The US Healthcare System: Unavoidable Realities, Harsh Truths and Stark Choices

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Laguna Niguel, 20 July 2009
A Few Current Challenges for the US Healthcare System

- $2.4 trillion dollar expenditures (2008): 16% of GDP ($1 in every $7)
- Escalating and unsustainable fraction of GDP
- Highest per capita expenditure in OECD
- $510 billion cost of chronic disease
- 2 million annual hospital-acquired infections
- 2.5 million hospitalizations due to adverse Rx reactions
- Highly variable treatment patterns
- Slow diffusion of best practices
US Government Healthcare Expenditures (2007)*

- 28% total revenues
- Medicare = 13% Federal budget = 20% US healthcare expenditures
- Medicaid = approx 22% of state expenditures
  - versus 21% for K-12, 10% for higher education, 8% transportation
  - increased from $89 billion in 2000 to $151 billion in 2007
- Medicare Trustees project Hospital Insurance Trust Fund will be exhausted in 2019

* From: M. Hartman et. al. (2009) Health Affairs 28,246
focus on late-stage detection and intervention
  – high cost
  – low reversibility of chronic disease processes
multiple reimbursements for fragmented (siloed) care versus integrated management of patient needs
illness versus wellness
inadequate social and economic incentives for wellness
Fee-for-Service and Runaway Healthcare Costs

- the invisible hand of Adam Smith is absent from healthcare
- terminal illness for governments, business and patients/consumers
- supply creates its own demand
- caregivers make more money by providing more care
- consumers don’t select treatment choice
- caregivers don’t consider cost in treatment decisions
- neither consumers nor caregivers evaluate cost or benefit and simply seek “maximum” care
U.S. Healthcare Costs are Unevenly Distributed

- 0.5% patients consume 25% of healthcare budget
- 1% consume 35%
- 5% consume 60%
- 10% consume 70%
- 75% of cost is for patients with chronic diseases
- end-of-life care

Source: Healthcare Reform Now
G. Halvorson,
Chairman and CEO
Kaiser Foundation Health Plan and Hospitals
Wiley, NY 2007 p.2
Five Chronic Diseases Impose the Highest Cost in Healthcare Expenditures

- diabetes
- CAD
- CHF/COPD
- asthma
- depression
- cancer = 8%
- infectious diseases = 7%
- trauma = 6%
- ob/gyn. = 4%
- bone and joint care = 2%

70% total healthcare costs
Demographic Trends and the Clinical and Economic Burden of Complex, Chronic Conditions/Co-Morbidities

- 23% Medicare beneficiaries have 5 or more conditions
- polypharmacy and AEs
- poor patient compliance
- multiple physician/venue encounters
- poor communication/coordination between siloed healthcare services
- procedure-based reimbursement versus care continuum integrated
Swine Flu (“Hamageddon?)
The Strategic Future of Healthcare

Economic Unsustainability

or

Reform and Rational Care

Confronting the Imbalance Between Infinite Demand and Finite Resources
Reasonable Expectations for Rational Healthcare

- what works
- why it works
- who it works for
- what works best
- when should it be used optimally

- validated evidence
- mechanism of action
- personalized medicine
- comparative effectiveness
- best practice guidelines, standard-of-care and malpractice

VALUE
Mencken’s First Law

“For every complex problem, there is always a simple solution and it is almost always dead wrong”

H.L. Mencken
Mencken’s (Second) Law

“Whenever they tell you it’s not about the money.....it’s about the money.”
Complex and Pervasive Problems in Healthcare with No Easy Solutions

- different ‘value’ metrics for different constituencies
  - patients, physicians, payors, politicians
- public expectations and populist politics
  - zero-cost, zero-risk = zero care
- lack of transparency in costs, billing and reimbursement
- anachronistic institutional mechanisms for national health policy debate

CHANGING MINDS AND CHANGING BEHAVIORS
OMB on Four Pillars of US Health Reform

- health information technology
- comparative effectiveness research
- prevention and wellness efforts
- financial incentives to provide better care and reduce unnecessary or excessive care

