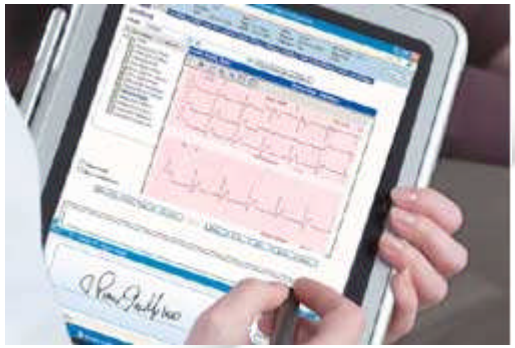

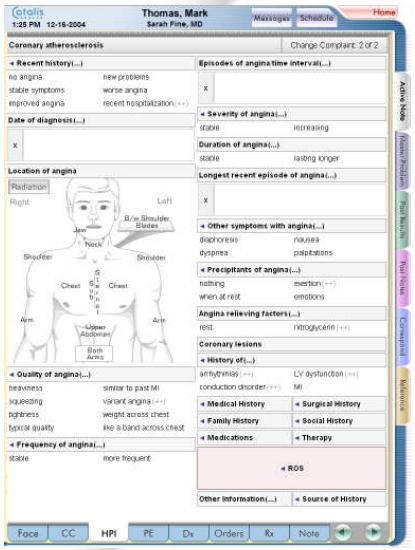

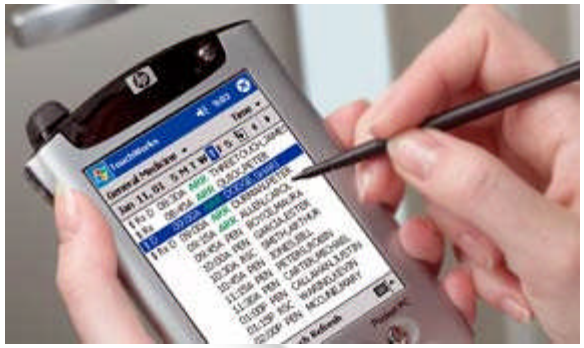

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Health Informatics Technology

Suzanne Markel-Fox, PhD

Strategy & Process Excellence

11 October 2005

Message

- Perspective
- Current development
- Implications for pharmaceutical R&D

Institute of Medicine (IOM)

- Committee on improving the patient record
  - *The computer-based patient record: An essential technology for health care* (1991,1997)
- Committee on regional health data networks
  - *Health data in the information age: Use, disclosure and privacy* (1994)
- Committee on quality of healthcare in America
  - *To err is human: Building a safer health system* (2000)
  - *Crossing the quality chasm: The IOM healthcare quality initiative* (2001)
- Committee on engineering and the healthcare system
  - *Building a better delivery system: A new engineering/ health care partnership* (2005)

Computerised medical records <1990

1960's:

- The Medical Record (TMR) - Duke
- Computer-Stored Ambulatory Record (COSTAR) - Harvard
- Lockheed's early Clinical Information System

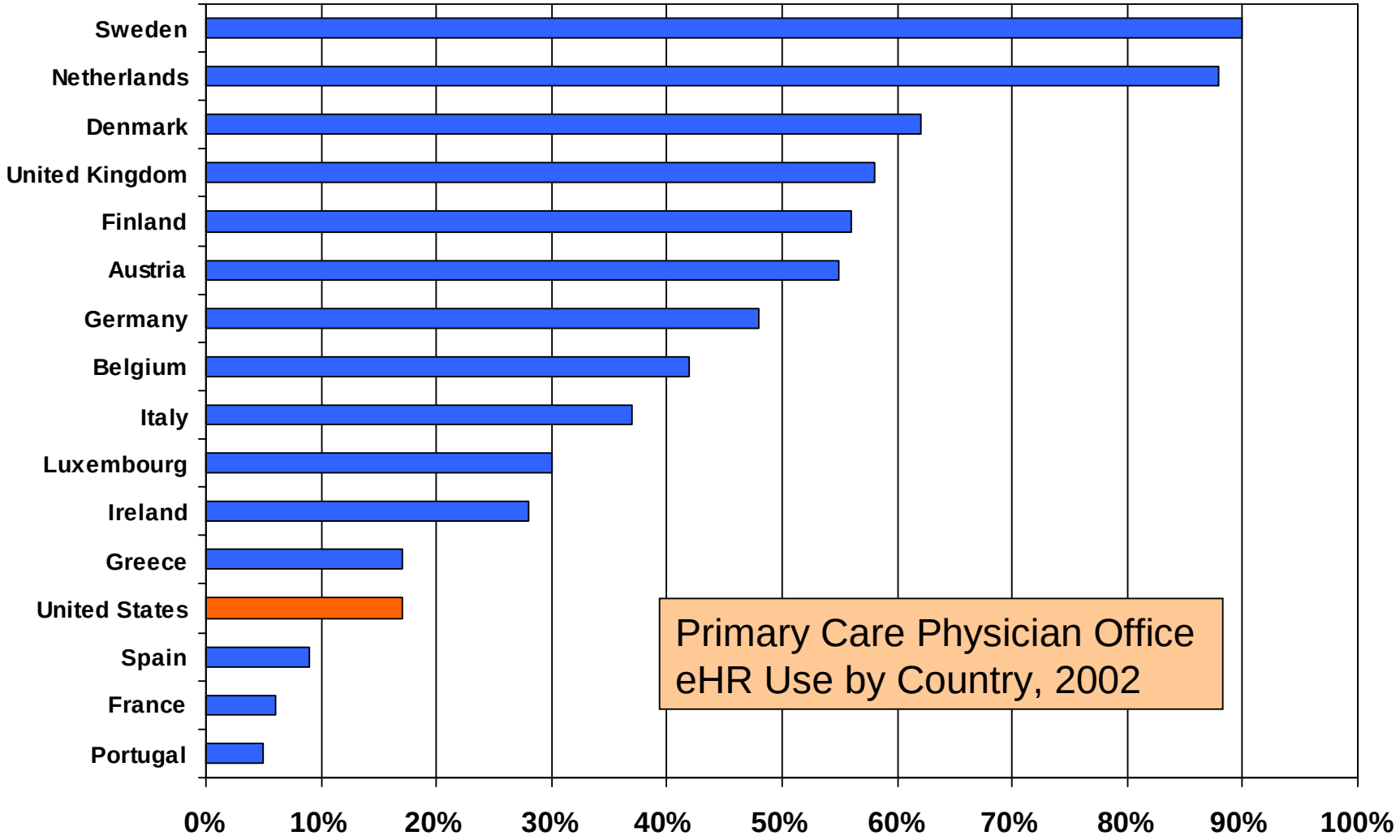
1970's:

- Health Evaluation through Logical Processing (HELP) - IHC
- Beth Israel/Brigham & Women's clinical information system
- Decentralised Hospital Computer Program (DHCP) - VHA

1980's:

- THERESA - Emory
- Composite Health Care System (CHCS) - DoD
- DIOGENE - Geneva
- The Exmouth Project - UK

eHR adoption - 2002



Source: "European Physicians Especially in Sweden, Netherlands, and Denmark, Lead U.S. in Use of Electronic Medical Records." Harris Interactive Health Care News 2(16), in Brailer, 2003.

