The Strategic Landscape for the US Health Ecosystem: Challenges and Opportunities

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EMED 227/127 Health Care Leadership
Stanford University School of Medicine
Virtual Lecture
12 January 2022
Leadership

- identify and implement the organizational and functional skills needed to achieve strategic aspirations, operational goals and superior performance
- understand the network of key internal and external participants and systems that will enable or impede success
- promote and constantly adapt organizational competencies to respond to new challenges and opportunities
- every sector presents unique leadership challenges
Leadership

- insatiable intellectual curiosity and work intensity
- talent selection, mentoring and celebrate the career advancement of colleagues
- open debate of best approaches to complex problems, particularly those with no precedent
- credit others (and always say ‘thank you’)
- no BS: willingness to say, “I don’t know (but I’ll find out)”
- accountability is not a dirty word
- humor helps!
- epitomize the ethos/ethic of the desired organizational culture and reputation
Leadership

- relentless proactive evaluation of risks and opportunities in an era of accelerating change
- timely identification of emerging disruptive trends
  - cross-domain technology convergence and cross-sector private sector alliances
- agile decision making in the face of escalating complexity and uncertainty
Leadership in an Era of Increased Complexity in Biomedical Research and New Demands to Improve Health System Performance
The US Healthcare Ecosystem

- the $4.1 trillion US health system (c. 20% GDP) is unmatched in the scale and diversity of organizations and functions
- over 450,000 entities involved in the development and delivery of highly specialized services to heterogenous populations over their lifetimes
- health ranks highest in public and political expectations regarding access, availability and affordability of care
The US Health Ecosystem

- economically and clinically unsustainable
- domination of care-centric activities (sick care) versus investment in health risk reduction (wellness)
- demographics of an aging society and increased chronic disease burden
  - 50% cost incurred in last six months of life
- disturbing increase in mental illness, SUD, suicide even before the COVID pandemic
- large disparities in access to care and wide variation in clinical practice
- poor coordination and continuity of care across the health/health care system
- inefficient integration and analysis of data to drive evidence-based/best practice protocols
The US Health Ecosystem

- urgent imperative to increase access to care, reduce cost and improve clinical outcomes
- adoption of new systems-based approaches to identify and mitigate disease risk
- need for greater recognition of social determinants of health (SDoH) in disease risk and access/cost of care
- system fragility
  - lack of preparedness/resiliency for unanticipated large-scale disruption (pandemic, cyber, grid collapse, supply chains)
A World Transformed By SARS-CoV-2
Sars-CoV-2 Revealed Major Shortcomings in US Public Health Capabilities

840,581 US Deaths (1/11/2022)

PREPARED? NO!

Key
- Most Prepared
- More Prepared
- Least Prepared
## A Report Card on US Response to COVID-19

<table>
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The Commitment and Resiliency of Front-Line Personnel: Pre-Vaccine Risk Exposure in Healthcare Delivery

first responders  military services  ICU’s

clinical laboratories  waste disposal  burn-out
### The Relentless Ever-Changing Dynamics of Infectious Diseases

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- Old foes resurgent: Rx – resistance
- Traditional pandemic threats
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- Climate change and new vector ranges
- Bioterrorism and bioweapons
- Dual-use research of concern and threat expansion

- SARS-CoV-2
Biosecurity

- imperative to rebuild comprehensive global surveillance and preparedness for known and future pandemic threats from emerging infectious diseases
- new dual-use technologies an expanded biothreat spectrum

Presentation: Biosecurity and Pandemic Preparedness
BIOE122, EMED 122/222, PUBLPoL 122/222
12 January 2022 https://casi.asu.edu/presentations/
Precision Health and Digital Health: Inter-dependent Strategic Drivers in the Evolution of Healthcare Policies and Priorities
The Strategic Landscape for the US Health Ecosystem

- technology convergence and cross-disciplinary/cross-sector networks
- escalating burden of chronic disease

- data capture and analysis for better care decisions
  - precision health (PH)
    - defining disease at the molecular level
    - digital health (DH)
      - identification of disease risk and mitigation

- aging populations
- mental illness
- SUD
- suicide
- SDoH disparities
- cv, diabetes, cancer, neurodegeneration
- new alliance networks
- computing
- engineering
- biomedicine
The Strategic Landscape for Biomedical Research and Health Services