Peter Orszag, Director, OMB
Remarks at Institute of Medicine Workshop
Washington, DC, 21 May 2009
Quoted in “The Gray Sheet” 25 May 2009
“We cannot, in a responsible sustainable way, go to universal coverage unless we’re going to take cost control seriously”

“I go where the money is. Most of the increase in health spending comes from volume, not price, so that’s the appropriate target. By and large affecting price will have a relatively small effect”
Defining New Value Propositions for Healthcare Delivery

- social and economic value of reducing disease burden will rise
  - earlier disease detection and mitigation
  - rational Rx and guaranteed outcomes
  - integrated care management of complex chronic diseases
  - extension of working life
Defining New Value Propositions for Healthcare Delivery

- prospering in an environment of increasing constraints
- managing the limit(s) of society’s willingness and ability to pay for innovation
- controlling costs while enhancing quality and outcomes
- building new alliances to optimize value-driven outcomes
  - integration of Dx, Rx, Ix
- reliable information drives rational decisions
The Three Forces Shaping the Evolution of Healthcare

- Molecular medicine and personalized medicine
- Access, cost and quality of care
- Proficient use of information (e.health)

Demonstrating Value
“Fortunately, treatment will be relatively inexpensive, since you have the generic form of the disease.”
Ignoring The Obvious in Clinical Practice

- diseases are not uniform
- patients are not uniform
- a “one-size fits all” Rx approach cannot continue

- inefficiency and waste of empirical Rx
- cost of futile therapy
- medical error and AEs
Rational Therapeutics and Personalized medicine: Key Drivers

Science

Policy

Cost and Outcomes
Targeted Therapeutics:
Identification of Subtypes of Disease with Different Molecular Pathologies

- right Rx for right disease subtype

Dx – Rx combinations
K-RAS Profiling and Anti-EGFR Monoclonal Antibody Therapy

- higher response in patients with K-RAS versus mutant-K-RAS
- estimated $604 million/year savings (ASCO)
- regulatory demand
- clinical guidelines
- regulatory inertia
- payor adoption
The Emergence of Drug: Diagnostic Combinations

Invader® chemistry

5-Fluorouracil
Personalized Medicine
The Initial Era: Targeted Rx

- Opening era in linking disease molecular pathology to rational Rx
- Increasing payor, regulatory and public pressures for reliable ID of Rx-responsive patients
- Demand for Dx-Rx combinations will intensify
- Dx-Rx combination will become an obligate element of NDA/BLA submission and product labeling
- Development of Dx-Rx combinations as intrinsic components of R&D programs for investigational Rx
Molecular Diagnostics, Disease Subtyping and Pharmacogenomics

“Riches in the Niches”

- right diagnosis, the first time
- right Rx selection, the first time
- rise of Dx-Rx combination
- Rx approval and labeling/reimbursement only with obligate Dx?
UK: National Health Service

- full or partial refund for non-responders

- four Rx cycles
- 50% reduction in serum M protein
- NHS continues to fund
- <50% response company refunds cost of Rx
Outcomes-Based Risk-Sharing Agreements (ORBAs) Come to the USA

- reimburse average treatment cost (not just Rx) for fractures incurred after 6 months therapy
- improved Hb1Ac levels in diabetics over one year increases Rx discount to Cigna
• 1.5 to 3 million annual hospitalizations (US)
• 80 to 140 thousand annual deaths (US)
• est. cost of $30-50 billion
### Table of Valid Genomic Biomarkers in the Context of Approved Drug Labels

- **Alert**
  - 7/24/08

- **update labeling for Abacavir (Ziagen) to require pre-therapy screening for HLA-B*5701 allele to avoid fatal hypersensitivity**

http://www.fda.gov/cder/genomics/genomic_biomarkers_table.htm
From Pharmaceuticals to Pharmasuitables

Disease Subtyping:

