and personalized treatment, what are the economics behind this approach?

What do Evidence-based Medicine, Protocols and Personalized Medicine have in common?

- Evidence-based Medicine focuses on how medicine is practiced;
- Protocol-driven Medicine describes a methodology for advancing research through clinical practice;
- Personalized Medicine describes what many think medical practice should be;
- However, among other commonalities, all three of these trends are:
 - Data-driven;
 - Data-driven;
 - Data-

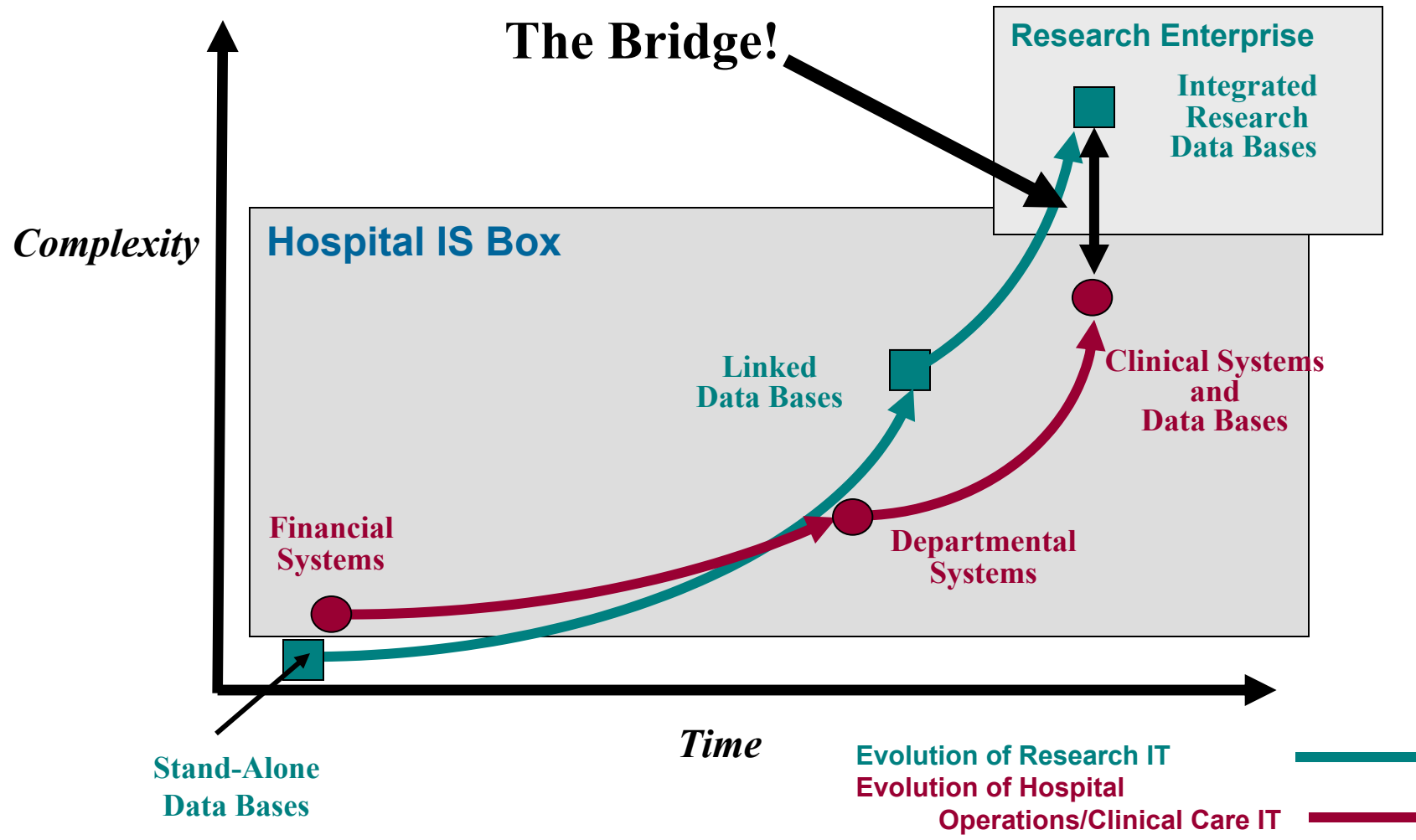
Trends in research are also bringing the “bench” closer to the “bedside”.

