

The Impact of Informatics on Lab Services

Jan W. Steiner, MD, FRCP(C)
Park City Solutions/Laboratory Services Group
Ann Arbor, Michigan



“Nothing is permanent but change.”

**Heraclitus
500, B.C.**

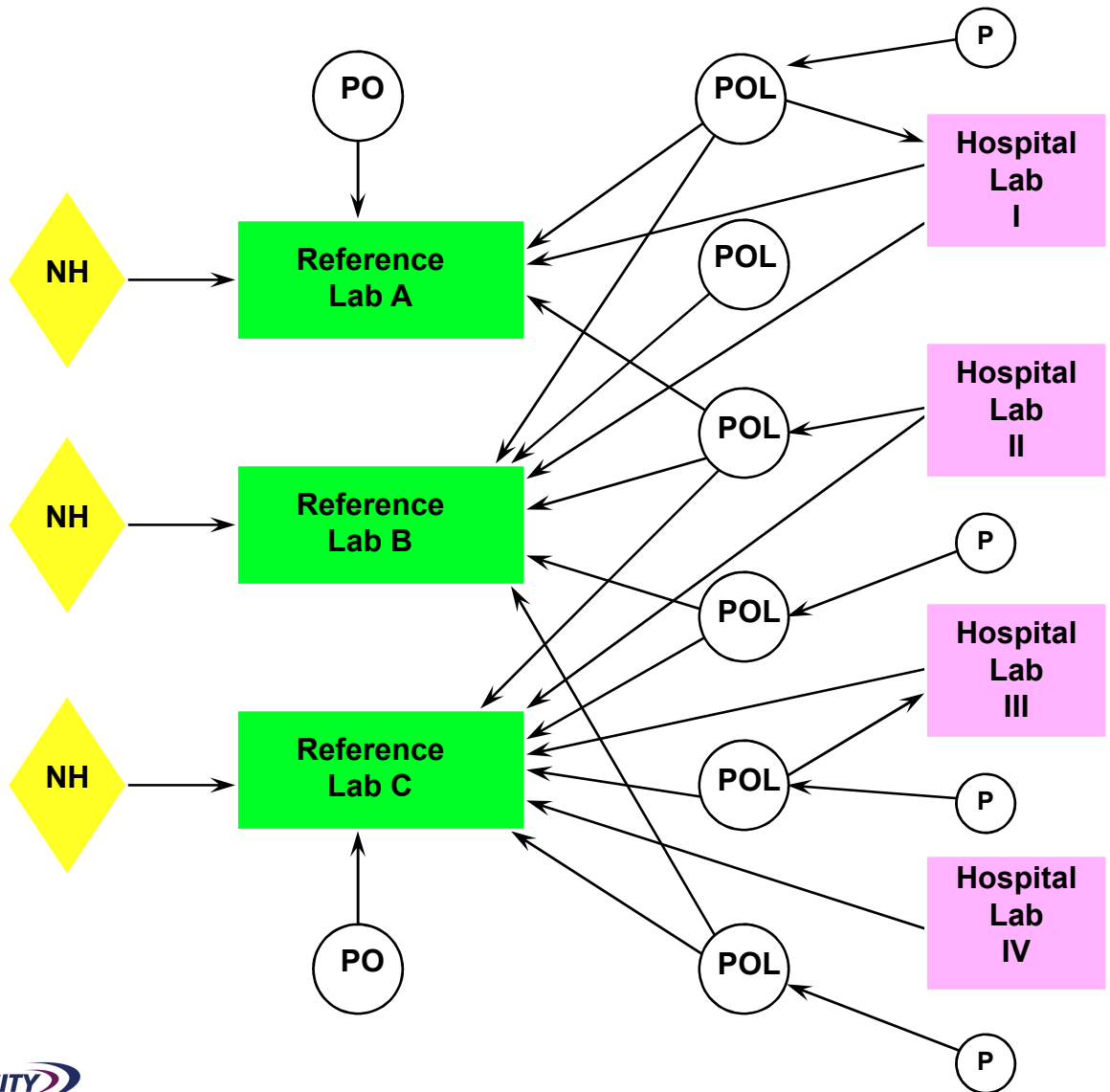
The Vision of Regionalization of Hospital Laboratories

- Multi-institutional ventures, coordinated to **eliminate undue duplication** of resources
- High quality through **sharing of expertise and technology transfer**
- **Client responsiveness**
- **Unified terminologies**, normal values and ranges
- **Integrated information system** with compatible regional database
- **Shared outreach** infrastructure
- **Unified operational philosophy** attuned to clinical goals
- **Standardized** equipment, methodologies and procedures
- **In-common** medical, technical and administrative **leadership**
- **In-common purchasing**
- **Dedication to Innovation**

Goals of Regionalized Laboratory Systems

- ◆ **Seamless delivery** of laboratory services (equal patient access to high quality laboratory services);
- ◆ **Continuity of care** - provision of a regional compatible laboratory database covering services from cradle to grave which would allow for movement from M.D. office to Hospital to Nursing Home, etc. without repeat pre-admission or pre-examination testing;
- ◆ **Regional purchasing** plans to standardize equipment, reagents and supplies to reduce cost of laboratory activities;
- ◆ **Reduction of fixed costs** by sharing of high cost human resources;
- ◆ **Low cost structure and competitive pricing;**
- ◆ **Institutionalized technologic innovation and technology transfer;**
- ◆ **Joint managed care bidding** through control of a large population base and geographic coverage combined with optimum quality of service;
- ◆ **Inreach lab services development** taking advantage of the traditional allegiance of medical staffs to their institutions;
- ◆ **Joint inreach and outreach infrastructure** through creation of Laboratory Service Organizations which share the cost and activities of marketing and sales, client servicing, logistical services (couriers), billing, form design, etc.