Right Rx for Right Disease

Individual Variation and AE risk

Right Rx for Right Patient
The Evolution of Molecular Medicine and Information-Based Medicine: The Foundation for Rational Care and Personalized Medicine
Adoption of New Technologies in Healthcare

- not merely innovation in technology
- parallel evolution and adoption of new business, financial and organizational models
- complexity of harmonizing incentives for diverse constituencies
- critical role of public policies in defining market entry barriers
  - regulation, reimbursement
  - professional standards and sustaining status quo
  - administrative procedures
  - governance of third party health insurance payments
- cost-based, event-/procedure-based incentives versus integrated care and disease management
Reimbursement for Diagnostic Tests

- inadequate US Medicare coding and payment mechanisms
  - outmoded, out-dated, lacking in transparency, inconsistently applied
- inappropriate assignment of existing CPT codes to new tests
- off-label use but with tangible clinical benefits
- engagement of third party payers who derive economic/clinical value from new Dx

VALUE-BASED REIMBURSEMENT VERSUS COST-BASED REIMBURSEMENT
Personalized Medicine:
Disease Predisposition Profiling
unproven validity of many claimed gene-disease associations

communication of probabilistic risk

health literacy and consumer response to ‘risk’ information

effectiveness in motivating health improvements

role of MD and/or genetic counselors in request/interpretation of test in varied care settings

psychological impact on future behavior and knowledge of familial implications
Personalized Medicine: A Broader Definition

Health Status Monitoring and the Promotion of Wellness
On Body: In Body Sensors/Devices
For Real Time and Remote Monitoring of Individual Health Status
“Savings from broad-band remote monitoring
for all chronically ill patients
are potentially quite remarkable
....as much as 30 percent
of all hospital, out-patient and drug expenses”

Robert Litan
Kaufman Foundation December 2005
cited in: Advancing Healthcare Through Broadband
Internet Innovation Alliance White Paper 2007
Objective

- remote monitoring of health status

Applications

- multi-feature monitoring and broadband wireless networks
  - ubiquitous sensing
- enhanced autonomy for in-home aged
- proactive alerting and intervention to mitigate health incidents
- monitoring of patient compliance
- coupled linkage to remote Rx dispensing for efficient disease management
The Costs of Non-Compliance with Rx Regimens

- $177 billion projected cost
- 20 million workdays/year lost (IHPM)
- 40% of nursing home admissions
- projected 45-75% non-compliance (WHO)
- 50-60% depressed patients (IHPM)
- 50% chronic care Rx (WHO)
Challenges in the Management of Complex Chronic Conditions and Co-Morbidities

- multiple conditions
- multiple providers
- multiple coding and reimbursement policies
- multiple treatments
- multiple medications
State of Technology in Aging Services According to Field Experts and Thought Leaders

By:
Majd Alwan, Ph.D.,
Center for Aging Services Technologies (CAST)
American Association of Homes and Services for the Aging (AAHSA)

and

Jeremy Nobel, M.D., M.P.H.,
Harvard School of Public Health

Report Submitted to: Blue Shield of California Foundation

February 2008
Challenges to Moving Forward with the (Advanced) Medical Home Model for Coordinated Care

- lack of suitably trained PCPs
- downward trend in PCP population
- insufficient capital, incentives and facilenes of HIT infrastructure
- uncertain financial rewards and savings
- inadequate reimbursement policies for preventive care
- turf wars and tensions
  - care management
  - vendors/health plans
  - reduced revenues for hospital with significant PCP network
  - assignment of malpractice liabilities
The Pathway to Covering America

Ensuring Quality, Value and Access
Seeking ‘Quality’ in Healthcare

The Joint Commission
AMA
JCAHO
DHHS
ACP
HIPAA
Hospital Quality Alliance
NCQA
HIPAA
AHRQ
Leapfrog
NCQA
H-CAPHS
ATA
AHIMA

BlueCross BlueShield Association
HEDIS
Certification Commission for Healthcare Information Technology (CCHIT)

Tax Relief And Health Care Act (TRHCA)

National Alliance for Health Information Technology

National Quality Forum
RHIO
“You have a (healthcare) system that traps us into bad performance because it’s the only way you can bill”

Hon. Newt Gingrich
Medical Device Daily (2009) 27 Jan. p8

“If it isn’t billable – it isn’t going to happen!”
Knowing What Works (or Doesn’t)

- Pervasive Inefficiencies and Errors in Healthcare Created by Empirical Care and Lack of Robust Outcomes and Performance Data
Knowing What Works (Or Doesn’t!)

