Biotechnology, Molecular Medicine and the Future Evolution of Healthcare

Dr. George Poste, Chief Scientist, Complex Adaptive Systems Initiative Arizona State University

Keynote Address: Invest NorthWest Conference Seattle, 17 March 2009
A Few Current Challenges for the US Healthcare System

- $2.3 trillion dollar expenditures (2007)
- 16% of GDP ($1 in every $7)
- 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
- no reserve capacity for disasters, epidemics or pandemics
Market Distortions and Perverse Incentives in Modern Healthcare Delivery

- focus on late-stage disease detection and intervention
  - high cost
  - low reversibility
- multiple reimbursements for fragmented (siloed) care versus integrated management of patient needs
- illness versus wellness
- inadequate social and economic incentives for wellness
- uniform dissatisfaction
  - payors, physicians, patients, politicians
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
Global Health: Understanding the Implications of Major Economic and Environmental Dislocations
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
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
The Quest to Achieve a $634 Billion “Health Reform Reserve Fund”

“Cost savings estimates developed by CBO will “make or break” prospects for healthcare reform”
Pink Sheet 2 March 2009

- incentives for ‘leaner insurance packages
- revised cost sharing in Medicare
- bundling Medicare hospital and post-acute-care payments
- FOBs
- Medicaid drug rebate and lower Medicare Advantage (MA) increases
- competitive MA bidding and direct negotiation for Rx discounts
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
The Strategic Environment for Healthcare: New Value Propositions

- 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 Strategic Environment for Healthcare: New Value Propositions

- 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
  - disease patterns in emerging global markets mirror G8 nations
Personalized medicine: Key Drivers

Science

Policy

Cost and Outcomes
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
Molecular Diagnostics and Biomarkers: The Fundamental Technology Platforms For Molecular Medicine and the Future Healthcare Value Chain
US Healthcare Costs

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

- diagnostic tests influence 85% of clinical actions
The Evolving Market for (Bio)Pharmaceutical Therapies

- **”Blockbuster” Rx**
  - empirical “one-size-fits-all”
  - population-based Rx

- **Stratified/Targeted Rx**
  - Rx targeted to patient subgroups with common molecular pathology
  - Dx-Rx combinations and Rx labeling

- **Individualized Rx**
  - relevant disease subtype
  - AE risk profiling
  - compliance monitoring

- **Personalized Healthcare**
  - integrated framework of coordinated care and longitudinal care
Targeted Therapeutics: Identification of Subtypes of Disease with Different Molecular Pathologies

- right Rx for right disease subtype

Dx – Rx combinations
Personalized Medicine: The Initial Era

Targeted Therapeutics

Drug-Target Networks for FDA Approved 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?
Molecular Diagnostics and Targeted Therapeutics

- premium pricing for predictable Rx outcomes
- pay-for-performance (P4P)
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
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
**REMS:**
Risk Evaluation and Mitigation Strategies

<table>
<thead>
<tr>
<th>Product</th>
<th>Manufacturer</th>
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<tbody>
<tr>
<td>Plenaxis (abarelix) * for prostate cancer</td>
<td>Praecis</td>
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<tr>
<td>Lotronex (alosetron) for irritable bowel syndrome</td>
<td>Prometheus</td>
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<tr>
<td>Letairis (ambrisantan) for pulmonary arterial hypertension</td>
<td>Gilead</td>
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<tr>
<td>Tracleer (bosentan) for pulmonary arterial hypertension</td>
<td>Actelion</td>
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<tr>
<td>Clozaril (clozapine), Fazaclo ODT (clozapine) for schizophrenia</td>
<td>Novartis, Azur and generics</td>
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<tr>
<td>Tikosyn (dofetilide) for atrial fibrillation/atrial flutter</td>
<td>Pfizer</td>
</tr>
<tr>
<td>Soliris (exulizumab) for paroxysmal nocturnal hemoglobinuria</td>
<td>Alexion</td>
</tr>
<tr>
<td>Ionsys (fentanyl hydrochloride) *, Actiq (fentanyl citrate) for pain</td>
<td>Alza, Cephalon</td>
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<tr>
<td>Accutane (isotretinoin) for acne</td>
<td>Roche and generics</td>
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<tr>
<td>Revlimid (lenalidomide) for myelodysplastic syndromes and multiple myeloma</td>
<td>Celgene</td>
</tr>
<tr>
<td>Mifeprax (mifepristone) for pregnancy termination</td>
<td>Danco</td>
</tr>
<tr>
<td>Tysabri (natalizumab) for multiple sclerosis and Crohn’s disease</td>
<td>Biogen Idec/Elan</td>
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<tr>
<td>ACAM2000 (smallpox vaccine, live)</td>
<td>Acambis</td>
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<tr>
<td>Xyrem (sodium oxybate) for daytime sleepiness and cataplexy</td>
<td>Jazz</td>
</tr>
<tr>
<td>Thalomid (thalidomide) for multiple myeloma and leprosy</td>
<td>Celgene</td>
</tr>
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</table>