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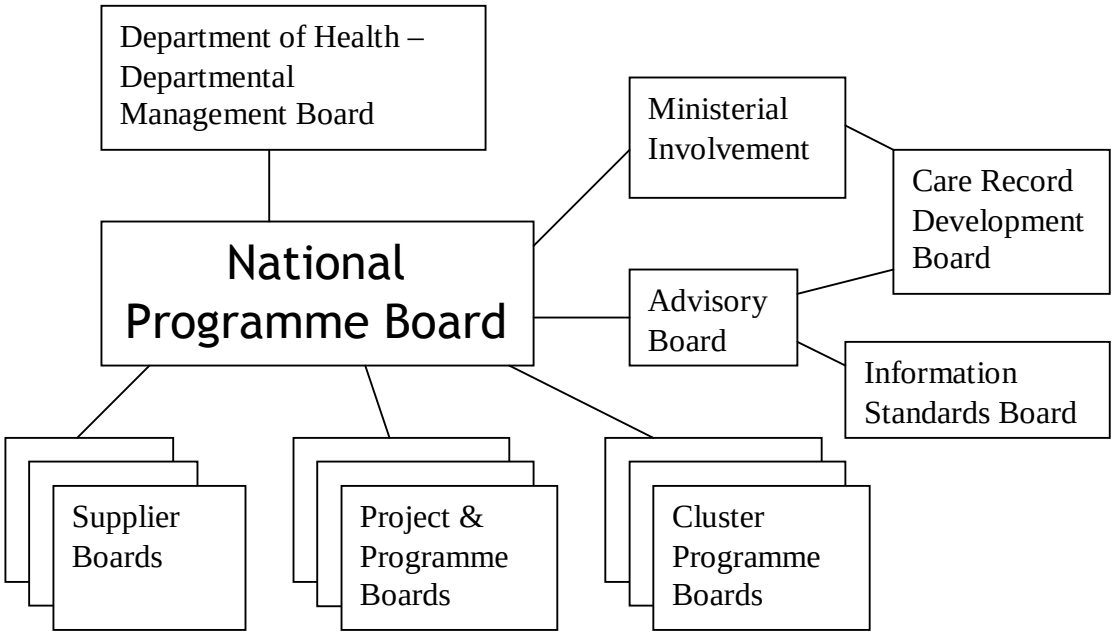
NHS Connecting forHealth (C4H)

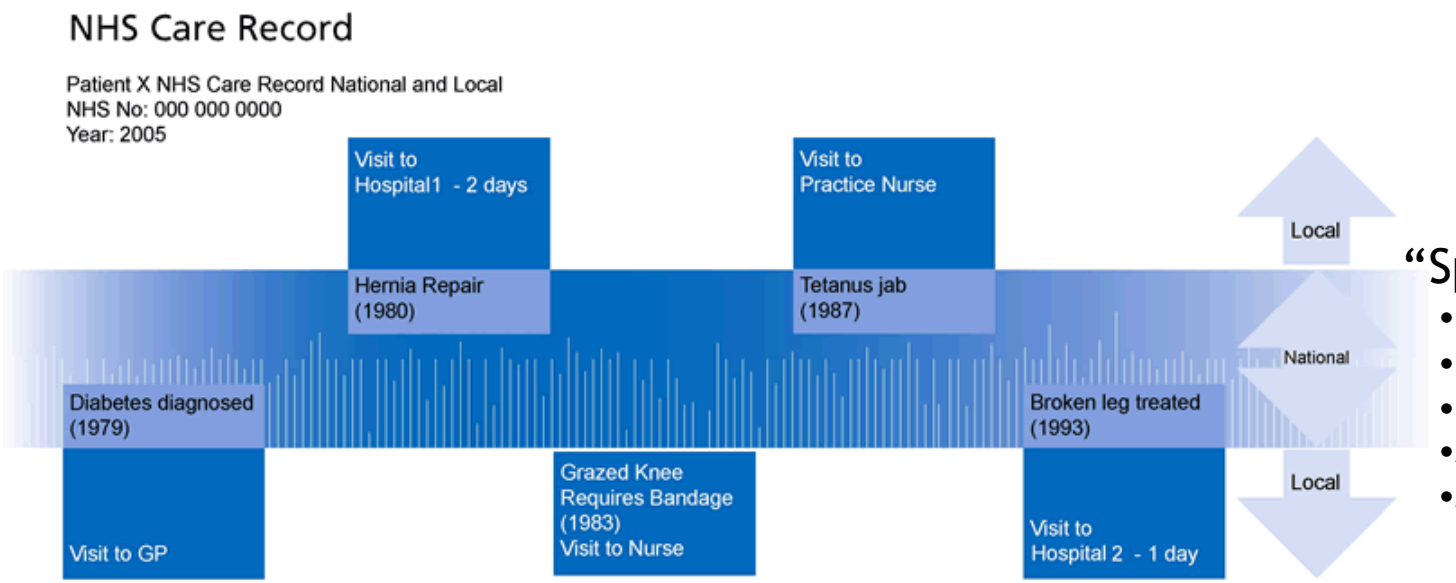


The National Programme for IT (NPfIT) is being delivered by one of the new Department of Health agencies known as NHS Connecting for Health (C4H).

