Making Precision Medicine A Reality: Molecular Diagnostics, Remote Health Status Monitoring and the Big Data Challenge

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Aspirations for the U.S. Healthcare System: National Academy of Medicine

The Triple Aim
- improved outcomes
- reduced cost
- value-based care

The Learning Healthcare System
- right information
- right decisions
- right culture
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The Learning Healthcare System

The Triple Aim
Aging Societies and the Chronic Disease Burden: Confronting the Largest Clinical and Economic Disruptions and Threats to Sustainable Healthcare

cancer  neurodegeneration  cardio-vascular/metabolic disease  mental illness
Convergence of Advances in Biomedicine, Materials Science, Engineering, Telecommunications, Robotics, Advanced Computing and Data Science

Blurring the Boundaries of Biomedicine

Technology Convergence and New Cross-Sector Alliances
The Path to Precision Medicine: From Superstitions to Symptoms to (Molecular) Signatures

humors, astrology, shamanism, sin and divine fate

biochemistry and organ-based pathophysiology

molecular biology and multi-omics profiling
Precision Medicine:

-Epi)Genomics

Causal Relationships Between Disruption of Molecular Signaling Networks and Disease

- terabytes per individual
- zettabyte – yottabyte population databases

Patient-Specific Signatures of Disease or Predisposition to Disease

Big (Messy) Data
Molecular Diagnostics and Biomarkers as the Intellectual Drivers of Precision Medicine

- disease predisposition risk
- increased accuracy of disease classification (molecular subtypes) and staging
- more rational treatment selection based on presence/absence of specific molecular targets for $R_x$ action
- pharmacogenetic profiling to avoid $R_x$ adverse events
Molecular Diagnostics and Biomarkers as the Intellectual Drivers of Precision Medicine

- monitoring $R_x$ efficacy
- detection of emergence of $R_x$ resistance (microbiology; oncology)
- early alert of pending relapse and/or minimal residual disease
Precision Medicine and Digital Medicine: Obligate Inter-Dependencies

Individual Data

Population Databanks

integration and analysis of large scale, diverse data categories

“matching” individuals to ‘best match’ cohorts using data on similarities of molecular profiles and treatment outcomes
Still Two Largely Separate Worlds

- precision medicine
- routine healthcare delivery and SOC

- research and early clinical adopters

- $100-125^\ast$ billion (estimated)
- $3.4$ trillion (19% GDP)

*includes investment in investigational $R_x$ candidates
Large Scale Genome Sequencing Projects: The Dangers of Reductionism and Ignoring Biological Complexity
Impact of Different Factors On The Risk of Premature Death

Interaction Network of Genotypes and Phenotypes in Obesity

Most Events That Affect Our Health Occur Outside of the Healthcare System And Are Not Monitored

Need for Continuity of Care Record: From Womb to Tomb

Behavior

Environment
Remote Monitoring of Health Status
Building Value in Wellness Apps and Wearables

- legitimacy and clinical value still viewed as marginal by physicians/payers
- lack of robust data on improved outcomes
- regulation: accuracy, reliability, security and privacy
Gray Technologies and Aging in Place:
The Rapid Expansion of Telemedicine for Remote Health Monitoring

- Rx adherence
- Cognitive stimulation
- In home support and reduced readmissions
- Reduced office visits
Chatbots and Support Robots in Healthcare
VR/AR and Neuromodulation

- promote behavior change via altered sensory inputs and feedback
- mental illness: PTSD, physical rehabilitation, substance abuse and pain control
Now Comes the Hard Part!

Driving Precision Medicine and Data-Driven Healthcare Into Routine Clinical Practice

The Problem with Real World Data is the Real World
Welcome to The World of Biomedical Research and Healthcare Information Systems
Precision Medicine and Digital Health: Building a Learning Healthcare System

**Qualitative, Descriptive Information:**
- Information of uncertain quality and provenance

**Quantitative Data:**
- Data of known provenance and validated quality

**Complex Ecosystem:**
- Complex ecosystem of largely unconnected data sources

**Evolving, Inter-connected Networks:**
- Evolving, inter-connected networks of data sources for robust decisions and improved care
Automated Context: Data Finding Data
“Intelligence at Ingestion”

- Feature Extraction and Classification
- Context Analysis
- Persistent Context
- Relevance Detection
- Learning Systems
- Situational Awareness
- Rapid, Robust Decisions
Major Investments in Digital Health by Major Corporations Within and Outside of Traditional Healthcare
“People Analytics”
Social Activities and Behavior Become Quantifiable

• who knows why people do what they do?
  – the fact is that they do!
• these actions can now be traced and measured with unprecedented precision
• with sufficient data, the numbers reveal increasingly predictable behavior and individual risk patterns
• the confessional of social media
• the blurring of private and public spaces
• complex ethical and legal issues
  – consent, privacy, security, surveillance
Mishandling of Patient Information Shows How Governments and Companies Must Become More Worthy of Trust
The Co-evolution of Augmented Humans, Robotics and Human-Machine Interactions
Human-Computer Interactions

VR/AR and Training for Complex Tasks
Technology Acceleration and Convergence: The Escalating Challenge for Professional Competency, Decision-Support and Future Medical Education

Data Deluge

Cognitive Bandwidth Limits

Automated Analytics and Decision Support

Facile Formats for Actionable Decisions
Machine Learning and Image Analysis in Clinical Medicine

- large scale training sets and classification parameters
- standardized, reproducible and scalable
- 260 million images/day for $1000 GPU
Living in a World Where the Data Analytics and Interpretation Algorithms Are Obscure to the End User

- ceding decision authority to computerized support systems

- culturally alien to professionals in their claimed expertise domain but they accept in all other aspects of their lives

- who will have the responsibility for validation and oversight of critical assumptions used in decision tree analytics for big data?
  - regulatory agencies and professional societies?
  - humans?
  - machines?
Artificial Intelligence (AI) and Healthcare

- how will AI algorithms/decision analytics be validated/regulated?
- how will AI be integrated into current work flow or will radical reorganization/re-training be required?
- how will AI platforms alter payment schemes?
- what new malpractice liabilities will emerge by failure to use/interpret AI platforms
- legal liability for AI-based clinical decision software
The Future of Healthcare: Precision Medicine and Digital Medicine

- New technology platforms
  - Multiplex profiling of molecular network topologies
  - Automation and advanced computing
  - Sensors, robotics

- The expanded care space
  - Wearables, sensors, telemedicine
  - Patient engagement
  - Social media and lifestyle metrics

- Molecular classification of disease

- Remote monitoring of health status
The Future of Healthcare: Precision Medicine and Digital Medicine

- new technology platforms
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Big Data
- PHR/EHR
- population health
- precision medicine
- digital medicine
- AI

The expanded care space
- patient engagement
- wearables, sensors, telemedicine
- social media and life style metrics

analytics for improved decisions and clinical outcomes at lower cost (value)

remote monitoring of health status

molecular classification of disease
Precision Medicine and Digital Medicine: Obligate Inter-Dependencies

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