* Plenaxis and Ionsys are currently not marketed in U.S.
Social Media: Ignorance Not Bliss For Pharma, DIA Panelists Say

Drugmakers must start monitoring adverse event data and product discussions on the Internet or run the risk of facing legal scrutiny, marketing specialists said at a Feb. 25 Drug Information Association conference in New York City.

Drug companies, for the most part, have shied away from online marketing mediums like blogs and chat rooms because regulatory oversight in the area remains so unclear, but “pleading the fifth” is no longer an option, Novo Nordisk Associate Director of E-Marketing Craig DeLarge said.

controversy even before it is properly reviewed. But while determining how best to monitor adverse events online remains a trial and error process for now, companies cannot afford to avoid it, the panelists agreed.

Innovative Marketing Opportunities Abound

Despite challenges, social media also presents innovative marketing opportunities. Some of the firms that best engage with consumers and physicians online moderate their own venues, including Web sites, blogs, social networking groups and YouTube channels.
VCs Think Twice About Type 2 Diabetes Investments

Venture capitalists are reevaluating type 2 diabetes investments in light of daunting new regulatory hurdles and an economic climate that limits their ability to cash out of such companies in a timely fashion. But, say some VCs, truly innovative compounds may be worth the bigger R&D bills and longer time to exit given the dazzlingly large market at stake.

As part of the general economic malaise, endowments and institutions have much less to invest in venture capital (“The Pink Sheet” DAILY, Jan. 5, 2009).

Paoli, chief medical officer at privately-held start-up InteKrin Therapeutics in Los Altos, Calif. Diabetes costs generally range from $15,000 to $30,000 per patient. As a rough guide, Phase III expenses are likely to rise by from 25 percent to 50 percent, he estimates. Added expenses for drugs used in lower-risk patients with early stage disease – such as dipeptidyl peptidase 4 inhibitors – will be much higher than for medications used later, such as glucagon-like peptide 1 agonists and insulin.
• update labeling for Abacavir (Ziagen) to require pre-therapy screening for HLA-B*5701 allele to avoid fatal hypersensitivity

Table of Valid Genomic Biomarkers in the Context of Approved Drug Labels

http://www.fda.gov/cder/genomics/genomic_biomarkers_table.htm
The Evolution of Molecular Medicine and Information-Based Medicine: The Foundation for Rational Care and Personalized Medicine

new competencies in molecular medicine and biomedical informatics

molecular diagnostics

real-time information for optimum decision-making

disease management protocols, patient information

gene
genetic profiling

drug

drug

package insert

Rx 2009

Medicine 2019
• useful only when correlated with additional parameters
  – clinical outcomes
  – clinical utility
  – actionable information
  – demonstrable economic value
Molecular Diagnostics and Biomarkers for Personalized Medicine

The Validation Challenge

- technical sophistication (novel multianalyte tests)
- scale (size of case: control cohorts)
- analytical standards
- interpretation algorithms for complex multivariate datasets and probabilistic risk
- clinical utility and health benefits
- economic benefits
- regulatory oversight
Development of Molecular Diagnostics and Biomarkers for Personalized Medicine: The Need for End-to-End R&D Solutions