Core components of C4H

- NHS Care Record Service (NCRS)
- Electronic booking (Choose and book)
- Electronic Transmission of Prescriptions (ETP)
- New National Network (N3)
- Quality Management & Analysis System (QMAS)
- Picture Archiving & Communications Systems (PACS)
- Secondary Uses Services (SUS)
- Contact (e-mail and directory services)

NHS Care Record Elements



"Spine" (National):

- NHS number
- DOB
- Name, address
- Allergies and ADRs
- Major tx summary

UK Computer Literacy

- *European Computer Driving Licence* (ECDL): IT qualification established in 1988
  - Promoted by British Computer Society as of 1996
  - NHS (England) adopted *ECDL* as reference standard for basic computer skills (2001)
- *Information Management and Technology* is a core part of the curriculum for General Medical Practice for 2007 (Royal College of General Practitioners)
- British Medical Association has established a new *Working Party for NHS Information Technology*

Health*Connect* Australia

- July 2000 – National Electronic Health Records Task Force Report
- Joint venture between Australian, state and Territory governments
- National health information network
  - Collection, storage, exchange of consumer health information via secure network, within strict privacy safeguards
  - Facilitate better integration of care and improve outcomes across health care system
- Well-defined business case, business architecture, project plan, benefits, governance
- Participation of both providers and consumers is voluntary (encouraged)

Some principles of scope of Health*Connect* solutions

- Support continuity of care across all levels and provider types
- Not intended to replace providers' clinical information systems
- Not required to provide CDS, but should be capable of providing data in form usable by such function
- Support, use and facilitate development of national health infostructure:
  - National provider director
  - National health consumer identifier
  - Health metadata repositories
  - Health information standards
  - Approved terminologies
  - Australian Catalogue of Medicines
- Should be extensible, to accommodate new types of providers and new types of eHR information without requiring redevelopment or replacement of core systems and services

Europe

- Goals for the European Community in health:
  - Maintain sustainable healthcare for all
  - Improve healthcare safety, reduce medical errors
  - Support secure authorised access to healthcare data, anytime, anywhere
  - Support the mobile citizen in seeking high quality care throughout Europe
- Centre européen de normalisation (CEN/ISSS) eHealth Focus Group
  - ...priorities and objectives for eHealth standardisation and interoperability
  - ...application of information and communication technologies (ICT) across the whole range of functions and services... which affect the health of citizens...

CEN/ISS Focus Group

The commission should formally establish an independent high-level European body for eHealth interoperability

- Priority strategic aims:
  - Improving access to clinical records
  - Enabling patient mobility and cross-border access to healthcare
  - Reducing clinical errors
  - Improving safety
  - Improving access to quality health information
  - Improving efficiency of healthcare processes

US Federal health IT initiatives

- Federal Health Architecture (FHA): Cross-agency activity to improve
  - coordination & collaboration on national HIT solutions
  - efficiency, standardisation, availability reliability of comprehensive health solutions
- Committee on Systemic Interoperability (CSI) – established by MMA in 01/2005 to
  - develop a strategy (priorities & timelines) for adoption & implementation of privacy-protected systems of electronic personal health information
- Consolidated Health Informatics (CHI) – OMB initiative for
  - cross-agency identification, implementation and maintenance of HIT standards
- e-Prescribing (eRx)
- CMS' VistA office eHR

US Department of HHS

- 04/2004 - Office of National Coordinator for Health HIT (ONCHIT) established
- 05/2004 – David Brailer appointed to ONCHIT
- 11/2004 – RFI for Nationwide Health Information Network (NHIN) published
- 06/2005 – Report on RFI issued (512 responses)
- 08/2005 – ONC structure, authority expanded
  - Immediate office of Nat'l Coordinator (IO/ONC)
  - Office of HIT Adoption (OHITA)
  - Office of Interoperability & Standards (OIS)
  - Office of Programs & Coordination (OPC)
  - Office of Policy & Research (OPR)

Commission on Systemic Interoperability recommendations to HHS (8/2005)

- Modify Stark Act and anti-kickback rules
- Ensure that individuals who disclose or misuse health information are subject to criminal prosecution
- Provide incentives for the use of health information technology
- Identify complete set of interoperable and not overlapping health data standards
- Require that medications and medical instruments be labeled electronically by their manufacturers

American Health Information Community (AHIC or "The Community")

- Established by Secretary of HHS in 09/2005 to:
  - Advise Secretary ... recommend specific actions to achieve a common interoperability framework for HIT
  - Serve as a forum for participation from a broad range of stakeholders and to provide input on achieving interoperability of health IT
- Composition: 17 voting members
  - Key leaders from public & private sectors
  - who represent stakeholders interests in advancing the Community and have strong peer support
  - appointed by Secretary for 2-year terms
- Chartered for 2 years, renewable to 5 years max
- Long-term governance to be assumed by private-sector HIT initiative within 5 years of charter

Certification Commission for HIT (CCHIT)

- Mission: To accelerate the adoption of interoperable HIT throughout the US healthcare system, by creating an efficient, credible, sustainable mechanism for the certification of HIT products
- Voluntary, private-sector initiative organised into 3 work groups
  - Functionality
  - Interoperability
  - Security & Reliability
- Accomplishments to date
  - 04/2005: Initial requirements published for comment
  - 08/2005: Revised requirements published for comment
  - 09/2005: Use cases, certification process work products published for comment
- To come
  - 12/2005: Recommendations for ambulatory eHR
  - 01/2006: Methods to evaluate ambulatory eHR
  - 10/2006: Test inpatient eHR
  - 10/2007: Test network infrastructure for transmitting records