Dissociated Regional Laboratory System “The Tower of Babel Syndrome”



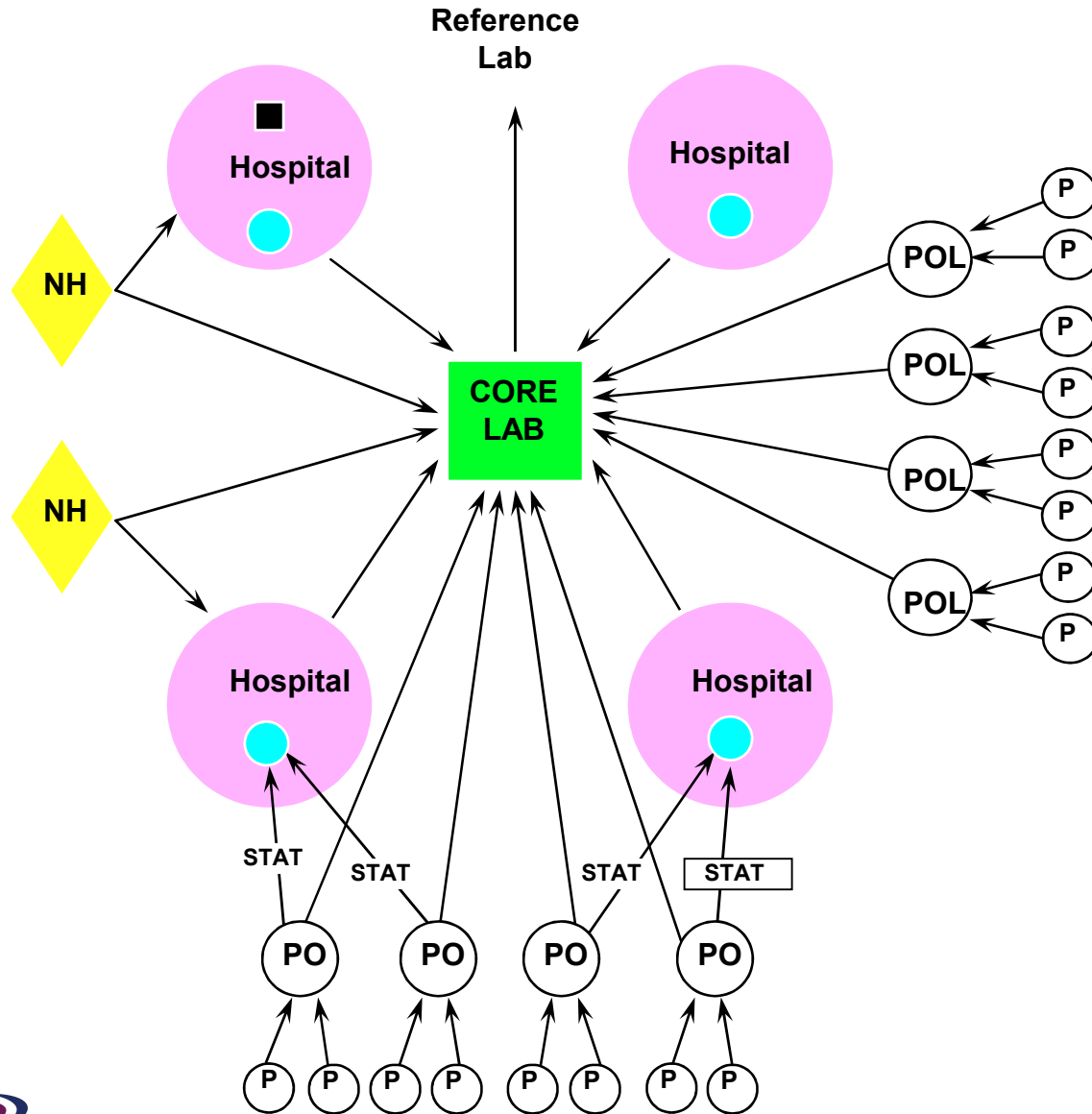
NH: Nursing Home

POL: Physician's
Office Laboratory

PO: Physician's Office

P: Patient Self-Testing

Integrated Regional Laboratory System



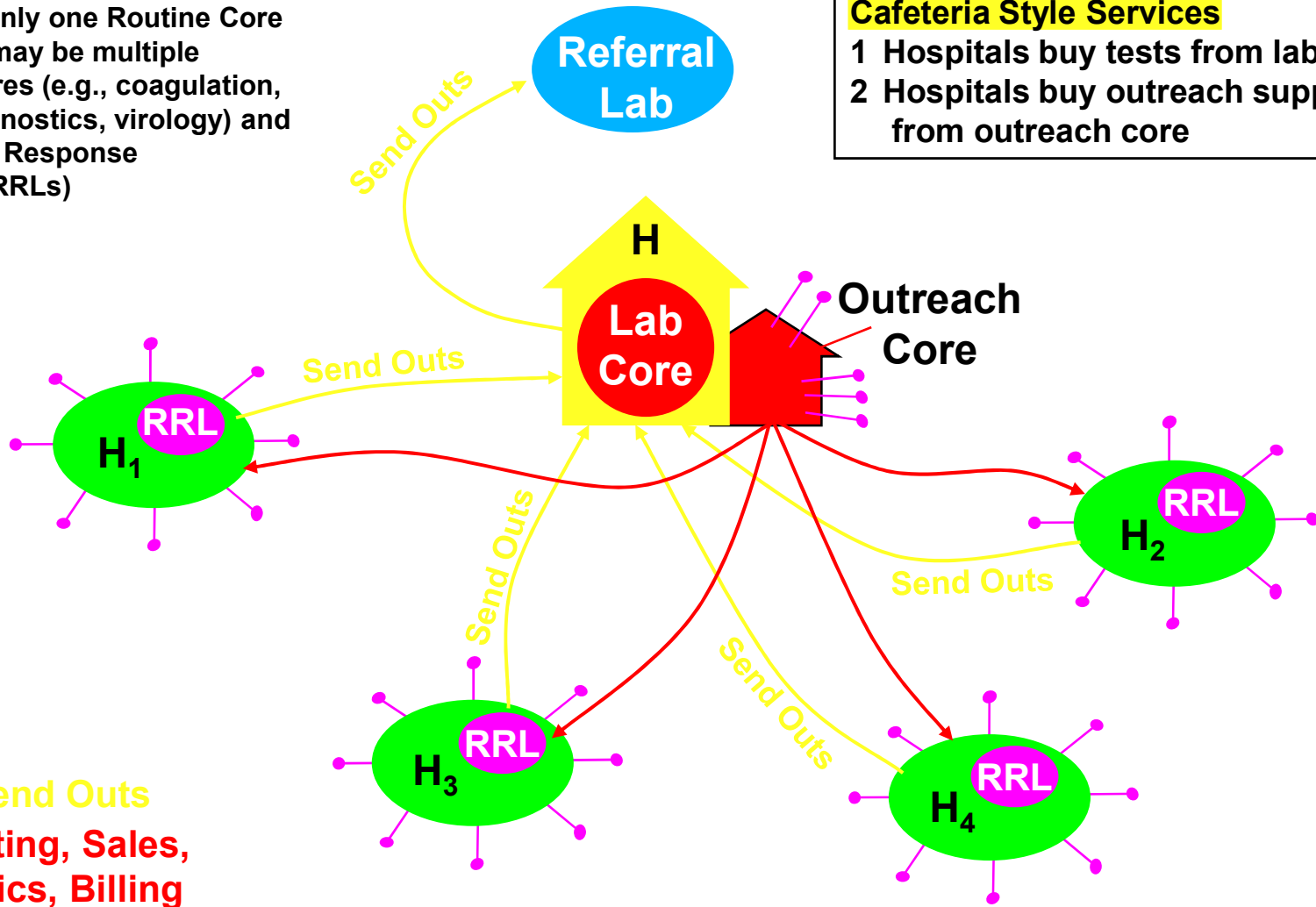
Key

- Rapid Service Labs
- Specialized Core Lab
- PO: Physician's Office
- POL: Physician's Office Lab
- P: Patient Self-Testing