Complex Biosignature Profiling

<table>
<thead>
<tr>
<th>genomics</th>
<th>proteomics</th>
<th>immunosignatures</th>
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</tr>
<tr>
<td>multiplex assays</td>
<td>novel test devices (POC)</td>
<td>new algorithms</td>
</tr>
</tbody>
</table>

Signature Detection, Deconvolution and Multivariate Analysis
Next-Generation Molecular Diagnostics and New Patterns of Regulatory Oversight
K-RAS Profiling and Anti-EGFR Monoclonal Antibody Therapy

- greater response in patients with K-RAS versus mutant-

- estimated $604 million/year savings (ASCO)

- regulatory demand

- clinical guidelines

- regulatory inertia (ODAC 12/08)

- payor adoption
patient-specific result (score or index)
analytical/interpretational algorithm non-transparent to end user
result cannot be independently derived or confirmed by another laboratory without access to proprietary information used in the development and derivation of the test
unresolved ambiguity for validation
  - retrospective data
  - retrospective: prospective data
  -Prospective trials
December 2008

“request FDA regulatory jurisdiction over all LDTs”

January 2009

“Genetech’s proposal poses a chilling effect on innovation in patient care while stifling the promise of personalized medicine.”
Personalized Medicine: Disease Predisposition Profiling
Genome-wide association defines more than 30 distinct susceptibility loci for Crohn’s disease

Jeffrey C Barrett¹¹, Sarah Hansoul², Dan L Nicolae³, Judy H Cho⁴, Richard H Duerr⁵,⁶, John D Rioux⁷,⁸, Steven R Brant⁹,¹⁰, Mark S Silverberg¹¹, Kent D Taylor¹², M Michael Barnada⁶, Alain Bitton¹³, Themistocles Dassopoulos⁹, Lisa Wu Datta⁹, Todd Green⁸, Anne M Griffiths¹⁴, Emily O Kistner¹⁵, Michael T Murtha⁴, Miguel D Regueiro⁵, Jerome I Rotter¹², L Philip Schumm¹⁵, A Hillary Steinhart¹¹, Stephan R Targan¹², Ramnik J Xavier¹⁶, the NIDDK IBD Genetics Consortium³³, Cécile Libiouelle², Cynthia Sandor², Mark Lathrop¹⁷, Jacques Belaiche¹⁸, Olivier Dewit¹⁹, Ivo Gut¹⁷, Simon Heath¹⁷, Debby Laukens²⁰, Myriam Mni², Paul Rutgeerts²¹, André Van Gossum²², Diana Zelenika¹⁷, Denis Franchimont²², Jean-Pierre Hugot²³, Martine de Vos²⁰, Severine Vermeire²¹, Edouard Louis¹⁸, the Belgian-French IBD Consortium³³, the Wellcome Trust Case Control Consortium³³,³⁴, Lon R Cardon¹, Carl A Anderson¹, Hazel Drummond²⁴, Elaine Nimmo²⁴, Tariq Ahmad²⁵, Natalie J Prescott²⁶, Clive M Onnie²⁶, Sheila A Fisher²⁶, Jonathan Marchini²⁷, Jilur Ghori²⁸, Suzannah Bumpstead²⁸, Rhian Gwilliam²⁸, Mark Tremelling²⁹, Panos Deloukas²⁸, John Mansfield³⁰, Derek Jewell³¹, Jack Satsangi²⁴, Christopher G Mathew²⁶, Miles Parkes²⁹, Michel Georges² & Mark J Daly⁸,³²

Several risk factors for Crohn’s disease have been identified in recent genome-wide association studies. To advance gene discovery further, we combined data from three studies on Crohn’s disease (a total of 3,230 cases and 4,829 controls) and carried out replication in 3,664 independent cases with a mixture of population-based and family-based controls. The results strongly confirm 11 previously reported loci and provide genome-wide significant evidence for 21 additional loci, including the regions containing STAT3, JAK2, ICOSLG, CDKAL1 and ITLN1. The expanded molecular understanding of the basis of this disease offers promise for informed therapeutic development.
Disease Predisposition Risk Profiling for Common, Multigenic Late-Onset Disorders

- slower evolution than many predict
- Genome-Wide Association Studies (GWAS)
  - high cost, complexity and poor replication
  - multiple low penetrance alleles
- substantial ambiguities regarding probabilistic risk of overt diseases
  - epistasis
  - epigenetics
  - environmental confounders
  - source of poor replication of GWAS studies?