Consider

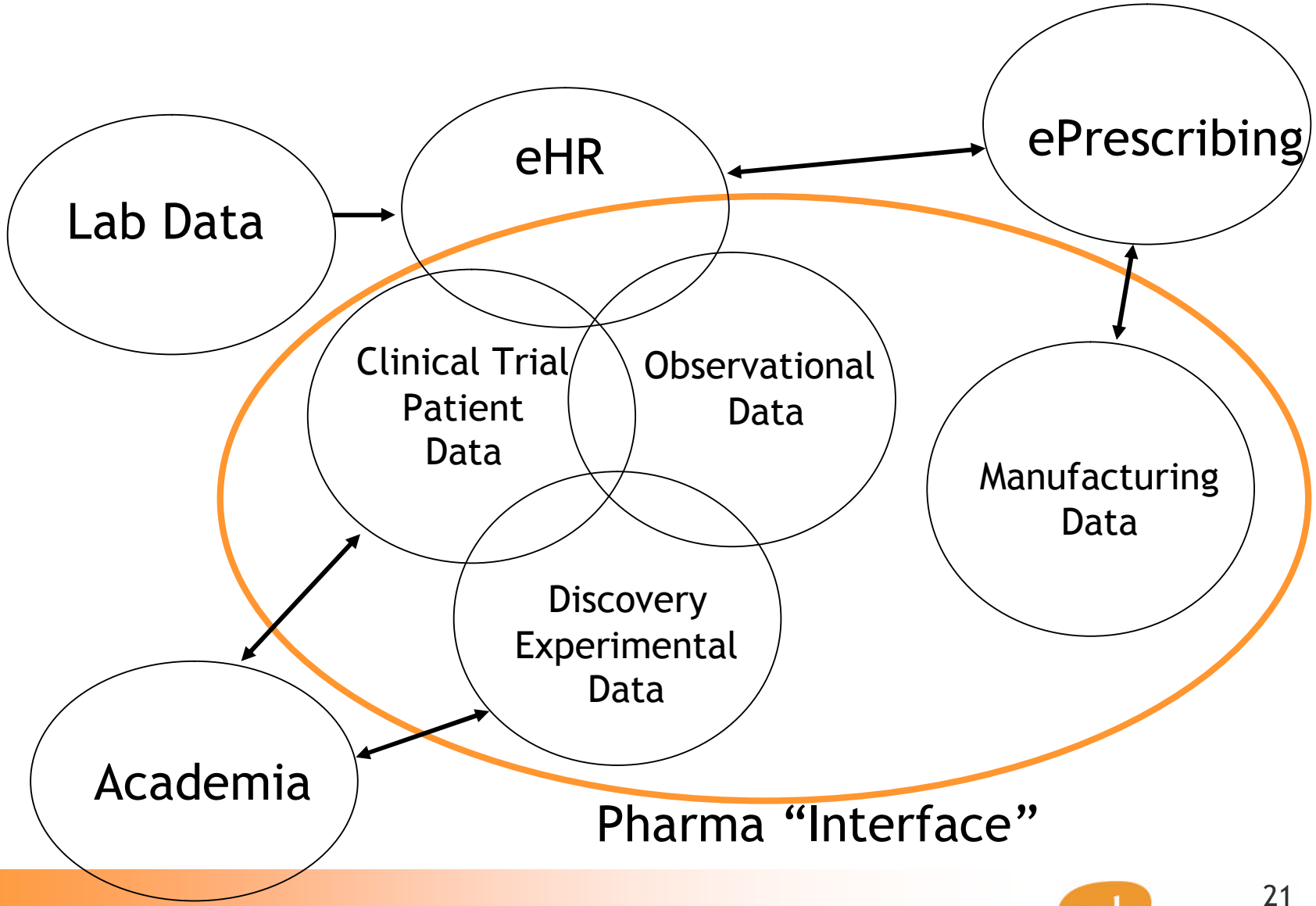
The features, challenges, value to pharma R&D of:

- Patient registry
- Claims/Billing data
- Computerised Physician Order Entry (CPOE)
- Results viewing
- Electronic prescribing (eRx)
- Computerised Decision Support Systems (CDS)

Barriers to adoption

- Lack of standards
  - Content
  - Structure
  - Terminology: SNOMED, MedDRA, LOINC, ICD
  - Exchange, messaging, network
- Limited interoperability
- Concerns about security, privacy
- Cost (initial investment, maintenance)
- IT/Health IT literacy

Information Network across Healthcare Domain



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Focused industry-related efforts

- HL7
- CDISC
- PhRMA IMPACC
- Interoperability Consortium
- Next steps...

IMPACC general recommendations

- Biopharmaceutical industry strategy that ensures support of the federal governments' efforts including HIT adoption incentives, eHR investment risk mitigation, and integration of clinical and practical HIT
- Industry involvement and influence in the development of RHIOs
- Strategic relationship with the Office of the National Coordinator of HIT (ONCHIT)

McKenzie et al, DIA Annual Meeting, 2005

IMPACC specific recommendations

Specific to eRx, eHR

- Influence CMS's eRX Proposed Rule by coordinating comments through the Medicare Part D PhRMA workstream
- Work with CMS and OIG to revisit safe harbour legislation
- Develop approach for biopharmaceutical industry to assist physicians with the adoption of HIT
- Support existing P4P programs and encourage adoption of broader programs that value improving quality of care and patient health outcomes
- Participate in groups that influence the development of health information data and technology standards

McKenzie et al, DIA Annual Meeting, 2005

IMPACC specific recommendations

Specific to RHIOs

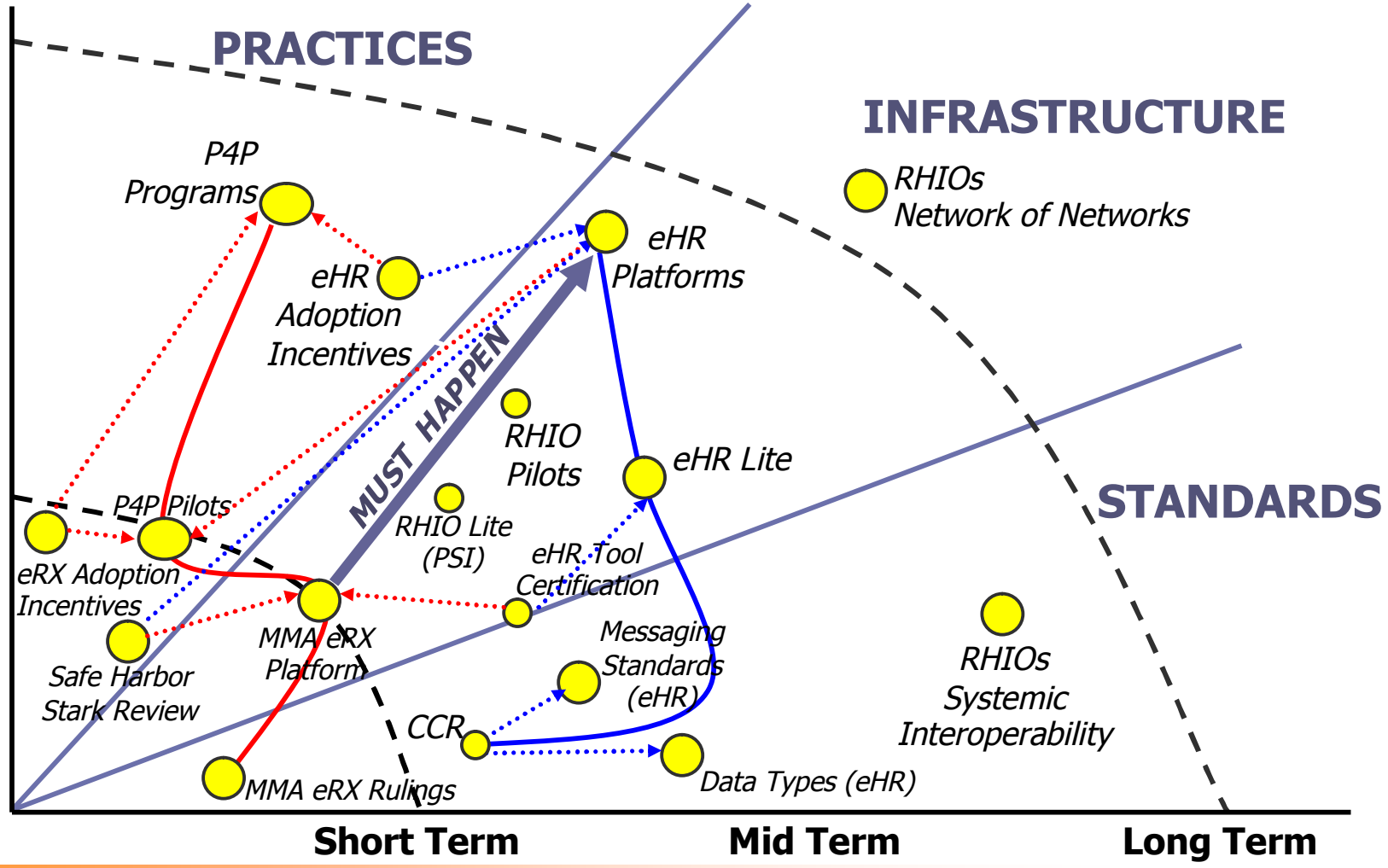
- Actively participate in groups that are shaping the future of RHIOS
- Identify statewide RHIO initiatives and participate through investments and “in kind” services in promoting their development