- NH: Nursing Home

Laboratory Cooperative In-common Model

NB: There is only one Routine Core Lab but there may be multiple specialized cores (e.g., coagulation, molecular diagnostics, virology) and multiple Rapid Response Laboratories (RRLs)

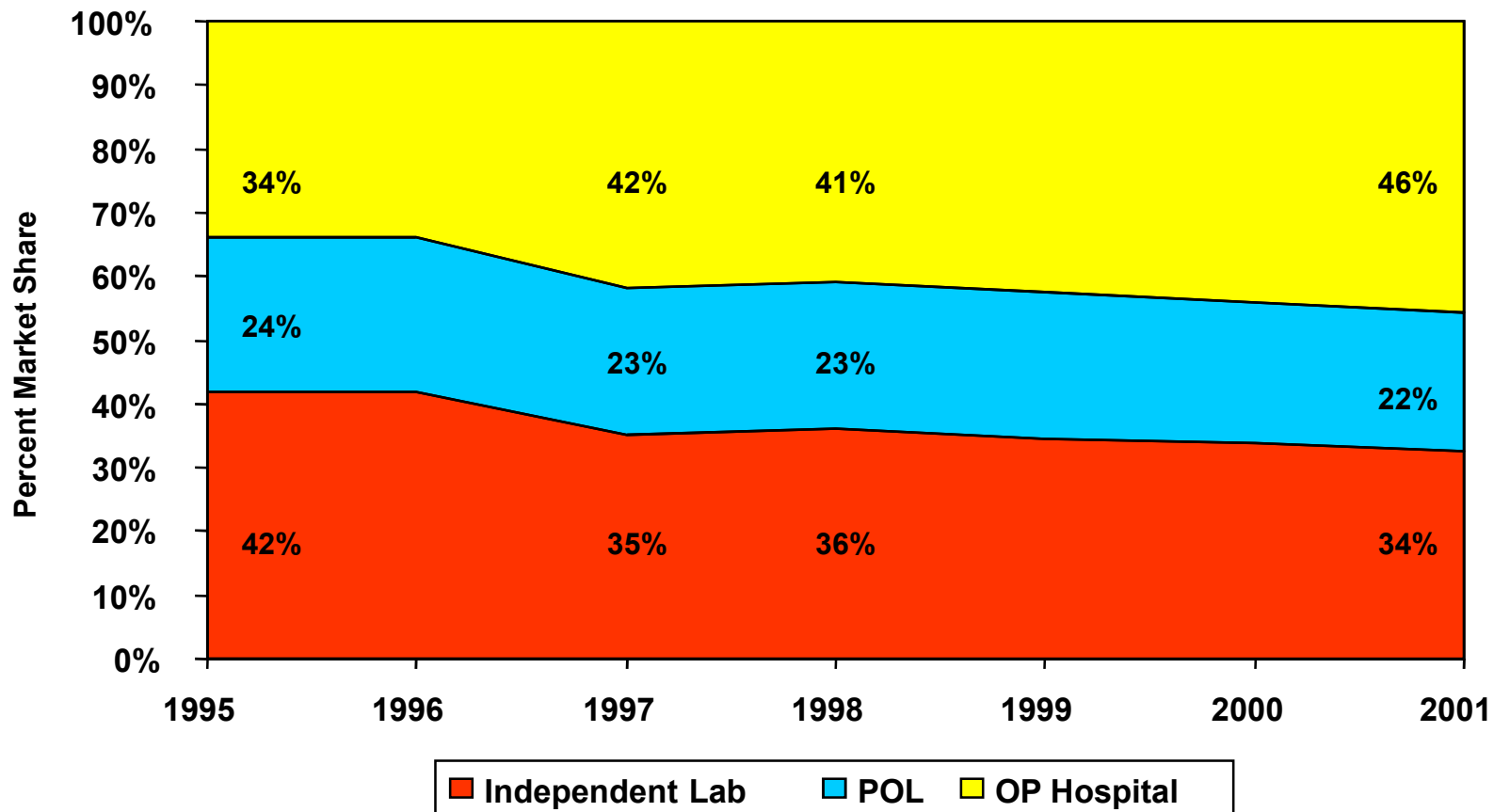
Cafeteria Style Services
 1 Hospitals buy tests from lab core
 2 Hospitals buy outreach support from outreach core