- NIH Funding for basic sciences research is increasingly competitive as research institutes develop competitive offerings;
- Clinical and translational research is becoming a strong priority for NIH funding;
- New fields are being defined (and re-defined) to combine molecular biology, cell biology, chemistry, radiochemistry, physics, clinical medicine and public health, for example:
 - Clinical Genomics
 - Pharmacogenomics
 - Genetic Epidemiology
 - Molecular Imaging
- The search for the underlying causes of cellular variation provides direct links between research and the provision of clinical care.

There are important differences between IT requirements for research and for clinical care.

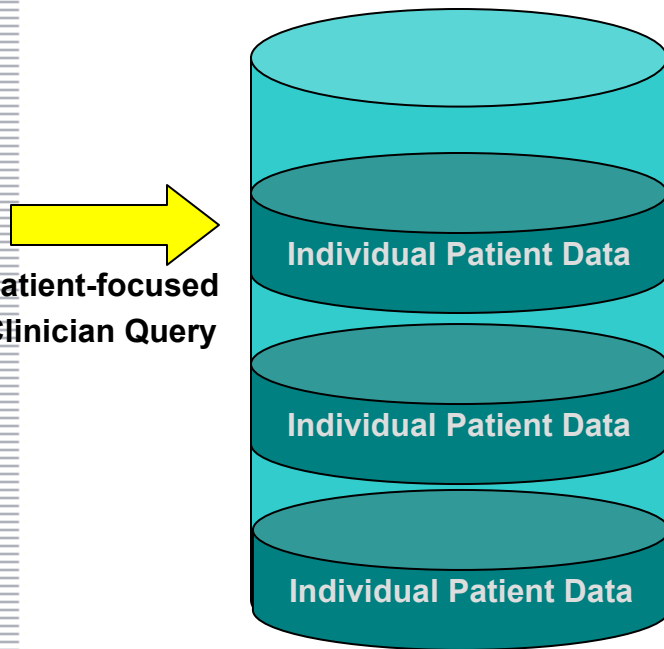
- At the level of the data element, the differences between data for clinical care and data for research are merely semantic;
- However, clinical care is:
 - Episodic;
 - Patient-focused;
 - Often time-focused.
- Historically, data systems supporting research and those supporting clinical care have not been integrated;
- And even much of the time, systems within the research and the clinical care communities have not been integrated.

The history of research and provider-based IT systems differs significantly.



Structure and access for production clinical systems and for research are fundamentally different.