Specific to PHRs

- Identify emerging vendors that will likely lead the development and deployment of PHRs
- Participate in vendor pilots to measure and project the rate of adoption of PHRs and patients’ improved adherence to drug therapy
- Participate in public and private working groups focused on creating demand for PHRs

McKenzie et al, DIA Annual Meeting, 2005

US Healthcare Transformation



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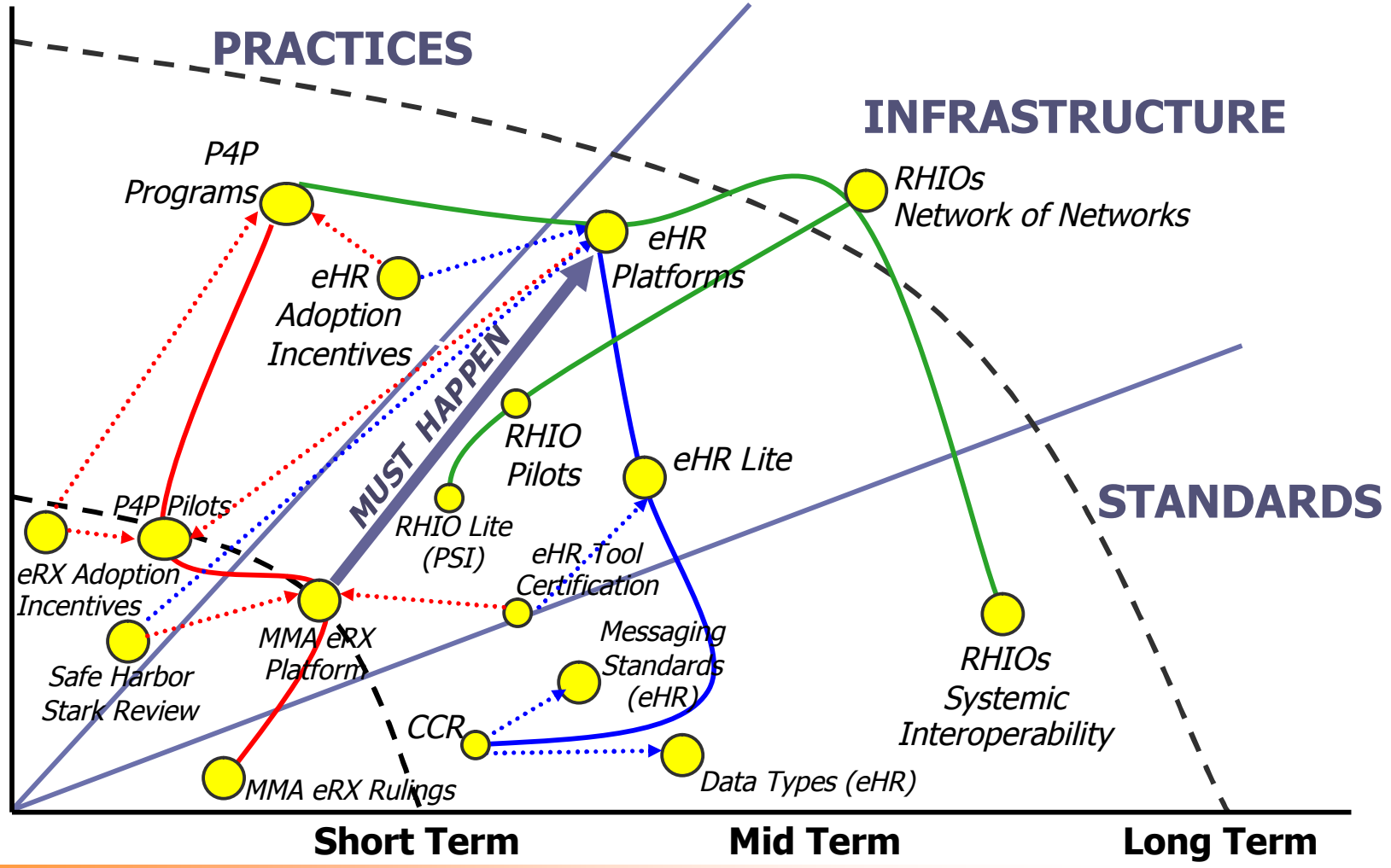
US Healthcare Transformation Towards NHIN