- Technology convergence and cross-disciplinary/cross-sector networks
- More proficient use of data
- Escalating burden of chronic disease

Risk management of major cost drivers:
- Remote health monitoring to identify/mitigate risk
- Reduce (re)hospitalization
- The expanded care space and continuity of care
- SDoH and health disparities
- Predictive data analytics for at risk patients

Focus areas:
- Biomedicine
- Engineering
- Computing
- New alliance networks
- Aging populations
- CV, diabetes, cancer, neurodegeneration
- Mental illness
- SUD suicide
- SDoH disparities
The Path to Precision Health: 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
Molecular Classification of NSCLC and Identification of Single, Largely Non-Overlapping Oncogenic Alterations


Data from TCGA (Sanchez-Vega et al.\textsuperscript{178}, Ellrott et al.\textsuperscript{179} and Hoadley et al.\textsuperscript{180}), Imielinski et al.\textsuperscript{62} and Kadara et al.\textsuperscript{133} (n = 741)

Data from MSK-IMPACT (Jordan et al.\textsuperscript{59}) and FoundationOne (Frampton et al.\textsuperscript{15}) panels (n = 5262)
Precision Health

- (Epi)Genomics and MultiOmics Profiling
- Detection of Altered Molecular Signaling Networks in Disease: A New Taxonomy of Disease and Subtype Classification
- MDx Signatures of Disease Predisposition and Subtyping of Overt Disease for Optimum Rx Selection
- The Challenge of Big (Messy) Data

- terabytes per individual
- zettabyte – yottabyte population databases
Moving Beyond Static “Snapshots” of Individual Health Status to Real Time, Continuous Monitoring of Multiple Aspects of Health Status
Professor M. Snyder, Stanford University
A Prototypic Example of Comprehensive Multiparameter Profiling of Health Status

Deep Phenotyping: “Much More Than Omics” - Overcoming the Curse of Reductionism

From Womb to Tomb: Systematic Integration of Diverse Health Data

SDoH, Lifestyle, Environment, Health Disparities
Precision Health and Digital Health: Evolving Inter-Dependencies

Individual Data

- populating individual profiles to “best matched” cohorts for clinical decisions

Population Databanks

- integration and analysis of large scale (petabyte, exabyte) diverse data classes

Deep Phenotyping:

- multiOomics
- clinical history- EHR/PHR
- remote health monitoring
- socio-behavioral data
- environmental exposures
Building Personalized ‘Digital Twins’: Matching Individual Deep Phenotypes to ‘Best Fit’ Cohorts

- ‘digital twins and siblings’ and imputed phenotypes
- disease predisposition and prevention
- earlier detection of subclinical disease and intervention
- selection of optimum treatment regimen for overt disease
- improved outcomes and QOL
Precision Health and Digital Health

- Expanding ‘The Care Space’ in Health and Illness
- Monitoring Health Beyond the Clinic
- Telemedicine and Remote Health Monitoring (RHM)
● the majority of events that influence wellness/disease risk and treatment adherence occur largely outside of formal interactions with the healthcare system

● daily decisions by individuals have greater effects on their health than decisions controlled by the healthcare system
Social Spaces 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
Invasion of the Body Trackers: Expanding the “Care Space” in Healthcare

- Healthcare Beyond The Clinic
- Remote Health Status Monitoring
- Smartphones, Wearables, Devices and Digital Services
- M4: Making Medicine More Mobile
- AORTA: Always On, Real Time Access
Wearables, Sensors, Mobile Devices and New Patient-Centric Delivery Channels

- better real time patient-specific data and decision-support tools
- each individual becomes their own control
- new patterns (touch points) of patient engagement with the health system
  - external reach and continuity in care
  - new delivery channels and services
  - targeted care and ability to monitor larger number of patients
Wellness Apps for Fitness, Diet and Exercise
Remote Monitoring of Health Status
Implantable Devices and Wireless Monitoring (and Modulation)

- next-generation miniaturized power sources
- security and hacker protections
Smart Devices for Automated Drug Delivery and Improved Therapeutic Adherence

Propeller Health

Gecko (now Teva)

