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

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A Few Current Challenges for the US Healthcare System

- 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
- Shortage of 1 million nurses
- No reserve capacity for disasters, epidemics or pandemics
Pervasive Inefficiencies and Errors in Healthcare Created by Empirical Care and Lack of Robust Outcomes 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
- Protracted 15 to 25 yr timeframe for adoption of best practice(s)
- Wide geographic variations in quality and cost of care
Improving Care for Patients with Complex Conditions

- 23% Medicare beneficiaries have 5 or more chronic conditions
- # 65 year olds as Medicare beneficiaries will double by 2017
- multiple physician/venue encounters
- duplicate testing
- polypharmacy and potentially conflicting treatment strategies
- poor communication of essential clinical information between physicians
- poor regimen compliance by patients
- increased risk of poor quality care and avoidable costs
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

*Source: Healthcare Reform Now
G. Halvorson, Chairman and CEO
Kaiser Foundation Health Plan and Hospitals
Wiley, NY 2007 p.2
Share of Personal Health Care Expenditures Paid Out of Pocket

<table>
<thead>
<tr>
<th>Year</th>
<th>Percent</th>
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<tbody>
<tr>
<td>1975</td>
<td>33%</td>
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<tr>
<td>1985</td>
<td>26%</td>
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<td>1995</td>
<td>17%</td>
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<tr>
<td>2005</td>
<td>15%</td>
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<td>2015</td>
<td>13%</td>
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The Management of Expectations in Healthcare

- the entitlement mentality: no limits
- public cynicism of government/corporate motives
- public literacy and comprehension of risk: benefit
  - expect constant progress but zero-risk
- inadequate social and economic incentives for ‘wellness’ and personal responsibility for health
“The mantra of competition based on value is that there is no such thing as a national health care market. What we have is a network of local markets.”

Michael O. Leavitt, Secretary
US Dept. of Health and Human Services
November 5, 2007
THIS MIGHT HURT A LITTLE.
The Audacity of Hype
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.”
The Threat Posed by Unconstrained Growth in Healthcare Costs

- fiscal balance of governments
- cost structure of employers/companies
- incomes of individual patients
- inequity in access to care
- eroded quality of care
- rationed end-of-life care
- political inertia and eventual draconian rationing policies
The Strategic Future of Healthcare

Economic Unsustainability or Reform and Rational Care

Confronting the Imbalance Between Infinite Demand and Finite Resources
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)

VALUE
Value

- trigger change in clinical behavior
  plus
- demonstrable health benefits
  plus
- demonstrable economic benefits — direct/indirect
Maintenance of Health and Wellness: A Critical Economic and Clinical Dimension to Healthcare Delivery

The Principle Intentions of Physick
Thomas Curteis (1704)

Key Needs

- earlier detection of disease (pre-symptomatic) or disease progression
- remote monitoring of “wellness”
- instant access to patient information
  - anytime, any place, any patient
- increased personal responsibilities for wellness and disease management
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 caused by empirical Rx
- cost of futile therapy
- medical error and AEs
“If it were not for the great variability among individuals, medicine might be a science, not an art”
Sir William Osler (1892)

“Because of the great variability among individuals, medicine must finally become a science, not an art”
US Healthcare Costs

- administration 35%
- personnel costs 35%
- procedures 18%
- drugs 12%
- in vitro diagnostics 0.01%

- Diagnostic Tests (Dx) Influence 85% of Clinical Actions
- From Cost-Based Reimbursement Policies to Full Value-Based Pricing of Nex-Generation Dx
Next-Generation Molecular Diagnostics and Biomarkers

The Fundamental Technology Platforms For Molecular Medicine
and
Vital Elements of the Future Healthcare Value Chain
“You may believe you’ve been overcharged, but, remember, you’re overmedicated.”