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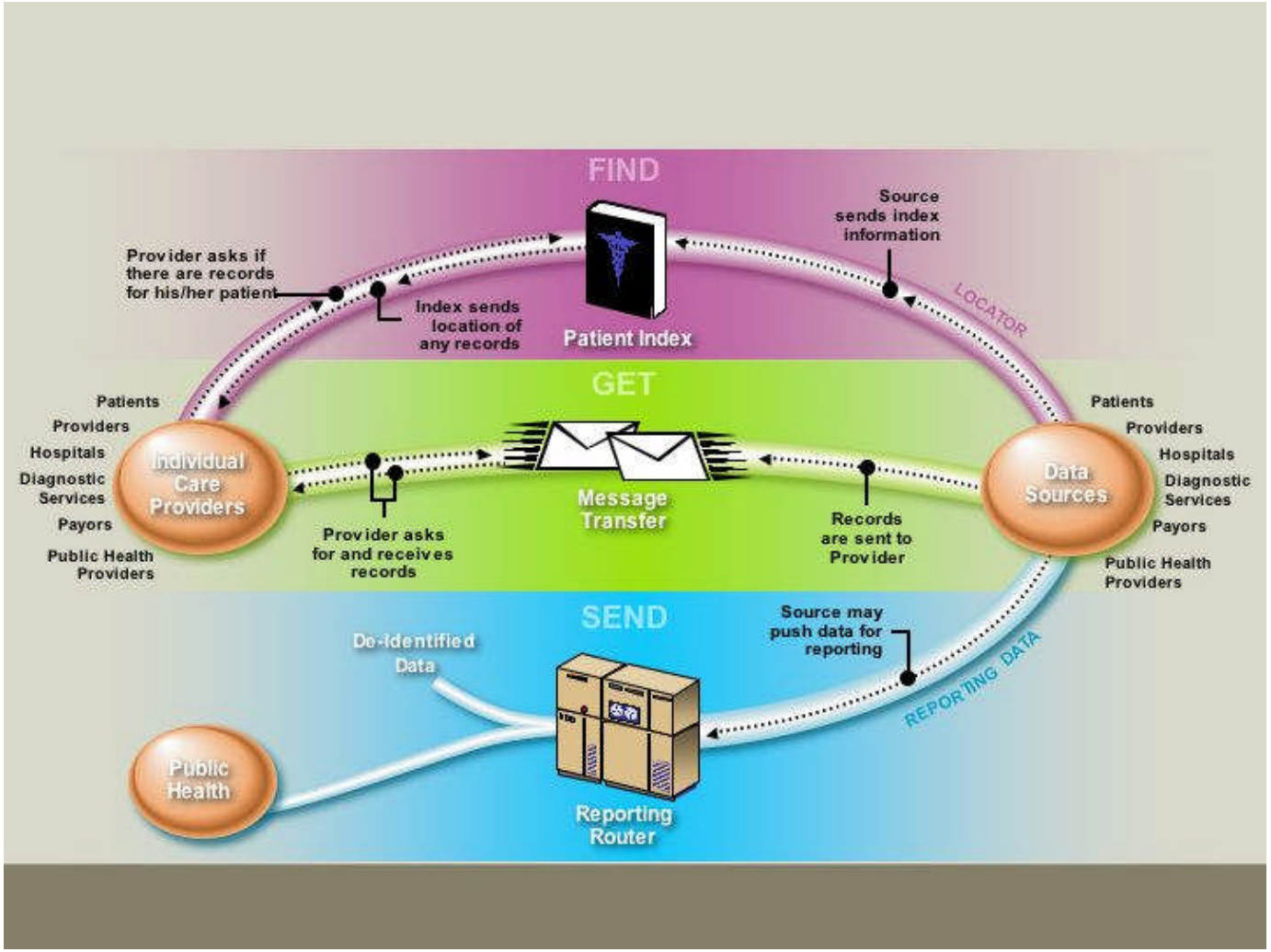
Selected reference websites

- www.ahima.org
- www.amia.org
- www.cchit.org
- www.cdisc.org
- www.ehealthinitiative.org
- www.himss.org
- www.hl7.org
- www.leapfroggroup.org
- www.nahit.org
- www.wedi.org
- www.connectingforhealth.nhs.uk
- www.healthconnect.gov.au
- europa.eu.int/information_society/activities/eten
- www.CENehealth.org
- www.ahrq.gov
- www.hhs.gov/healthit
- www.nci.nih.gov
- www.ncvhs.hhs.gov/050909lt.htm
- www.whitehouse.omb.gov/egov/gtob/health_informatics.htm
- http://forums.rsna.org
- www.centerforhit.org/x983.xml (AAFP center for HIT)
- www.acponline.org
- www.chcf.org/programs
- www.govhealthit.com

Backup

Health Information Environment



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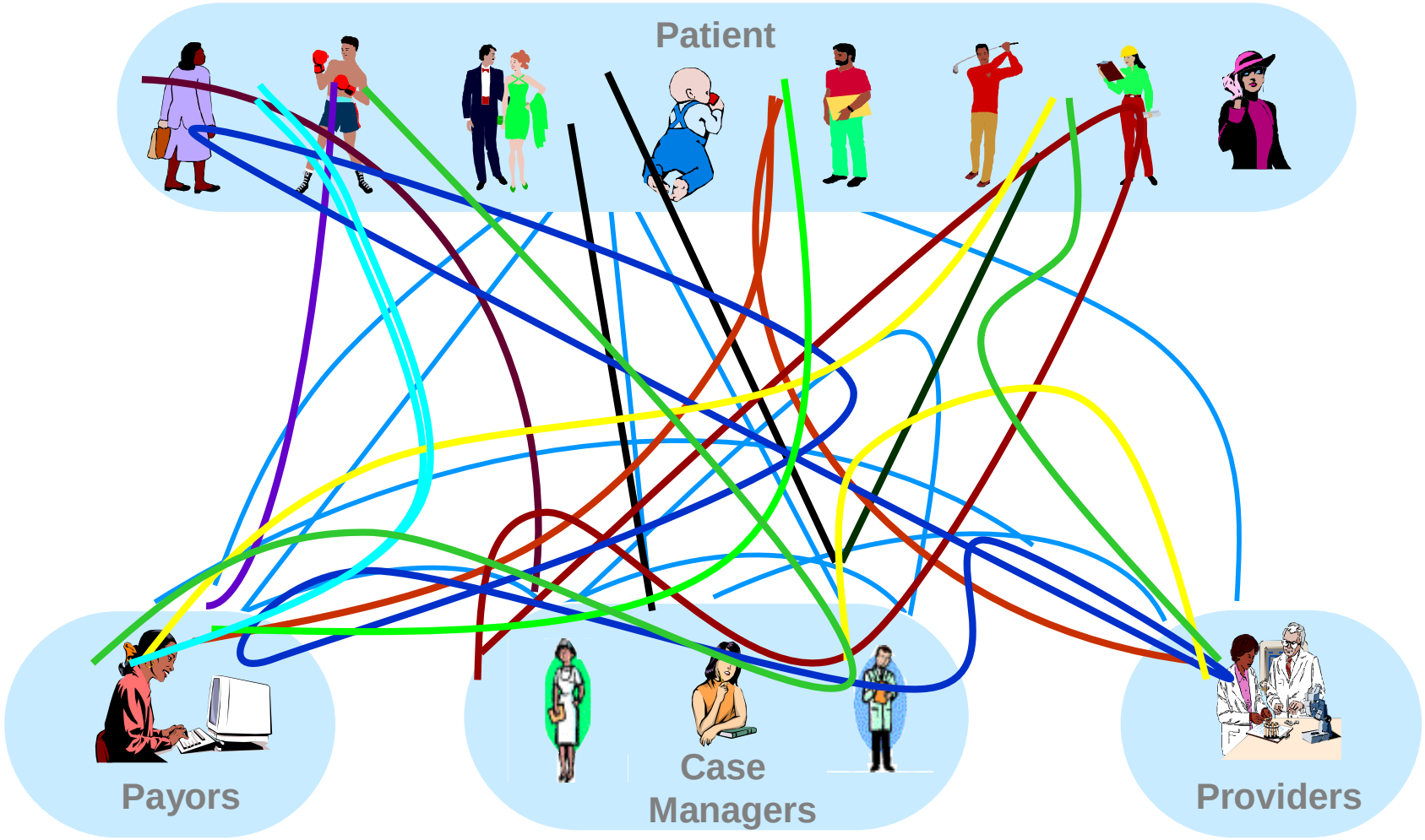
Healthcare Information Flow