- Test Send Outs
- Marketing, Sales, Logistics, Billing
- MD Offices and Clinics

Concept Validation

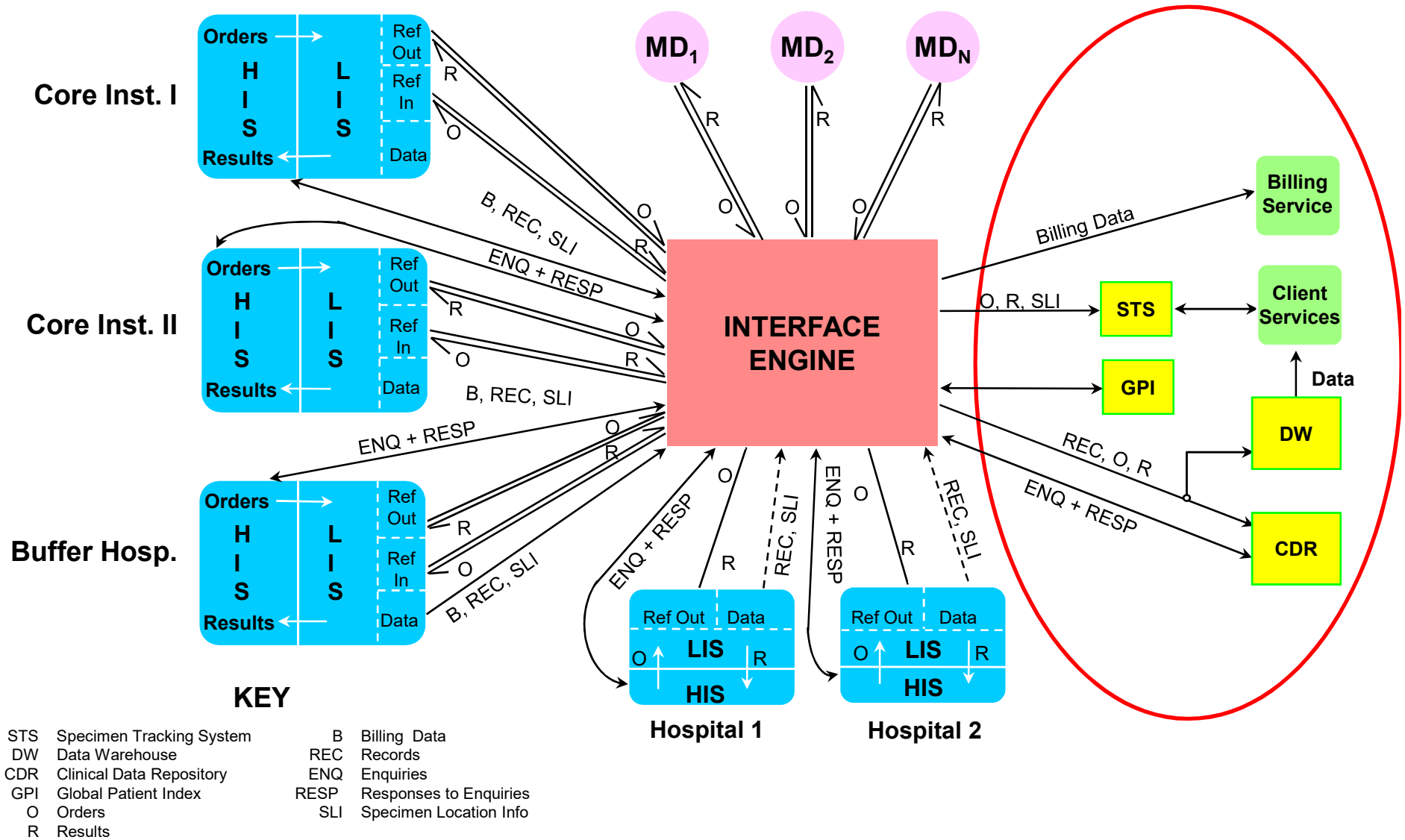
Market Share Trends for Medicare Lab Services



Source: HCFA Office of the Actuary, 1999

- Notes:
1. 1995-1997 figures are actual.
 2. 1998 figures are preliminary estimated.
 3. 1999-2001 figures are projected.

Conceptual Integration Architecture Heterogeneous LISs



Source: D. Covey and J.W. Steiner, MD

Information Systems Solutions

Integration System Capabilities

The Interface Engine has a number of components and an associated system that provide the infrastructure for the laboratory environment.

◆ Specimen Tracking System

Maintains overview of whereabouts of all specimens and report.

◆ Global Patient Index

A component of the integration system that links institution-specific patient identifiers to unique enterprise identifier, enabling the development of a longitudinal patient record regardless of the locus of care.

◆ Data Warehouse

A system that, via the interface engine, requests and stores all lab-related data (testing, financial, operational) to support management analysis, managed care reporting, and other analytic processing.

Information Systems Solutions (cont.)

◆ Clinical Data Repository

A system that, via the interface engine, requests and stores all clinical data, making it available for clinician access in support of the patient care process.

◆ Transaction Management System

A component of the integration system that vectors orders, results, records, and other data from a source to a destination based on rules (conditional statements) that can be revised as required, and allows monitoring of system performance.