The premature quest to provide consumer genomic testing (CGx) for future risk of major diseases
“Celebrity Spit”: 2008 Launch of 23andMe Personal Gene Profiling Service
Consumer Genomics: Predisposition Risk Profiling for Late Onset, Multigenic Diseases

- validity of 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
A Realistic Strategy for the Delivery of Rational Healthcare?
Or
An Erstwhile Intellectual Pursuit Doomed to be Dashed on the Rocks of Siloed Science, Clinical Conservatism and Commercial Myopia?
Payor Value Propositions Do Not Align with Clinical Value Propositions
inadequate US Medicare coding and payment mechanisms
  – out moded, out-dated, lacking in transparency, inconsistently applied

inappropriate assignment of existing CPT codes to new tests

engagement of third party payers who derive economic/clinical value from new Dx

The Imperative for Value-Based Pricing versus Current Cost-Based Models
Personalized Medicine: Challenges for Clinicians

- sustained awareness of relevant conceptual advances and new products/services
- timing and training for adoption into routine practice
- accurate identification of relevant patients for use of MDx profiling and targeted Rx selection
- understanding payor coverage to ensure appropriate reimbursement
- new malpractice risks
# Courses in Medical Genetics in US and Canadian Medical Schools 2004-2005

## Table 1

**General Characteristics of Courses in Medical Genetics Taught in U.S. and Canadian Medical Schools, 2004 to 2005**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>No. (%) respondents</th>
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<tbody>
<tr>
<td><strong>Type of course</strong></td>
<td></td>
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<tr>
<td>Stand-alone</td>
<td>52/112 (46)</td>
</tr>
<tr>
<td>Integrated</td>
<td>60/112 (54)</td>
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<tr>
<td><strong>Course taught with multiple instructors</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>99/112 (88)</td>
</tr>
<tr>
<td>No</td>
<td>12/112 (11)</td>
</tr>
<tr>
<td>Unspecified</td>
<td>1/112 (1)</td>
</tr>
<tr>
<td><strong>Year of curriculum in which course was taught</strong></td>
<td></td>
</tr>
<tr>
<td>First</td>
<td>86/112 (77)</td>
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<tr>
<td>Second</td>
<td>35/112 (31)</td>
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<tr>
<td>Third</td>
<td>6/112 (5)</td>
</tr>
<tr>
<td>Fourth</td>
<td>1/112 (1)</td>
</tr>
<tr>
<td>Unspecified</td>
<td>0/112 (0)</td>
</tr>
<tr>
<td><strong>Total hours taught in course</strong></td>
<td></td>
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<tr>
<td>&lt;20</td>
<td>20/112 (18)</td>
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<tr>
<td>20–40</td>
<td>69/112 (62)</td>
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<tr>
<td>41–60</td>
<td>15/112 (13)</td>
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<tr>
<td>&gt;60</td>
<td>5/112 (4)</td>
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<tr>
<td>Unspecified</td>
<td>3/112 (3)</td>
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<tr>
<td><strong>Type of sponsoring unit</strong></td>
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<tr>
<td>Clinical sciences</td>
<td>55/112 (49)</td>
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<tr>
<td>Basic sciences</td>
<td>32/112 (29)</td>
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<tr>
<td>Multidisciplinary/integrated</td>
<td>19/112 (17)</td>
</tr>
<tr>
<td>Other/Unspecified</td>
<td>6/112 (5)</td>
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</tbody>
</table>

* Column total exceeds 100% because some respondents reported teaching medical genetics in more than one year.