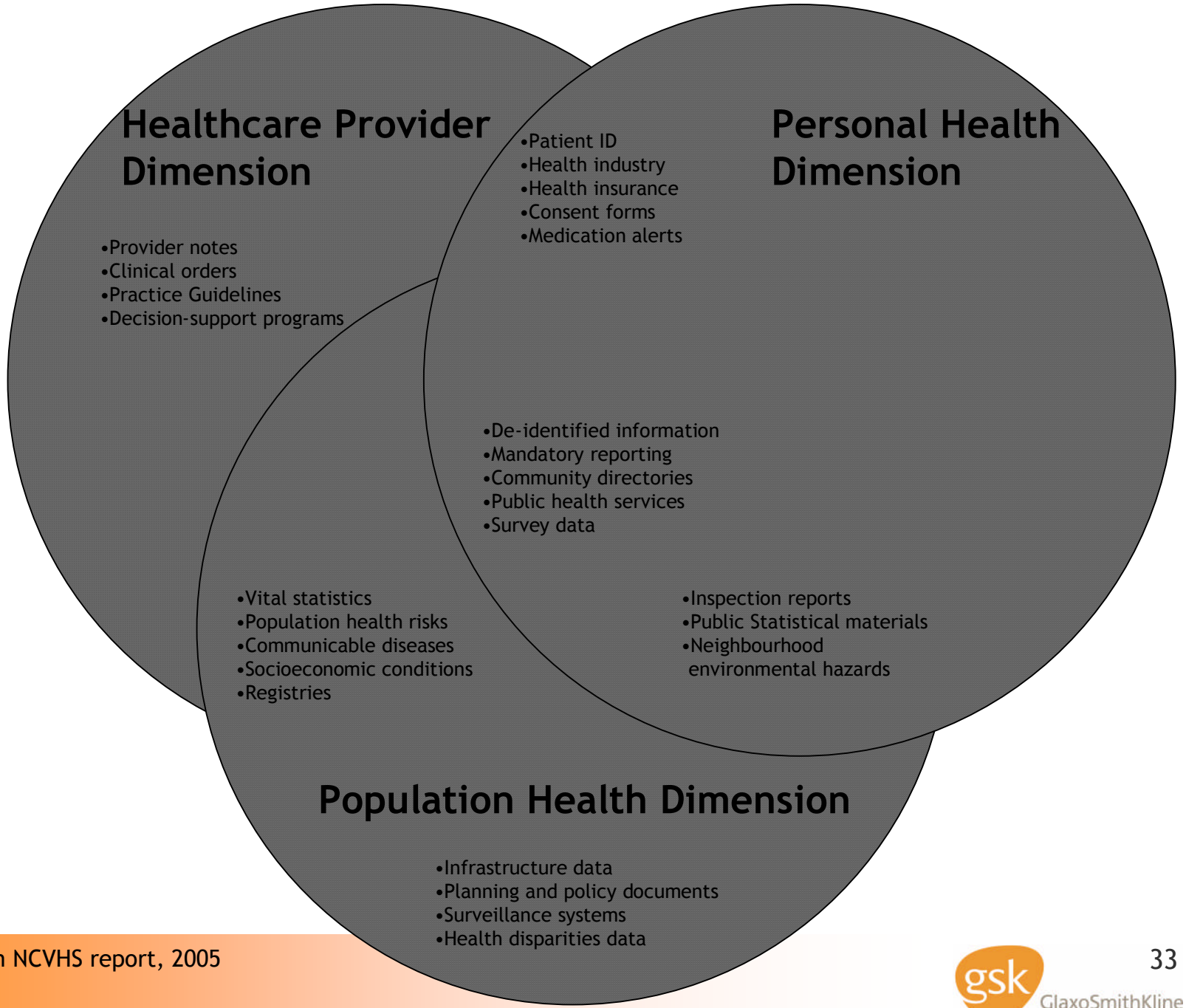


Source: Charlie Mead, MD, MSc. Oracle. HL7 Board Member. Presentation to CDISC Board. Jan 2004