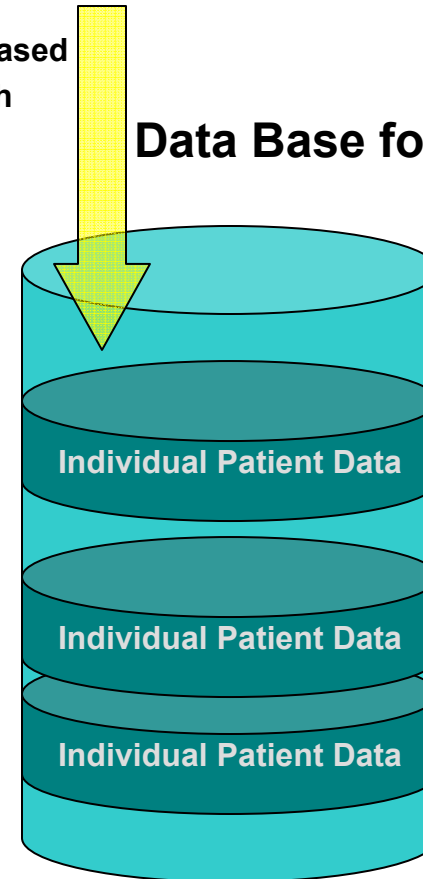
Production Clinical System



**Focus on Single Patient,
Many Attributes**

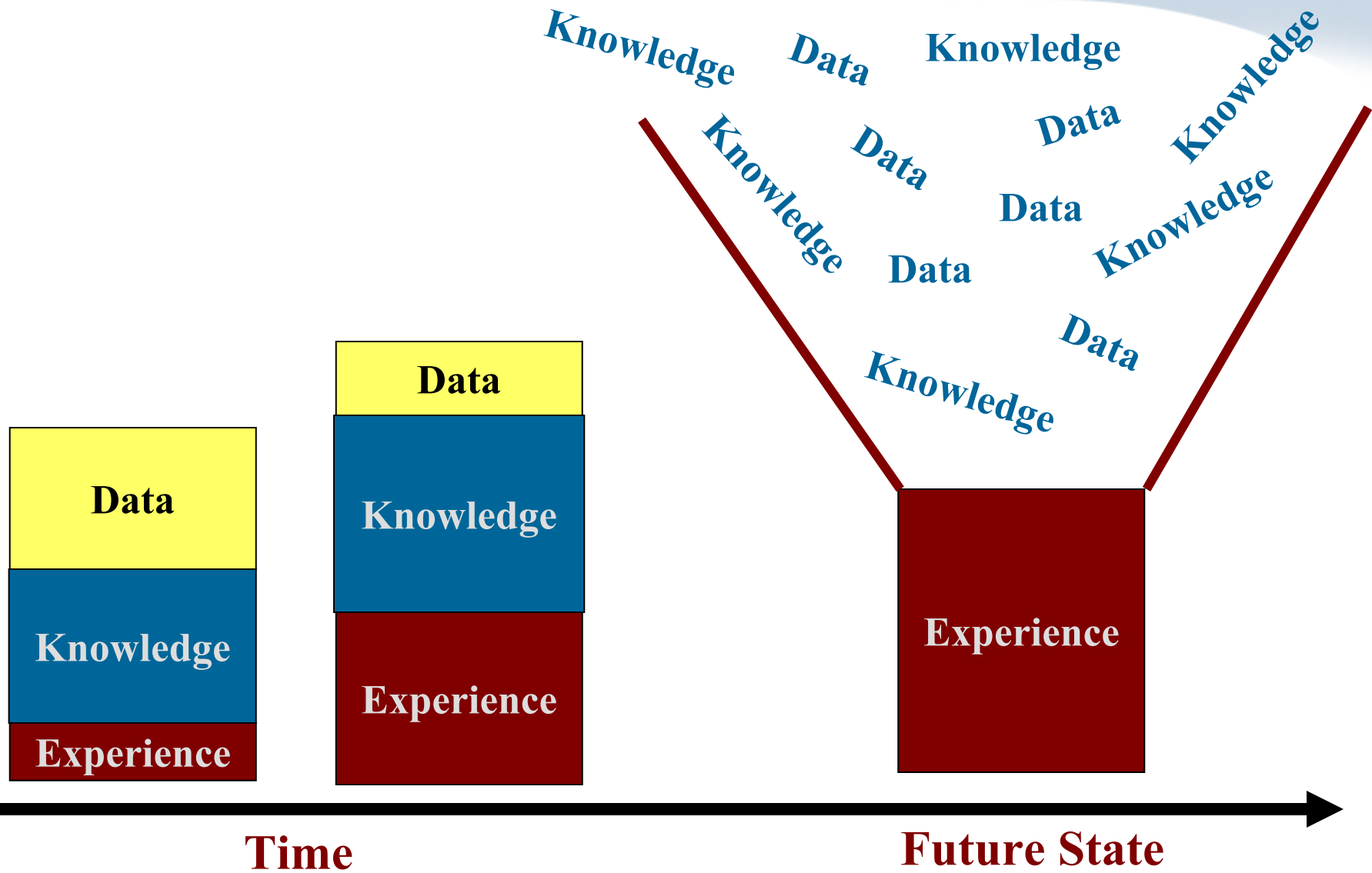
Algorithm-based
Research
Query

Data Base for Research



**Focus on Many Patients,
Few Attributes**

The balance for clinicians between experience, knowledge and data usage is changing significantly.



Data bases in general have grown significantly . . .

| Types of Databases | 1999 Typical Size | 2004 Typical Size | Reference |
|--------------------|-------------------|-------------------|--------------------------------|
| Data Warehouse | 1 terabyte | 100 terabytes | 1 PB = all printed material |
| Transactional | 100 gigabytes | 1 terabyte | 1 TB = 200 DVD Movies |
| Data Mart | 20 gigabytes | 1 terabyte | 1 GB = 10,000 songs in an iPod |
| Mobile Data | 100 megabytes | 10 gigabytes | 5 MB = works of Shakespeare |
| Pervasive Data | 100 kilobytes | 1 gigabyte | 1 KB = 1/2 typewritten page |

Data relating to research and to clinical care is becoming much more specialized.

- Genomic medicine itself represents new levels of depth and understanding;
- On the clinical side, specialized provider organizations are becoming more prominent:
 - Children's Hospitals
 - Heart Hospitals
 - Cancer Centers
 - Orthopedic Centers
 - Free-standing Imaging Centers
 - Free-standing surgical centers

Challenges for IT in facilitating the transition of results from the “bench” to the “bedside”.