The Clinical Laboratory Cost Effectiveness

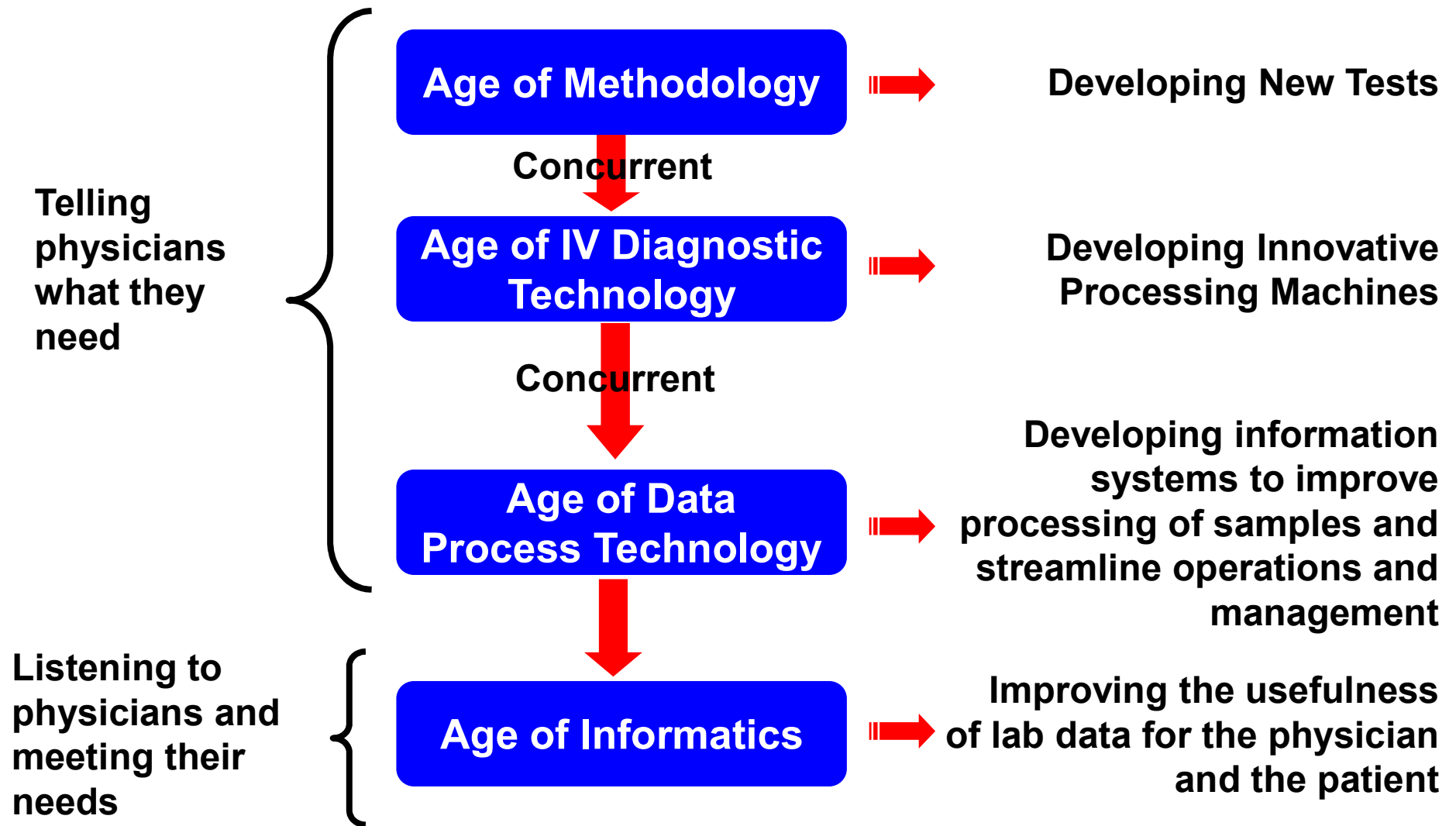
◆ Old Paradigm

Assumed that cost-effectiveness could be achieved by streamlining and automating laboratory processes and providing LIS support to ensure accuracy and performance monitoring and speeding result transmission.

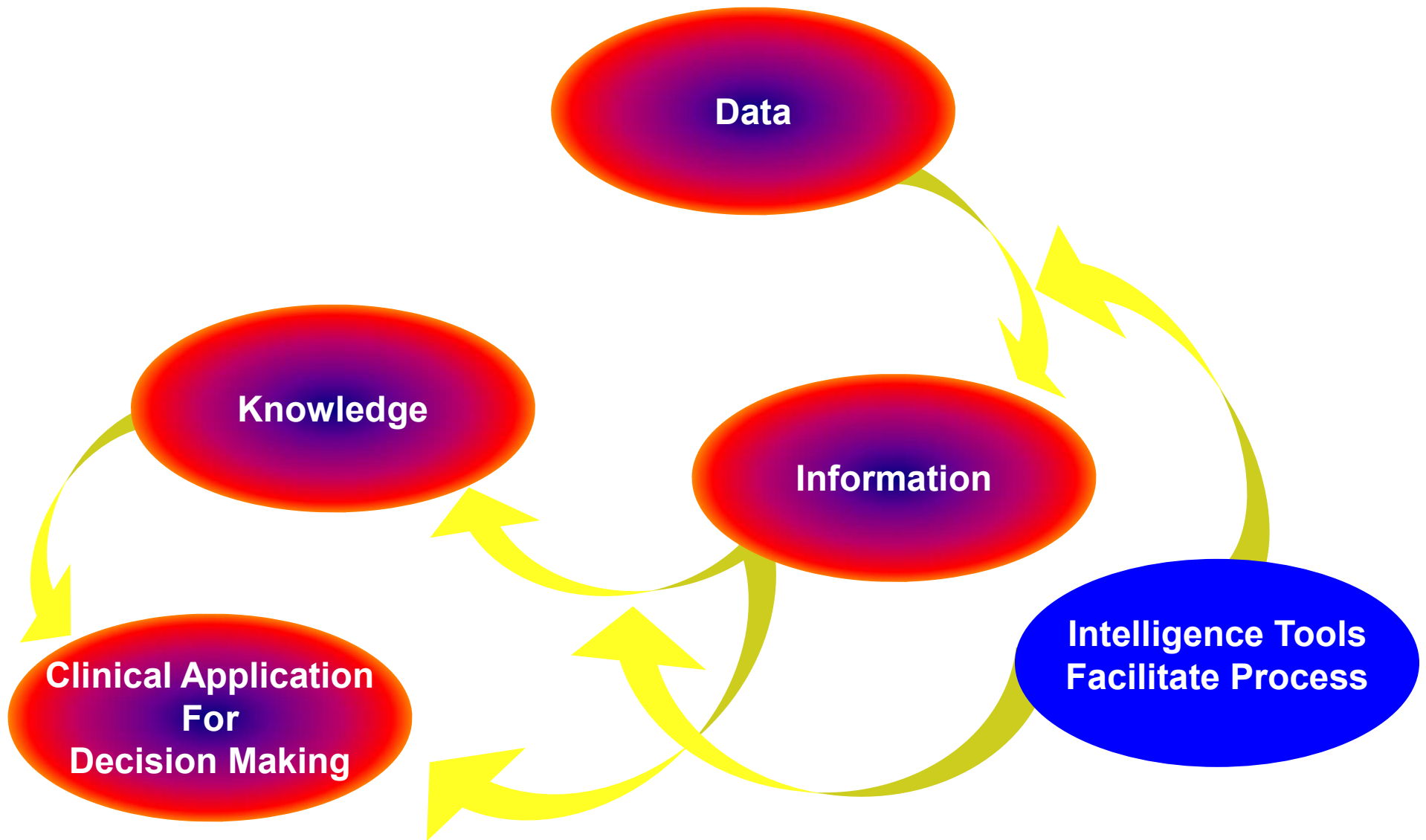
◆ New Paradigm

Overall cost-effectiveness hinges upon appropriate test selection and sequencing, and the presentation of results in a manner which facilitates clinical decision-making at the right time.