CapMedic

Biocorp Inspair

Help patients get **onboard** with **onbody** injections

**Onbody Trainers**
- Drug Administration
- Injection Site Selection
- Injection Technique
- Injection Safety

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Aterica Veta EpiPen
The SARS-CoV-2 Pandemic: Accelerated Adoption of Telehealth Services
The SARS-CoV-2 Pandemic: Accelerated Adoption of Telehealth Services

- digital social distancing
- high receptivity by both health professionals and patients/caregivers
- relaxation of legislative constraints on reimbursement for virtual versus in-person visits and asynchronous diagnosis/treatment consults
- major infusion of venture capital into new telehealth companies and corporate M&A
- irreversible change in patterns of primary health care and behavioral health consultations?
Networked Telehealth Between Provider Organizations

- Centralized 24/7 Monitoring of Multiple Critical Care Units
- Peer to Peer Consultations
- Expanded Access to Subject Experts
Economies of Scale, Convenience and Improved User Experience
Big Tech and Health Services: Disruptions Ahead?
Telehealth, RPM, PRO and the Growth of Decentralized Clinical Trials
Empowered Patients:
Social Networking Sites and Their Role in Clinical Care

• logical extension of the rapid rise of web/apps in mainstream culture to healthcare

• increasingly proactive and engaged consumers/patients/families

• greater access to information on treatment options, cost and provider performance

• new clinical practice tools to optimize physician-patient relationships

• Ux and formation of senior executive level Chief Patient Experience Officer posts in large provider organizations
The Growing Clinical and Economic Burden of Chronic Disease

- cancer
- neurodegeneration
- cardiovascular/metabolic disease
- mental illness
Defining “Value” in Healthcare Will Intensify

Medicare limits coverage of $28,000-a-year Alzheimer's drug

For Medicare to pay, patients will have to be part of clinical trials to assess Aduhelm’s effectiveness against early-stage dementia and its safety.

NCD Decision 1/11/2022
Defining “Value” in Healthcare Will Intensify

- improve clinical outcomes and QOL
  - QALY, DALY
  - socio-economic metrics: faster return to workplace/school
  - reduced demands and dependency on other societal support services

- new tools for ‘downstream’ future cost/benefit analysis
  - reduce demand for future resource use
Cancer Treatment Cost

Value Framework

Delivering Affordable Cancer Care in the 21st Century

The Costs of Cancer

ASCO

ESMO

Cost vs. Value and the Price of Innovation in Cancer Care: Oral Anticancer Drugs in Multiple Myeloma, as a Case Study

ICER

INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

Making Medicines Affordable

A National Imperative

Drug Pricing Lab

Memorial Sloan Kettering
Why Should Price Vary With Location?

- Price for oncology drugs administered in hospital versus typically double price paid for community clinic
- Herceptin
  - hospital/hospital outpatient $5,350
  - independent clinic $2,740
- Avastin
  - clinic ($6,620), hospital ($14,100)
- Incentive for trend for purchase of community clinics by hospital systems and reclassification as ‘hospital outpatient clinics’ and eligible for 340B discounts
The Demographics of an Aging Society: Clinical and Economic Challenges to U.S. Healthcare

- Wellness with longevity and high QOL
- OR
- Multiple co-morbidities and low QOL
Reducing Hospital Readmissions

- identification and focus on higher-risk, higher-complexity patient
- patient coaching/education on discharge instructions and self-management
- adherence to complex polypharmacy
- engage family members
- use of transitional care nurses and other care coordination professionals
Grey Technologies and Ageing in Place: Independent But Monitored Living for Ageing Populations

- Rx adherence
- Cognitive stimulation
- In-home support and reduced readmissions
- Reduced office visits
Chatbots and Support Robots in Healthcare
Amazon and Home Care

Development of Third-Party Alexa Apps

Allows seniors to verbally report medical data, get exercise and adherence reminders, call a caregiver, and coordinate transport

Mayo Clinic First Aid

“Tell me about spider bites”
“Help for a burn”

Ask My Buddy

“Alexa, ask My Buddy to alert everyone.”