- **Management of Clinical Data**
- **Development of Standards**
- **Vendors’ ability to respond to new data challenges**
- **Information Technology Leadership in Healthcare**

- **Clinical Data is not what it used to be!**
 - Lab results
 - Radiology results
 - H&P, progress notes . . . often on paper!
- **Recall what “personalized medicine” requires:**
 - Genotypic data;
 - Medical images;
 - Environmental data;
 - Genetic profiles;
 - Molecular and genetic research efforts
- **Clinical Data belongs to the patient!**
 - Much more restrictive than Amazon.com!
 - HIPAA can bring real consequences for data mismanagement
- **Volume of data is growing exponentially, requiring new technical capabilities!**

- **Historically, standards have been very specific, developed under the auspices of formal, standard-setting bodies:**
 - **Health Level Seven (HL7) – specifies the content of messages sent between two computer systems;**
 - **Digital Imaging and Communications in Medicine (DICOM) - designed to support the interoperability of medical imaging equipment.**
- **New Frontiers in Standard-Setting**
 - **Standards for Electronic Health Records: Draft Standards for Trial Use (DSTU);**
 - **Formal process for certifying compliance with EHR standards is being implemented by HIMSS and AHIMA;**
 - **Formation of Health Information Technology Certification Commission Vendor Advisory Council to offer an “open forum for vendors interested in certification of electronic health record (EHR) products”.**

HL7 EHR System Functional Model: Draft Standards for Trial Use (DSTU)



| ID | Name | Statement | Description | See Also | Rationale | Citations |
|-------------|--|--|---|---|--|--|
| DC.1 | Care Management | | | | | |
| DC.1.1 | Health information capture, management, and review | | For those functions related to data capture, data may be captured using standardized code sets or nomenclature, depending on the nature of the data, or captured as unstructured data. Care-setting dependent data is entered by a variety of caregivers. Details of who entered data and when it was captured should be tracked. Data may also be captured from devices or other Tele-Health Applications. | S.3.1.4 | | ISO/TS 18308 - Health Informatics - Requirements for an Electronic Health Record Architecture; ASTM E 1769 Standard Guide for Properties of Electronic Health Records and Record Systems |
| DC.1.1.1 | Identify and maintain a patient record | Identify and maintain a single patient record for each patient. | Key identifying information is stored and linked to the patient record. Static data elements as well as data elements that will change over time are maintained. A lookup function uses this information to uniquely identify the patient. | | Supports delivery of effective healthcare, Improves efficiency, Improves patient safety | |
| DC.1.1.2 | Manage patient demographics | Capture and maintain demographic information. Where appropriate, the data should be clinically relevant, reportable and trackable over time. | Contact information including addresses and phone numbers, as well as key demographic information such as date of birth, sex, and other information is stored and maintained for reporting purposes and for the provision of care. | S.1.4.0; S.1.4.1; S.1.4.2; I.1.4.4; I.1.4.5 | Supports delivery of effective healthcare, Improves efficiency, Improves patient safety | |
| DC.1.1.3 | Manage summary lists | Create and maintain patient-specific summary lists that are structured and coded where appropriate. | Patient summary lists can be created from patient specific data and displayed and maintained in a summary format. The functions below are important, but do not exhaust the possibilities. | DC.1.1.5; S.1.4.0; S.1.4.1; S.1.4.2; S.2.2 I.1.4.4; I.1.4.5 | Supports delivery of effective healthcare, Improves efficiency, Facilitates management of chronic conditions, Improves patient safety | |
| DC.1.1.3.1 | Manage problem list | Create and maintain patient- | A problem list may include, but is | | Supports delivery of | |

Ability of vendors to respond to changes in healthcare business and technology may be limited.



- Vendors must sell products to stay in business;
- Products must appeal to the widest possible audience (lowest common denominator?);
- Research and development costs must be recouped through sales;
- Healthcare IT market is difficult: many dollars overall, few for IT, and very challenging sales cycles;
- Challenge to current vendors to adapt to intensifying data requirements leads to opportunities for other players:
 - Announcement of IBM's relationship with Mayo Clinic and then with Cleveland Clinic, to "develop a platform that ties together patients' electronic health-record data with clinical, genetic and other research data."¹

¹ "Medicine gets Personal", Information Week, October 4, 2004, p. 12.