The Ages of Change in Laboratory Medicine



Basic Medical Informatics



Info-Catenation

Linking **data** in a chain or series of values (catena – *Lat.* Chain) to create clinically useful **information** for diagnostic and therapeutic decision making.

The Value of Routine Preoperative Medical Testing Before Cataract Surgery

Oliver D Schein, MD, MPH, et. al.

◆ Methods

- ◆ 19,557 elective cataract operations

- ◆ Standard battery of medical tests (electrocardiography, complete blood count, and measurement of serum levels of electrolytes, urea nitrogen, creatinine, and glucose)

◆ Conclusions

- ◆ Routine medical testing before cataract surgery does not measurably increase the safety of the surgery. (N Engl J Med 2000;342:168-75)

Source: The New England Journal of Medicine, January 2000

Vital Statistics

- ◆ **Almost 70% of a patient's medical record is generated by diagnostic procedures**
- ◆ **About 60% of medical decisions depend totally or in part on laboratory test results**

Source: The Genesis Report, September 1998

Clinicians Face Increasing Time Pressures

- ◆ Increasingly complex clinical environment
- ◆ More and faster communication channels
- ◆ Care process interruptions by external overseers
- ◆ Intrusive para-clinical documentation demands
- ◆ Demands for higher clinical productivity

Basic Assumptions

Generally, physicians do not know:

- ① What tests to order
- ② How to appropriately sequence testing
- ③ How to interpret large sets of data points
- ④ How to aggregate data from other sources with lab data (e.g., imaging, electrodiagnostics, etc.) to form integrated information

The Process of Medical Care

- ◆ **The physician depends on**
 - ◆ History taking
 - ◆ Physical examination
 - ◆ Knowledge of disease processes
 - ◆ Consideration of experience
- ◆ **Laboratory information is critical in**
 - ◆ Confirming or ruling out or suggesting diagnoses
 - ◆ Optimizing the choice and application of therapy

∴ Integration of laboratory data into the clinical workflow constitutes the basis for cost-effective use of clinical laboratory data and information
- ◆ **The burden**
 - ◆ Educate the physician in the appropriate use of constantly changing test methodologies in an environment of privacy and confidentiality - i.e., the *best practices* solution to achieve the optimal outcome.

The Clinical Support System Demands

Old System

- ◆ Lose few specimens
- ◆ Perform the right test consistently
- ◆ Report results accurately and in a timely fashion
- ◆ Provide reports on paper or by phone

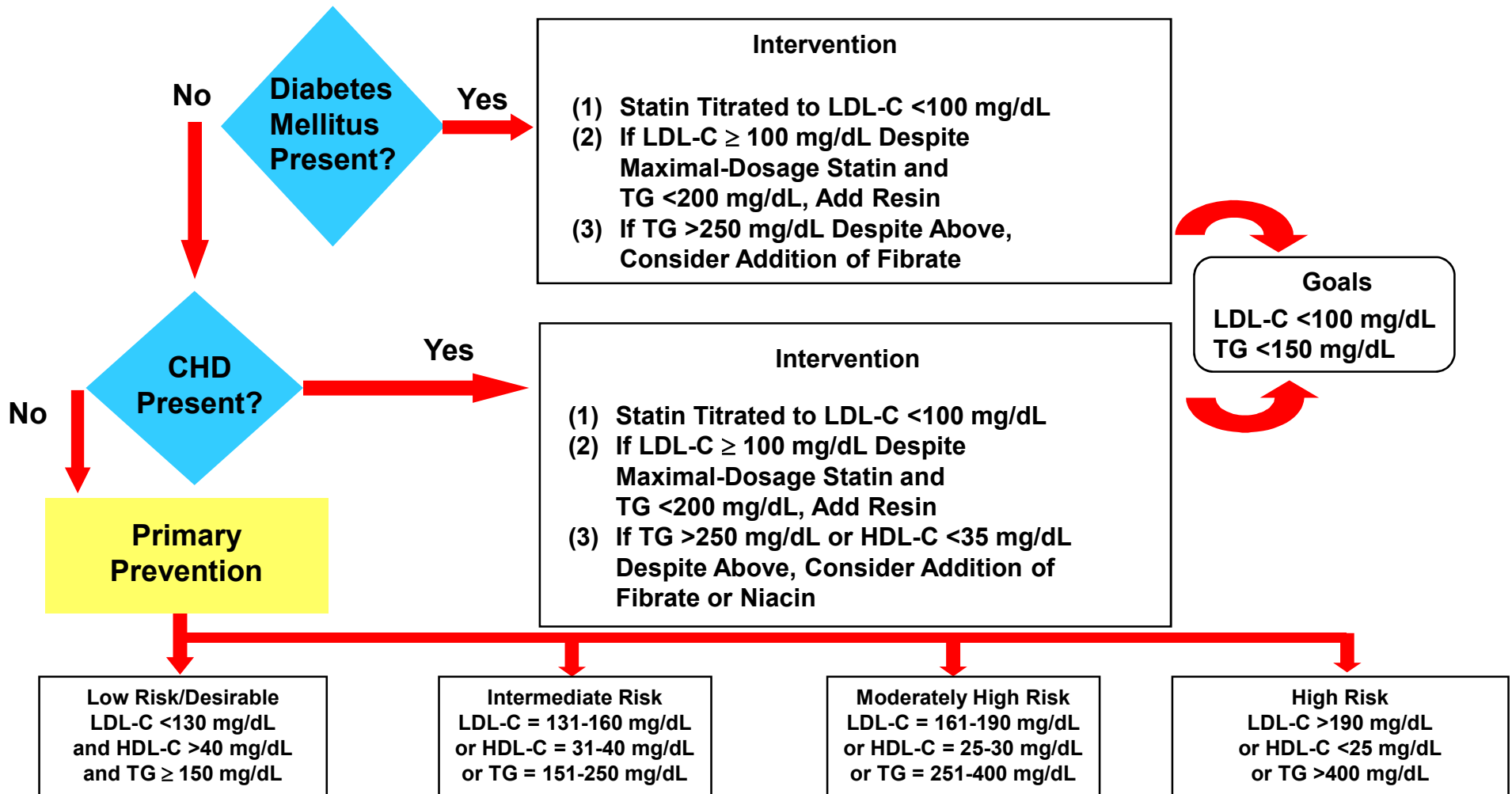
New System

Provide:

- ◆ Test method and process information
- ◆ Cost information
- ◆ Assessment of appropriateness of testing
- ◆ Evidence of overlapping test orders
- ◆ Status of specimen at time of inquiry*
- ◆ Expected time of result availability
- ◆ Seamless integration between ordering and result reporting
- ◆ A variety of notification choices (phone, fax, palm pager, PC, paper, etc.)