- patients have at best 50:50 chance of receiving most advisable care
- ineffective, redundant and inappropriate care
  - projected 30-50% of healthcare spending
- only 15% of clinical interventions validated by clinical trials/regulatory review
- wide geographic variations in quality and cost of care
- protracted 15 to 25 yr timeframe for adoption of best practice(s)
● urgent imperative to eclipse “the archeology of clinical practice”

● limited fraction of clinical interventions validated by rigorous analysis/evidence

● benefits/risks of new technology never fully known at launch

● evaluation in clinically-relevant context(s)

● cost of CER studies

● standard-of-care and malpractice
How Much New Technology Can We Afford?
“Half of all growth in healthcare spending in the past several decades was associated with changes in care made possible by advances in technology”

CBO January 2008
Key Questions

• what is the role of technology innovation in healthcare?

• do current public and private strategies support innovation and disruptive technologies?

• how should the ‘value’ of new technologies be assessed?

• how should dissemination of new value-added technologies be supported?
The High Price of the Lack of Evidence

- $2.3 trillion healthcare economy
- $110 billion R&D investment
- $0.9 billion on technology assessment
- additional $1.2 billion in 2009 “stimulus” package
Knowing What Works: Healthcare System Performance Assessment

- Allocation of incremental dollars to low-priority care as often or more frequently than high-priority care merely exacerbates current distortions.
- Refine analyses to focus resources where they will do the most good.
- Encourage optimal care via weighted measures that credit high-priority care over low-priority care.
- Lack of investment to devise pragmatic metrics suitable for longitudinal assessment.
- New incentives for CER.
- New incentives (carrots and sticks) for obligate adoption.
Comparative Effectiveness Research (CER)

- 2009-877
- American Recovery and Reinvestment Act (ARRA) of 2009
  - P.L. 111.5
- $1.1 billion
  - NIH ($400 million)
  - AHRQ ($300 million)
  - HHS ($400 million)
- Institute of Medicine (IOM) Report
  - 30 June 2009
  - top 100 priority projects

Federal Coordinating Council for Comparative Effectiveness Research Membership

Recovery Act Allocates $1.1 Billion for Comparative Effectiveness Research
superficial appeal of rational policy belies the complexity of rigorous CER
- endpoints/outcomes
- methodological and reporting standardization
- stringency of patient selection/treatment regimen/compliance
- prospective versus retrospective data

payor engagement and impact on reimbursement policies
- predisposition to choose lower cost intervention(s)?
- risk of abuse and rationing of care
Comparative Effectiveness Research (CER)

- superficial appeal of rational policy belies the complexity of rigorous CER
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Who sets priorities and evaluation criteria?
Comparative Effectiveness Research (CER)

- predisposition to select unidimensional interventions with quantitative direct costs
  
  versus

- complex, multidimensional interventions and assessment of direct/indirect benefits

- drugs, devices and procedures
  
  versus

- different ways of paying for care
  
  versus

- different organizational models for healthcare delivery
D**emonstrating Value:**

**Inadequate Evaluation Methods**

- lack of consensus on outcome metrics and their application
- inability to integrate direct (healthcare) and indirect (socio-economic, QOL) costs
- inadequate tools to identify ‘compounding’ of health benefits (impact on co-morbidities)
- methodological/regulatory/reimbursement policies
  - prospective versus retrospective data
  - role of randomized clinical trials (time, cost)
  - setting guidelines and compliance monitoring
  - QALYs: national differences
“Not everything that counts can be counted, and not everything that can be counted, counts”

Albert Einstein
Systems-Based Approaches to Complex, Multi-Dimensional Challenges