Telemedicine and Behavioral Health: Digital Psychiatry and Non-Pharmacologic Digital Therapeutics
Increased ED Behavioral Health Emergencies

- reported range of 8-25% of ED volume (outliers higher)
- 70% of behavioral health patients also have one or more co-morbidities
- opioid-related visits tripled between 2005-19
- approx. 1 in 4 individuals with serious mental illness also have substance abuse disorder
- 60% of adolescents in community-based SUD treatment programs also meet diagnostic criteria for mental illness
- dramatic increase in mental health needs in COVID-19 pandemic
Digital Psychometrics and Evaluation of Mental Illness

- eye micro saccades
- facial dynamics
- stimulus response and interaction speeds
- speech patterns (rhythm, tone, volume)
- semantic construction
- brain imaging functional MRI
- altered signal pathways
Digital Psychometrics and Mental Illness

- interaction with digital assistants/chatbots
- machine learning and AI analytics of large video banks and social media posts
  - bipolar disorder, schizophrenia, depression
  - suicidal ideation
  - PTSD
- alerts to care teams when immediate intervention indicated
“We envision empowering individuals with digital therapeutic solutions that address underlying motivational and technical deficits by deciphering neural pathways that support motivation, decision-making and reinforcement to prompt health.”

Dr. Ben Wiegand
Global Head, Janssen R&D
World Without Disease Accelerator
PharmaVoice 2017
Robotics and Human-Machine Interactions

Brain-Machine Interface Technologies and Augmented Sensory, Motor and Cognitive Functions
Robotic Assist Systems and Exoskeletons for Rehabilitation
Robot–Human Directed Interactions
Co-evolution of Human-Machine Interactions, Robotics and Augmented Cognition

VR/AR/MR and Preparation for Complex Procedures
VR/AR and Neuromodulation

- promote behavior change via altered sensory inputs and feedback
- mental illness: PTSD, physical rehabilitation, substance abuse and pain control
The Metaverse, Avatar Worlds and Immersive Sensory Technologies

• substantial opportunities for health education and training

BUT

• critical need for proactive development of oversight of applications in healthcare to avoid a dystopian déjà vu of social media disinformation and psychological manipulation
Now Comes the Hard Part!

Driving Precision Health and Large Scale Data Analytics into Routine Practice

New Incentives and New Delivery Models

New Participants and New Business Models
Welcome to The World of Biomedical Research and Healthcare Information Systems
Biomedical Data: Vast But Poorly Utilized

- inadequate standardization
- fragmented, incomplete, inaccurate data and uncertain provenance
- incompatible data formats as barrier to data integration and sharing
- obstacles to EHR integration of new data classes (multi-Omics; wearables; IoMT)
- legislative barriers to data transfer based on well intentioned privacy protections (HIPAA)
- organizational, economic and cultural barriers to open data sharing
- static, episodic snap shots of complex dynamic systems
- major impediments to research productivity, optimum clinical decisions and continuity-of-care for patients
Big Tech: Big Provider Linkups Fuel HIPAA Privacy Debate
Health Data Brokers and ‘Selling-On’
National Security Implications of Genome Data on Populations

Population Databanks

Individual Profiles

Foreign Access to Data

Data Security

icarbonX

华大基因

BGI
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
The Emergence of Big Data Changes the Questions That Can Be Asked

- **Isolated Data**
- **Complex Networked Data**
- **Complex Computational Data**
Automated Context: Data Finding Data
“Intelligence at Ingestion”

- Feature Extraction and Classification
- Context Analysis
- Persistent Context
- Relevance Mapping
- Learning Systems
- Situational Awareness
- Rapid, Robust Decisions
Precision Health and Digital Health: Building the Learning Health System

- qualitative, descriptive information of variable quality and provenance
- complex ecosystem of largely unconnected data sources
- quantitative data of known provenance and validated quality
- evolving, inter-connected networks of data sources for robust decisions and improved care
Machine Learning (ML) and Artificial Intelligence (AI) and the Analysis of Large Scale Heterogenous Health Data

The Future of ‘Automated Search’ and ‘Retrieval’

Deep Understanding of Content and Context

Collapse Time to Decision: Intelligence at Ingestion

Automated and Proactive Analytics: Why Wait for the Slow Brain to Catch Up to the Fast Machine
Machine Learning (ML) and Artificial Intelligence (AI): Massive Infusion of Private-Sector Funding and Entrepreneurial Activities

https://mattturck.com/data2021/
Just What the Data Ordered

Machine Intelligence and Algorithms for Clinical Diagnosis and Treatment Decisions

Black Box Medicine?
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
Bias: The Omnipresent Danger in ML/AL Datasets
IBM Watson and Cancer Care: A Classic Case Study

- overpromised and underdelivered
- underpowered training sets
- institution-specific data and bias
- risk to patients
- instructive precedent for more stringent AI validation standards
How Will ML-AI Algorithms/decision Analytics Be Validated and Regulated?