*Equivalent of Federal Express or UPS shipment status report

Adult Treatment Algorithm for Preference of Lipid-Lowering Therapy



Primary Prevention Goals

LDL-C <130 mg/dL, TG <150 mg/dL, HDL-C >40 mg/dL (Men), HDL-C >50 mg/dL (Women)

LDL-C indicates low-density lipoprotein cholesterol; TG, triglycerides; HDL-C, high-density lipoprotein cholesterol; CHD, coronary heart disease

To convert LDL-C and HDL-C from milligrams per deciliter to millimoles per liter, multiply by 0.02586. To convert triglycerides from milligrams per deciliter to millimoles per liter, multiply by 0.01129.

Past Misdeeds of Commercial Laboratories

Commercial labs did a great disservice to Medicine:

- They encouraged the unnecessary use of testing by clever packaging of tests which prevented logical medical decisions, e.g.:
 - Including differential counts in CBCs
 - Offering T₃T₄ tests in profiles when a TSH would suffice
 - Including Iron and Ferritin in profiles even if hemoglobin and RBC count is normal
- They created a format of report but did not invest in developing a better means of transforming data into information.
- They disdained the advice of pathologists in the formulation of reports for MDs.

Information Integration

Instrument - Driven Integration

- e.g., hemogram, leukocyte differential count listed in consistent sequence
- Cumulative reports – collate all results for day

Clinical Problem - Centered Integration

- e.g., diabetes view: glucose (fasting and time of day), glycated hemoglobin, creatinine, urinary sugar and ketones, microglobulin, etc

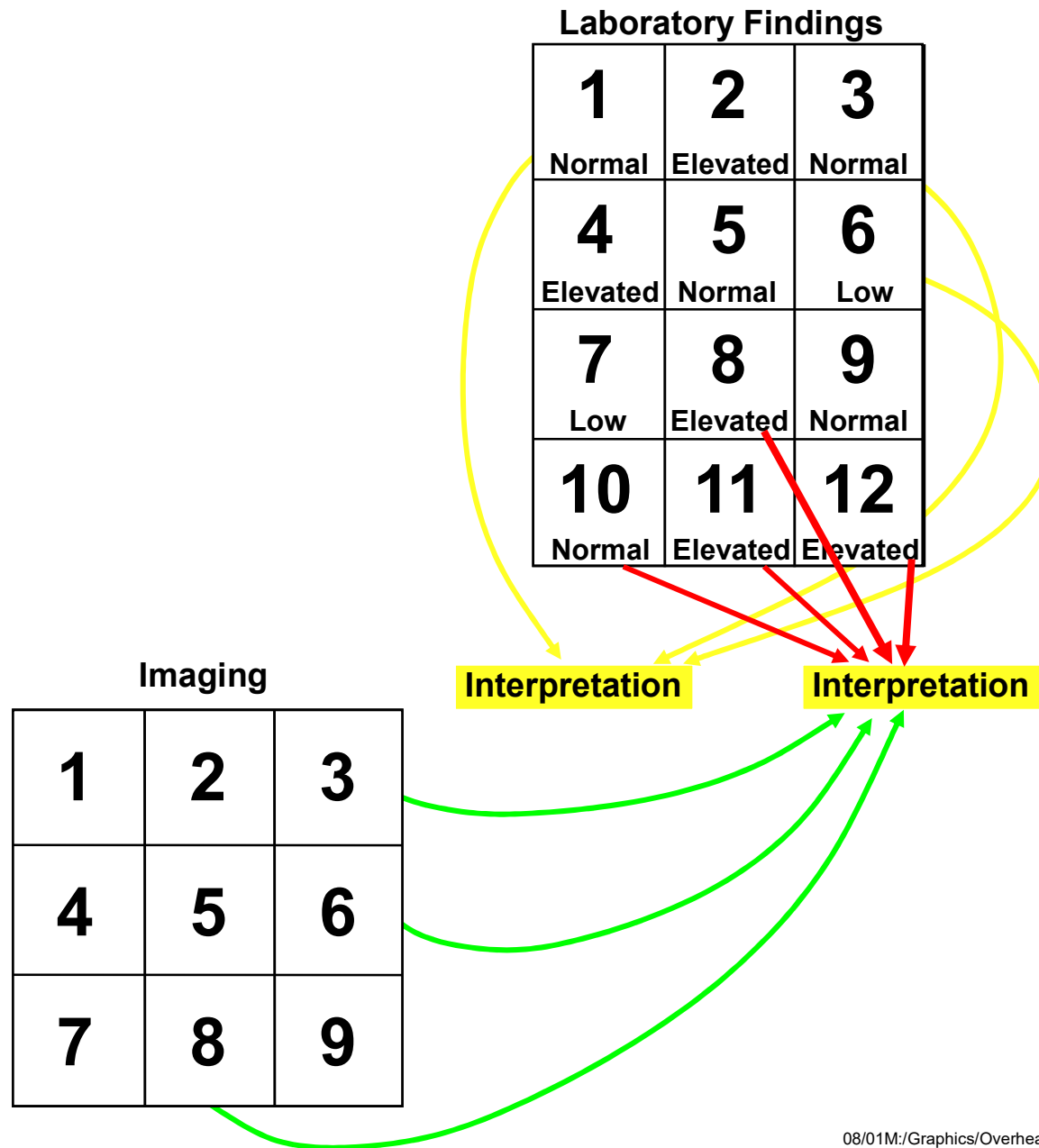
Horizontal Information Integration

- Lab results of all labs in an IDS + POC results, reference results + POL results + pathology results + pharmacy + radiology, etc.

Vertical Information Integration

- Information from all IDS testing units during patient's lifetime based on hospitalization, outpatient visits, home nurse visits, physician office visits, hospice care, rehab stays and screening or preventive care programs using HL7 for health data record.