- Improvement methods and metrics
- Evidence and best practices
- Human factors
CONNECTIVITY AND INTEGRATED CARE
Information-Based Medicine

HELL IS THE PLACE WHERE NOTHING CONNECTS — T.S. ELIOT
Paper Kills!:
The Inefficiencies and Risks Created by Sustained Dependence on Paper Healthcare Records
The Unacceptable Cost of Unconnected Healthcare

- extravagant waste via excessive duplication of tests/procedures
- error via lack of crucial data
- lack of data capture for outcomes analysis and individual physician performance
- failure to capture population-based disease parameters
  - sentinel public health/national security
  - meta-analysis of outcomes
  - drug and device safety and recall
“Until the person receiving the product is responsible in some fashion for the costs, there will be no incentive to spend responsibly”

Scott Serota
CEO, BCBS Association of Chicago
Chief Executive Magazine, March 2007 p. 50
After a Short Stay in America, Michelangelo's David Returned to Europe
The shape of things to come

Diabetes
POP 20,870,000
Annual Excess Healthcare Costs Related to Consumer Behavior

Conditions related to obesity and overweight: $200 billion

Smoking: $191 billion

Non-adherence to drug regimens: $177 billion

Alcohol abuse: $2 billion

The Case for Wellness

- 30-60% of health plan claims are related to health risks that are modifiable by nutrition, exercise, stress reduction, etc.
- Well-managed employer health and productivity management programs return $6-15 for every dollar spent.
- Cost of smoking: healthcare cost of smoking over a lifetime = $220K per person = $40 in healthcare cost per pack of cigarettes smoked!
- 67% of the US population is overweight or obese, and 22% of current healthcare costs are obesity-related.

Source: Wellness Councils of America
No two employees are alike.
And neither are their health decisions.

Your employees’ decisions impact not only their health, but also your company’s costs and productivity. To enable better decisions, UnitedHealthcare is leading the way with personalized health care solutions designed to help people—and businesses—stay healthy.

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- And more

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Personalized Medicine: Consumer-Centric Healthcare: A Key Driver

- cost-shifting to consumers
- clinical and economic benefits of coordinated care of complex chronic conditions
- lifestyle and disease risk mitigation
- cost-driven transitions from ‘passive patient’ to ‘engaged consumer’
- new information intermediaries
Telecommunications and Media Industry Convergence: Implications for Healthcare
The Infocosm: Emerging Networks of Global Connectivity
The Changing Nature of Social Interaction

Herd Behavior: 1951
1.3 Million Bathers, Coney Island, NY

Herd Behavior: 2009
Social Networks and Virtual Communities
Consumer-Directed Healthcare: The Wellness Premium

- leveraging social and peer networks
- increased role of fitness industry and entertainment in healthcare
  - "success via distraction"
- "virtual touch"
  - web-based consultation and diagnostic algorithms
  - emerging generational gap in need for direct physical interaction with physician
- evolution of ‘near-patient’ health status profiling
  - POC and in-home Dx
  - OBIBs
The Great Network Inflection Point

- multi-billion user internet
- AORTA (always on, real time, access)
- connectivity via low cost, portable, multi-function devices
  - “universal connection devices”
- every piece of information will have geographic and time coordinates
- ubiquitous access plus customized profiling creates a world shaped by individual choices
Connecting Patients (and Consumers) to Optimum Healthcare Resources

PMRs and patient support networks for linkage to clinical trials and expertise

Integrated care of chronic conditions and specialty Rx distribution
In-Home Health Connection: Engaging the Elderly
The Dominant Future Element in Primary Healthcare Delivery???
• 2010: 15 Petabits ($10^{16}$) / $250,000

• Human Genome: 10 Gigabits ($10^{11}$)

For a few million dollars, one could store the complete genome of every American and European

...for several more, could add credit card records, telephone logs, travel history,...
When Will Interoperable Electronic Medical Records Become a Reality?
• $19 billion for healthcare IT