“I think the dosage needs adjusting. I’m not nearly as happy as the people in the ads.”
Disease Subtyping Based on “Molecular Signatures”

From: C. Haqq et al. (2005) 102, 6092

B1 skin, B2, melanocytes, B3, melanoma, B4 and 5 metastatic melanoma
Pharmacogenetic Predisposition to Adverse Drug Reactions

- 1.5 to 3 million annual hospitalizations (US)
- 80 to 140 thousand annual deaths (US)
- est. cost of $30-50 billion
Personalized Medicine: From Pharmaceuticals to Pharmasuitables

Disease Subtyping: Right Rx for Right Disease

Reduction of Adverse Drug Reactions
Reimbursement for Diagnostic Tests

- inadequate US Medicare coding and payment mechanisms
  - out moded, out-dated, lacking in transparency, inconsistently applied
- no effort to link reimbursement to value
- inappropriate assignment of existing CPT codes to new tests
- engagement of third party payers who derive economic/clinical value from new Dx
  - Genomic Health Oncotype Dx
Identification of Predisposition to Future Disease: The Quest for Robust Biomarkers
Consumer Genomic Profiling

Knome
23andMe
ScientificMatch.com
Navigenics
On Body: In Body (OBIB) Sensors for Real Time and Remote Monitoring of Individual Health Status
On Body: In Body Sensors/Devices
“If I’d known I was going to live this long I’d have taken better care of myself”

James Herbert ("Eubie") Blake
Musician at age 100, in 1983
Remote Monitoring of Health Status

- Microtags
- In-Body Wireless Tags
- Sensor on a Chip
- Environmental Sensors
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% chronic care Rx (WHO)
- 50-60% depressed patients (IHPM)
Smart Pills and Smart Containers: Improving Patient Compliance

- high definition logos and bar codes
- electronic ID
- covert chemical taggants
- pearlescent coatings
- RFID tags
Annual Excess Healthcare Costs Related to Consumer Behavior

Conditions related to obesity and overweight

Smoking

$191 billion

Non-adherence to drug regimens

$567 billion

Alcohol abuse

$177 billion

$2 billion

The Unacceptable Cost of Unconnected Healthcare

- cultural, fiscal and legal barriers to transformational electronic connectivity achieved by other sectors
- major obstacle to safe and efficient healthcare delivery
  - 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
What Ever Happened to …… ?

  Assessment and accountability: the third revolution in medical care.
  NEJM 319, 1220-1222

  The Quality of Care: how can it be assessed?
  JAMA 260, 1743-48
The Pathway to Covering America

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

The Joint Commission
AMA
DHHS
ACP
HIPAA
JCAHO
CMS
HEDIS
NCQA
AHRQ
IOM
H-CAPHS
Leapfrog
ATA
BlueCross BlueShield Association
NCQA
National Alliance for Health Information Technology
Certification Commission for Healthcare Information Technology (CCHIT)
National Quality Forum
Dossia®
HITSP
HITSP
RHIO
Tax Relief And Health Care Act (TRHCA)
AHIMA
Dossia
National Alliance for Health Information Technology
“Not everything that counts can be counted, and not everything that can be counted, counts”

Albert Einstein
Performance Measurement in Healthcare

- frustrating, protracted and inconclusive quest for valid metrics
- “what you measure improves”
- “what is typically measured does not correlate with better outcomes”
- separate quality improvement efforts from cost containment pressures
- performance measurements are intrinsically different from clinical guidelines
Healthcare Performance Data

- highly fragmented data
- competing/conflicting needs of different stakeholders
- insufficient standardization
- disparate data
  - disease staging and reporting
  - diverse treatment options
  - settings of care
  - geography
  - insurance status
  - regulation
  - professional preferences
- collection burden and limited automation
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Inadequate and/or Misaligned Incentives
Performance Measurement

- 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
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
The Desperate Cure

$3.4 billion dollars, 42,000 treatments, and 9,000 deaths later
Evidence and Comparative Effectiveness (CE): The Foundation of Rational Healthcare Policy

- 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 CE studies
- standard-of-care and malpractice
Inadequate Funding of Research on Comparative Effectiveness*