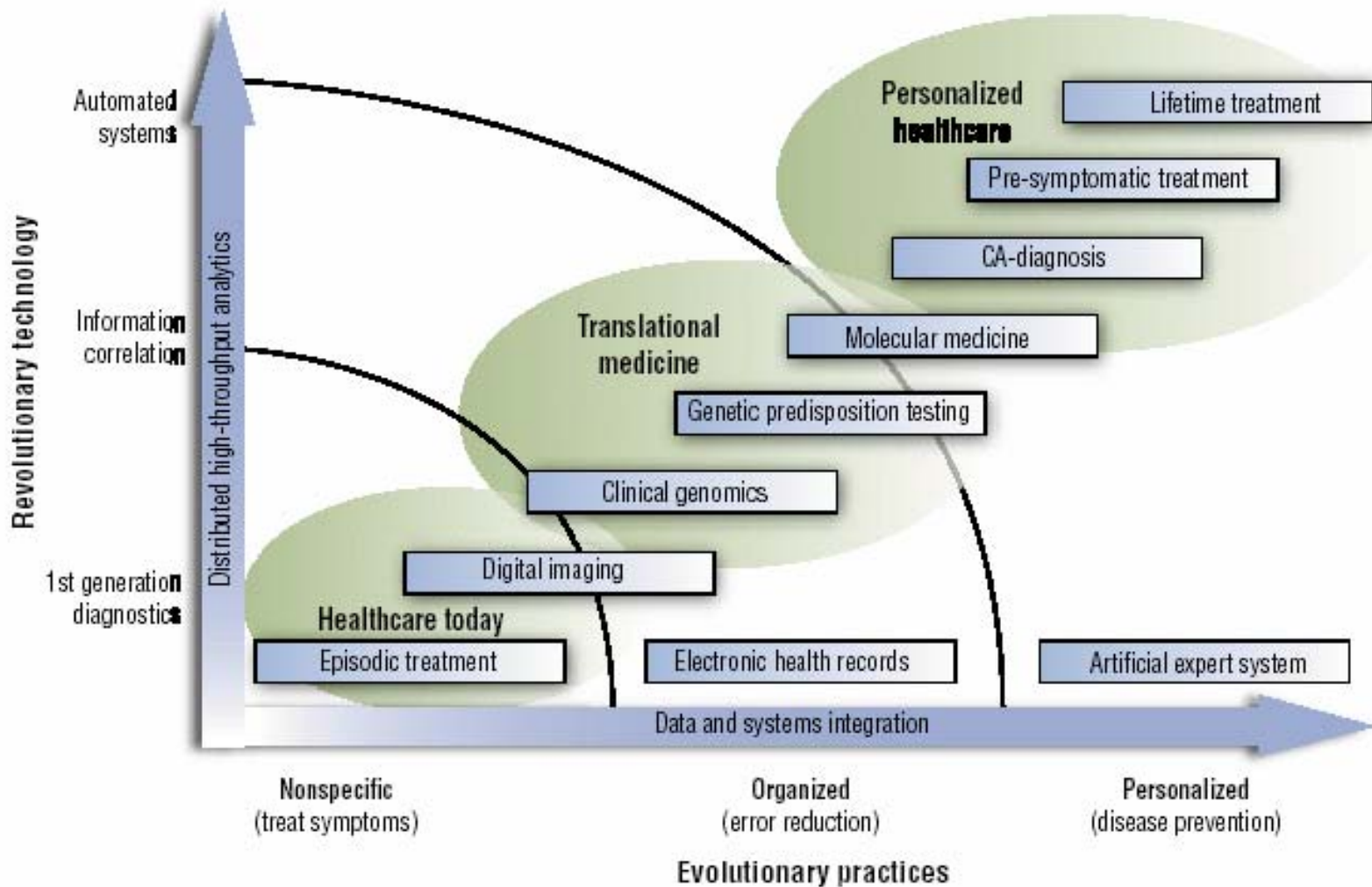
What's the status of Leadership in Healthcare Information Technology?



- Who is best qualified to be an IT leader in healthcare?
 - Those with MBA's? with degrees in Computer Science? Medicine?
 - How do we train IT leadership . . . or do we?
- What's happening to Chief Information Officers (CIO)?
 - “Since a year ago this June, 55 CIOs we know of have been fired, not laid off . . .”¹
- What about Chief Medical Information Officers (CMIO)?
 - Does medical training prepare you to be a leader in healthcare information technology?
 - Does informatics training facilitate the move into information technology management?

¹ Betsy Hersher, quoted in Healthcare Informatics, October 2004, p. 28.

Evolutionary Practice vs. Revolutionary Technology



Thank You!