• Medicare payment up to $44K for physician with qualifying EHRs (2011)

• Medicare reductions for physicians/hospitals that lack qualifying HER by 2014

• CPOE by 2011 to qualify for Medicare incentive payments

• HITECH: separate new law embedded in ARRA
  – Health Information Technology for Economic and Clinical Health (HITECH) Act
  – policies/standards for national HLx network
A New Healthcare Ecosystem Arising From Technology and Market Convergence

Data Mining and Integration Services

- passive/active data collection
- analytics and network architecture
- EMR/PMR performance and outcomes analysis

Integrating Technology Platforms
- Dx/Devices
- Rx
- Hlx

Patients
- consumers

Services for integrated care

Increasingly Targeted Care and Efficient Use of Finite Resources

Payors
we see
one doctor, many experts.

Microsoft is partnering with industry leaders to develop the health care system of the future. By creating a seamless national network that provides a more efficient flow of medical information, health care providers are better informed. Patients are better served. Find out more at microsoft.com/potential.
Creating a New Network of Connected Expertise to Accelerate Innovation in Healthcare Delivery

- ever faster generation of new information
- diversification of innovation sources
- current healthcare ecosystem is too fragmented to fully leverage novel content and shared learning
- global sourcing
- rise of new business models of ‘expertise networks’ that eclipse current monolithic single company innovation models
From Ambiguity to Certainty: Competitive Superiority via Analysis of a Burgeoning Infocosm

- new intermediaries for analysis/packaging of healthcare data
- global sourcing of data and expertise
- lower transactional costs
- higher efficiency in use of expensive, finite resources
- increasingly predictable cost structure and predictable performance of products and procedures
- improved clinical and economic outcomes
Healthcare Reform:
Identification of New Value Drivers

- Precision diagnostics: the most powerful driver of rational care decisions
- Structural shift in healthcare delivery from encounter-/procedure-driven to incentives for integrated disease management
- Clinical and economic benefits of coordinated care of complex chronic conditions
- Cost-shifting to consumers
- Lifestyle and disease risk mitigation
- Real-time health information and individual health status tracking
- Cost-driven transitions from ‘passive patient’ to ‘engaged consumer’
The Urgent Need for Reform of the Medical Education Curriculum

- molecular medicine
- engineering-based medicine
- information-based medicine
The Urgent Need for Reform of the Medical Education Curriculum

- molecular medicine
- engineering-based medicine
- information-based medicine
- recalibration of the role of the MD in healthcare delivery
  - from ‘art’ to ‘science’
  - from individual artisan to integrated team player
The Coming Convergence in Healthcare Delivery

Technologies

- biotechnology, medicine, engineering, computing

Clinical Practice

- molecular medicine and increasingly customized care
- diagnostic, drug and device combinations
- POC testing and remote monitoring
- reduced error and improved compliance
- improved clinical and economic outcomes

Realigned Incentives

- integrated care for complex chronic diseases
- earlier disease detection and risk reduction
- wellness versus illness
- health status monitoring
The Coming Convergence in Healthcare Delivery

Consumers

- increased personal responsibility for health
- new incentives for wellness/compliance
- health status monitoring

Connectivity

- integrated care networks for chronic disease
- improved outcomes and effectiveness
- social networks and informed consumers
- new supplier networks of specialized turnkey expertise
- value added ‘content’ services for clinical data mining
The Urgent Imperative for New Drivers of Efficiency and Equity in Healthcare Delivery

- Molecular profiling of patients and their diseases
- Proficient use of information: anytime, anywhere
- Earlier detection and prevention of disease episodes

- Rational Therapeutics and Personalized Medicine
- Optimum Use of Costly Resources
- Wellness versus Illness
Building an Integrated Framework for Personalized Medicine

- earlier detection and prevention of disease episodes
- optimum Rx selection and outcomes
- customized information for optimum decisions
- molecular profiling of patients and their diseases

- Patients
- Payors
- (Bio)Pharm. Cos.
- VALUE
- Rx
- Dx Devices
- Ix