From: V. C. Thurston et al. (2007) Acad. Med. 82, 441
Wellness: A Broader Perspective on Personalized Medicine
Wellness:
A Broader Perspective on Personalized Medicine

- economic and societal pressures for increased consumer responsibility for wellness
- remote monitoring of individual health status
- crucial role of healthcare information systems
  - integrated Rx care for complex chronic conditions
  - outcomes and comparative effectiveness
  - earlier detection of disease episodes and risk mitigation
- wellness versus illness
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

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 treatments
- Multiple coding and reimbursement policies
- Multiple medications
Knowledge and Evidence Doesn’t Translate easily into New (or Rational) Behaviors

- science (impact is too often unknown or abstract)
- industry (incremental timidity driven by short-term focus on markets and stock valuation)
- payors (cost control)
- physicians and healthcare professionals (status, revenue and recognition)
- patients (unaware and uninvolved in healthcare decisions)
- politicians (populism and short-term fixes)

How Much New Technology Can We Afford?
$2.3 trillion healthcare economy

$110 billion R&D investment

$0.9 billion on technology assessment

additional $1.2 billion in 2009 “stimulus” package
Information-Based Medicine

HELL IS THE PLACE WHERE NOTHING CONNECTS — T.S. ELIOT
Healthcare Records: Proliferating Paper and Primitive Electronic Systems
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
“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
Personalized Medicine:
Consumer-Centric Healthcare: A Key Driver

- structural shift in healthcare delivery from encounter-/procedure-driven to incentives for wellness and integrated disease management
- cost-shifting to consumers
- 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

Life's a game
Manipulating society has traditionally been the preserve of politicians and the gods. Does the current boom in virtual worlds give social scientists and economists an opportunity to join them? Jim Giles investigates.
Herd Behavior 1951: The Changing Nature of Social Interaction

1.3 Million Bathers, Coney Island

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
In-Home Health Connection: Engaging the Elderly
The Dominant Future Element in Primary Healthcare Delivery???
Healthcare Information Networks:
AORTA: Always On Real Time Access

- end-to-end continuity in use of internet and wireless technologies
- from routine remote monitoring of health status to advanced critical care
- comprehensive connectivity
  plus
- collapsing time
  plus
- global networks
A New Healthcare Ecosystem Arising From Technology Convergence

- **Dx/Devices**
- **Rx**
- **Hlx**

### Integrated Technology Platforms
- Data Mining and Integration Services

### Services for Integrated Care
- Increasingly Targeted Care and Efficient Use of Finite Resources

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

### Patients and Consumers
Personalized Medicine: Progressive Evolution Based on Increasingly Comprehensive Profiling of Disease Risk and Health Status

- Targeted Care
  - rational Rx based on profiling of underlying molecular pathology
  - MDx and disease subtyping

- Personalized Care
  - rational Rx based on comprehensive molecular profiling of individuals
    - disease subtypes and optimum Rx
    - Rx AE risk
    - disease predisposition risk and mitigation

- Individualized Care
  - integrated framework of longitudinal data on individual health status
  - real time remote health status monitoring
  - transition to disease prediction and preemption
The Coming Convergence in Healthcare Delivery
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

- Earlier detection and prevention of disease episodes
- Wellness versus Illness
- Rational Therapeutics and Personalized Medicine
- Optimum Use of Costly Resources

molecular profiling of patients and their diseases
proficient use of information: anytime, anywhere
Building an Integrated Framework for Personalized Medicine

- earlier detection and prevention of disease episodes
- optimum Rx selection and outcomes
- customized information for optimum decisions

• Patients
• (Bio)Pharm. Cos.
• Payors

• VALUE

• molecular profiling of patients and their diseases
Complex Adaptive Systems:
Mapping Information Flow in Dynamic Networks

- Synthetic Biology
  - Engineering of Biological Networks

- Ubiquitous Sensing
  - Remote Monitoring for Healthcare

- CAS Modeling and Simulation
  - Advanced Medical Diagnostics and Healthcare Information Systems

A New Industrial Ecology
Early Detection of Adverse Trends
Predict and Prevent Disease