- $15 million earmarked for AHRQ in 2006
  - 0.052% NIH budget
  - 0.008% national Rx expenditures
  - 0.004% Medicare spending
  - 0.00086% total healthcare spending

* source NIHCM Foundation: [www.nihcom.org](http://www.nihcom.org)
Improving Health Care Value: Quality and Cost
A New Institute for Comparative Effectiveness Research
Paper-Based Medical Records: Fragmented Care, Unacceptable Errors and a Major Hurdle to Performance Analysis
When Will Interoperable Electronic Medical Records Become a Reality?
Interoperable EMR is a Critical Enabler

Data Sources
- Hospitals
- Clinics
- Labs
- Claims Processors

Robust Data:
- Longitudinal
- Real-time
- Clinical & Financial

Real World:
- Research
- Safety Surveillance
- Product Effectiveness Studies

Trusted, Evidence-Based Knowledge

Transparency drives change in behaviors and business models

Providers
- Delivery of care based on evidence

Payors
- Reimbursement based on real-world product effectiveness

Consumers
- Early and affordable access and better informed decisions

Regulators
- Earlier detection of product safety & efficacy issues

Manufacturers
- Early and affordable evidence to support reimbursement for innovation
Managing Complexity in Chronic Care
“The Patient-Centered (Advanced) Medical Home”

- build on concepts from AAP (1967) and AAFP (2004)
- ACP http://www.acponline.org/hpp/statehe07_5.pdf
- Medicare demonstration projects for coordinated care – section 204 of Tax Relief and Health Act 2006
- build physician networks for coordinated patient care of complex chronic conditions
- crucial role of primary care physicians
- new reimbursement policies
- workforce training policies
- consumer-directed healthcare (empowerment)
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 faciliteness 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
Consumer Directed Healthcare Plans

“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
Drivers of Healthcare Consumerism

- Information Technology
  - Internet; Scorecards
- Employers/Insurance
  - Patient Choice (Cost Sharing)
- Health Care Consumerism
  - Patient demand for service quality, performance
  - Psychodemographics
  - Information development and dissemination
- Government Regulators, Purchasers
Herd Behavior: 1.3 Million Bathers, Coney Island 1951

The Changing Nature of Social Interaction

The New “Virtual” Community
Into the void
The Coming Era in Healthcare

- dramatic (unprecedented change)
- discontinuity (new technologies)
- dislocation (demographics/market structure)
- dependency (new inter-relationships)
- data (R&D, outcomes and standards of care, risk management)
- Darwinian (new competitive pressures)
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
<table>
<thead>
<tr>
<th>Current</th>
<th>Future</th>
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<tbody>
<tr>
<td>● empirical</td>
<td>● rational</td>
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<tr>
<td>● widespread unvalidated interventions</td>
<td>● knowing what works (evidence)</td>
</tr>
<tr>
<td>● protracted adoption of best practices</td>
<td>● adopting what’s best (comparative effectiveness)</td>
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<tr>
<td>● highly variable clinical interventions</td>
<td>● clinical guidelines and decision-support</td>
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<tr>
<td>● limited use of performance metrics</td>
<td>● transparency and pay-for-performance (P4P)</td>
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<tr>
<td>● misaligned incentives and zero-sum competition</td>
<td>● incentives matched to new market realities and demonstrated outcomes</td>
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The Imperative for Fundamental Reform in Healthcare

**Current**
- fragmented ‘silobed’ care provision
- reactive, incident-based interventions
- limited consumer/patient role in care decisions
- managing illness

**Future**
- coordinated care of complex conditions
- proactive management of disease condition/risk
- increased personal responsibility for risk reduction
- maintaining wellness
The Urgent Imperative for New Drivers of Efficiency and Equity in Healthcare Delivery

earlier detection and prevention of disease episodes

Rational Therapeutics and Personalized Medicine

Optimum Use of Costly Resources

Wellness versus Illness

molecular profiling of patients and their diseases

proficient use of information: anytime, anywhere

earlier detection and prevention of disease episodes