Interpretation via Multifactorial Analysis



Best Practices (in Relation to Laboratory Information)

Assist physicians to identify necessary tests and eliminate redundant testing which defies medical logic

Develop regional clinical data repositories to achieve continuity of laboratory care – data compatibility and cradle to grave data coordination through data mining technology

Re-educate physicians to order only:

- **Tests which are medically necessary**
- **Tests which meet federal necessity guidelines**
- **Tests which are less costly (do not order esoteric tests if routine test will provide answer)**

Technologic Innovation: Web-Based Laboratory Reporting

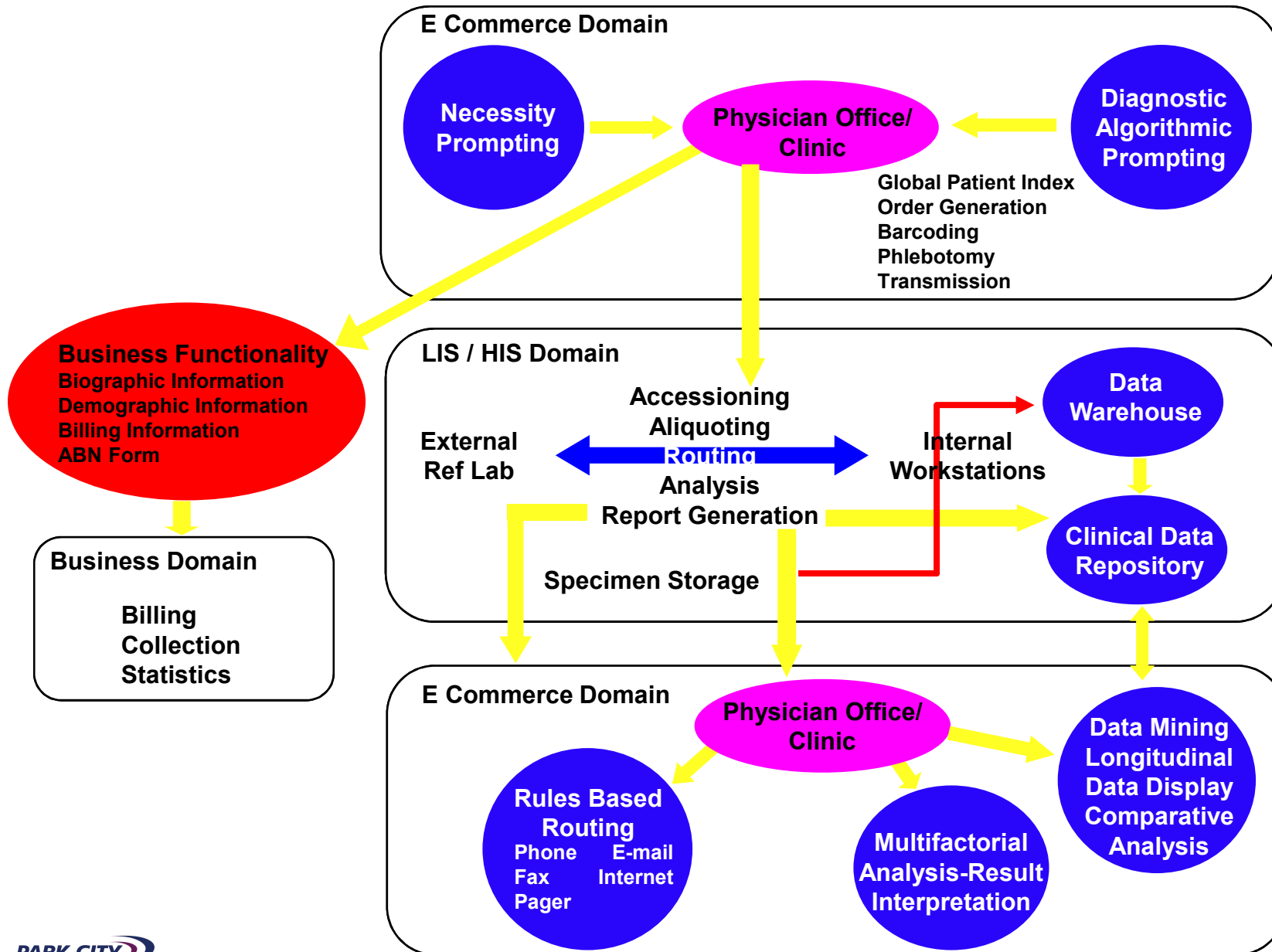
“Under managed care, LISs are being integrated rapidly into the larger group of hospital-based clinical information systems . . .The LIS architecture of the future most certainly will be Web-based.”

Bruce A. Friedman, MD

Advantages

- ◆ **Transmit test results quickly to off-site locations.**
- ◆ **Transmit simultaneously to parties on a need-to-know basis.**
- ◆ **Capture and integrate test results from off-site POCT testing into a single patient report.**
- ◆ **Transmit images for physician interpretation (microbiology, electrophoresis).**
- ◆ **Permit on-line consultations.**
- ◆ **Provide data links to other sites and reference to the medical literature.**
- ◆ **LIS Linkage to the Health Center’s Intranet for PC or laptop access.**

Outreach Connectivity Model



Standards for Establishing Unambiguous Laboratory Communications

Health Level 7

- Its mission is to provide HL7 standards for the exchange and integration of data that support clinical management of patients and the evaluation of healthcare services.

Logical Observation Identifier Names and Codes

- LOINC is a set of universal names and codes for identifying clinical observations and laboratory results. It is the basis of the ICD-10-PCS codes.

Snowmed International

- Snowmed provides a systemized nomenclature of human and veterinary medicine - a hierarchical terminology coding system organized in different axes and chapters. The chapters include laboratory and imaging procedures.

Snowmed RT

- This upcoming release provides clinical reference terminology for storing, receiving, and analyzing clinical information.

The future lies in the merger of LOINC and Snowmed to cover all detailed laboratory terms and their classification.

Extensible Markup Language

- XML serves to format material for presentation to a browser and via HTML (hypertext marking language) to navigate among pages and sites of the WWW. Next generation of Netscape and Microsoft will support the display and manipulation of XML documents using HL7, LOINC, and Snowmed standards.