Benefits of HIT Standards

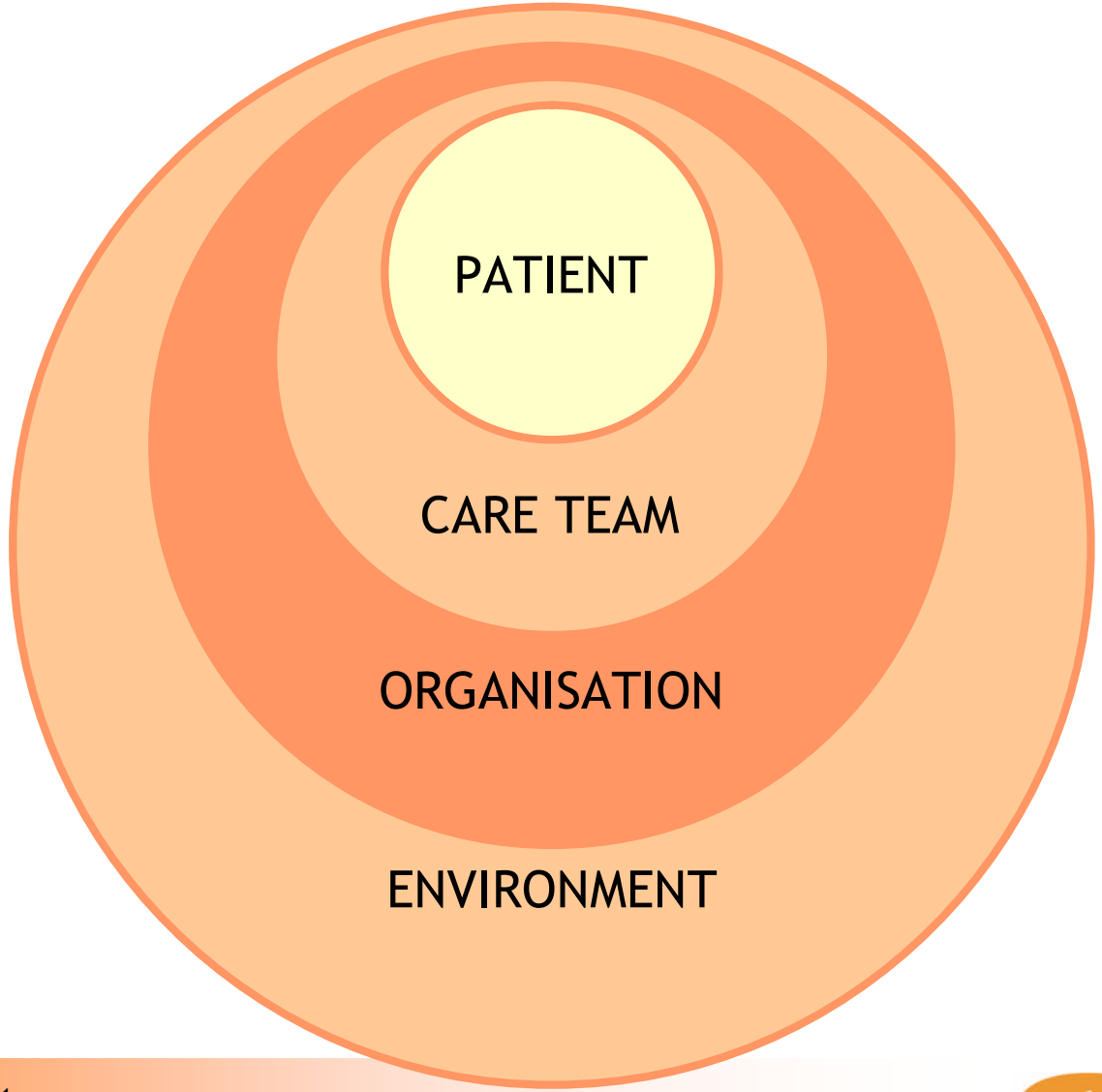
- Economies of scale
  - Increased productivity
  - Efficient operations; flexible resourcing
- Competitive advantage
  - Consistency, reliability, reproducibility
  - Focus on the science / core skills
- Added value
  - Easily re-use biomedical assets for new knowledge
  - Robust IT solutions
  - Rapid review of analysis-ready information
- Information Supply Chain is brought to order!

Information needs of three primary areas



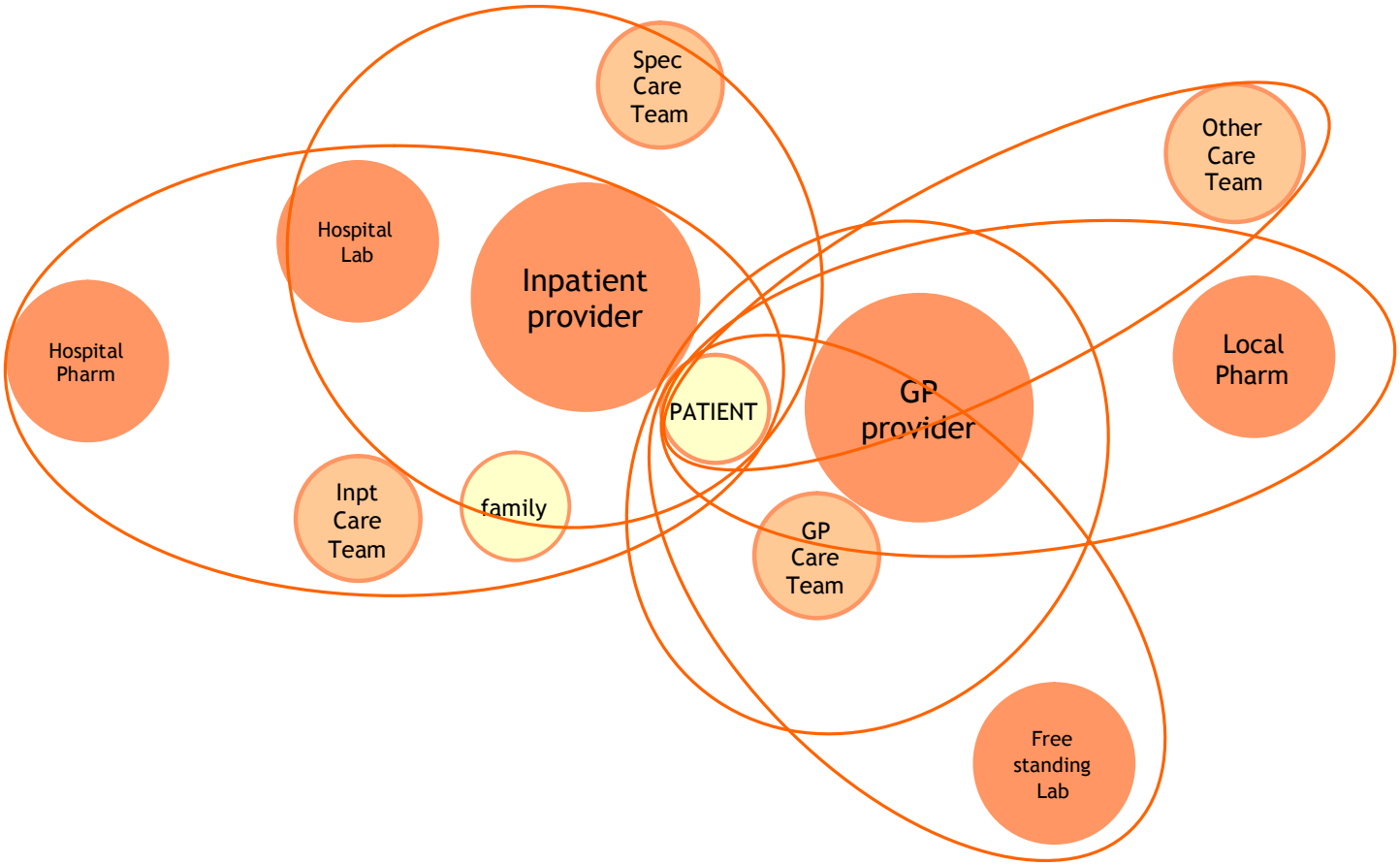
from NCVHS report, 2005

Four-tier healthcare system



Ferlie & Shortell, 2001

Ecology of Healthcare



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