- how will regulators accommodate accelerating pace of changes in inputs, outputs and code construction in ML/AI algorithms ($V_1$, $V_2$, $V_n$,...)?
Machine Learning (ML), Artificial Intelligence (AI) and Healthcare

- which clinical specialties/processes will be at risk of replacement by ML-AI and when?
- how will professional competencies in using ML-AI decision-support tools be developed and sustained?
  - MD curriculum, CME
  - non-medical data science professionals
- how will ML-AI platforms alter payment schemes?
- what new malpractice liabilities will emerge by failure to use/interpret ML-AI platforms?
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 automated decision tools in healthcare?
  - Regulatory agencies and professional societies?
  - Humans?
  - Machines?
“Digital Darwinism”:
A Looming Digital Divide

- understanding data structure and its productive application/customization to improve clinical decisions and care outcomes will become a critical institutional competency
- major skill gaps and personnel shortages in biomedicine
- training of a new cadre of data scientists (medical and non-medical)
- institutions lacking adequate computational infrastructure and critical mass in data analytics will suffer ‘cognitive starvation’ and relegation to competitive irrelevance
Major Transitions in Medical Education and Healthcare

1910 - present
(science-centric)

2000 - present
healthcare as a learning system (data-centric)

2015 - ?
mastery of escalating complexity and massive data (network-centric)
New Patterns of Learning
Leadership in an Era of Accelerating Complexity and Uncertainty in Biomedical Research and Demands to Improve Health System Performance
The Co-Evolution of Precision Health, Digital Health and Learning Healthcare Information Systems

- Convergent Technologies
- The Expanded Care Space

**BIG DATA**
- Computing and Automation
- Biomedical Research and Clinical Medicine
- Mdx, Sensors, Robotics

**Risk Analysis, Analytics for Improved Decisions and Clinical Outcomes (value)**
- Mapping the Complexity of Genophenotypic Relationships and Individual Risk(s)
- Longitudinal Monitoring of Individual Health Status

- Remote Patient Monitoring
- SDoH and Life Style Metrics
- Consumer/Patient Engagement
- Population Databases
- Individual EHRs
- Data Science
- ML/AI

Convergent Technologies
- Biomedical Research and Clinical Medicine
- Mdx, Sensors, Robotics
- Computing and Automation

The Expanded Care Space
Unidimensional “Quick Fixes”

“The greatest danger in times of turbulence, is not the turbulence, it is to act with yesterday’s logic.”

- Peter Drucker
The Challenge of Charting Health Policy in a Climate of Increased Social Divisions

- Dysfunctional National Governance, Lack of Bipartisanship and Legislative Paralysis
- Legislative Technical Illiteracy and the Retreat from Complexity
- Dangerous Societal Divisions on Multiple Issues
- Implications Well Beyond Healthcare: A Threat to National Security and Technological Competitiveness?
The Principal Challenges Facing the US Health Ecosystem

- the status quo is not sustainable
  - cost, outcomes, access, disparities
- silos subvert solutions
  - barriers to continuity of care, cost-effectiveness and reform
- imperative to rethink and redesign health ecosystem objectives, functions, capabilities and responsibilities
- widespread failure to apply systems-based analysis methods to optimize inter-depndencies and connectivities for value-based care both population and individual care services
“Strategic Design Spaces for the Evolution of Health Care”

Precision Health Biotechnology, Synthetic Biology

Population Demographics and Disease Burden

IoMT: Ubiquitous Sensing and Sensor Networks

Big Data Analytics, Machine Learning and AI

Technology Convergence, Acceleration and Escalating Complexity

“Bio-Space”

“Unmet Need Space”

“Connected and Monitored Space”

“Decision Space”

“Opportunity Space”

Improved Health Risk and Mitigation

Defining “Value” in Healthcare Will Intensify

New Knowledge Networks

New Participants

New Organizational Models
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Slides available @ casi.asu.edu/presentations

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