



“Love It or Leave It”
Biometric & Big Health Data Here to Stay:
Can't leave it... can we learn to love it?

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*You are familiar with
digital books and movies?*

Now ability exists to *digitize humans* - integrating a person's unique data including biometric and other big health data.

What is “Biometric Data”?

Includes fingerprints, earlobe geometry, retina and iris patterns, voice recognition, DNA, handwriting

GDPR definition:

“Personal data ... relating to the physical, physiological or behavioral characteristics of a natural person, which allow or confirm ... unique identification.....”





World's
Largest
Biometric
Database =
+ 1.2 Billion

- Includes fingerprints, iris scans, addresses, birthdates
 - India's Supreme Court held it does not violate privacy rights
- ...but, Court cut back scope:
Not required for use with bank, cellphone accounts or school.

What is “Big Health Data”?

Includes biometric data ± medical records, genetics, biopsies, medical bills, clinical trials, prescriptions, and more

750 quadrillion bytes everyday created — 30% all world's data production

Big health data is in Cloud systems: too much data to keep onsite: *Hospital on-site Datacenters will be as outdated as paper medical records*

Big health databases differ:

Funding (public,private)

Mandatory, voluntary

Patients opt-in / opt-out

Open/closed (access)

Analytic capabilities

Examples....

“Physicals for All Program” Xinjiang, China

DNA , fingerprints, iris facial scans & blood typing, medical data collected from all residents 12 - 65 yrs (not optional)

Total population = 21.81 million people

Testimonials describe treatments for previously undiagnosed, life threatening illnesses

World's 1st All-Digital Nation

population + 1.3 million all on X-Road government platform

~All health, voting, school, legal, banking, taxes more

~Individuals own their data

~Digitally linked NOT centrally held: Individual servers linked to end-to-end encrypted pathways

~Users must request information

~Accessing secure data recorded and reported
Accessing secure data without consent is a crime.



“All of Us”

U.S. Government

Precision Medicine Initiative



Initial goal *at least* one million Americans in database by 2020.

Opt-in program (**voluntary**)

Includes all:

- ✓ **Medical records**
- ✓ Genetic test results
- ✓ **Health questionnaires**
- ✓ Mobile app data

Europe's Answer to Precision Medicine- "EMIF" (European Medical Information Framework")



- ✓ EU + *pharmaceutical industry-funded*
- ✓ 56 partners from 14 countries
- ✓ User must *request access to data* and access not automatic nor guaranteed
- Projects limited to Alzheimers and metabolic caused obesity.

Epic

A private, for-profit U.S. company

- In 2017, +190 million patients' health data
- Expanding worldwide
- “Opt out”
- *Limited* open network



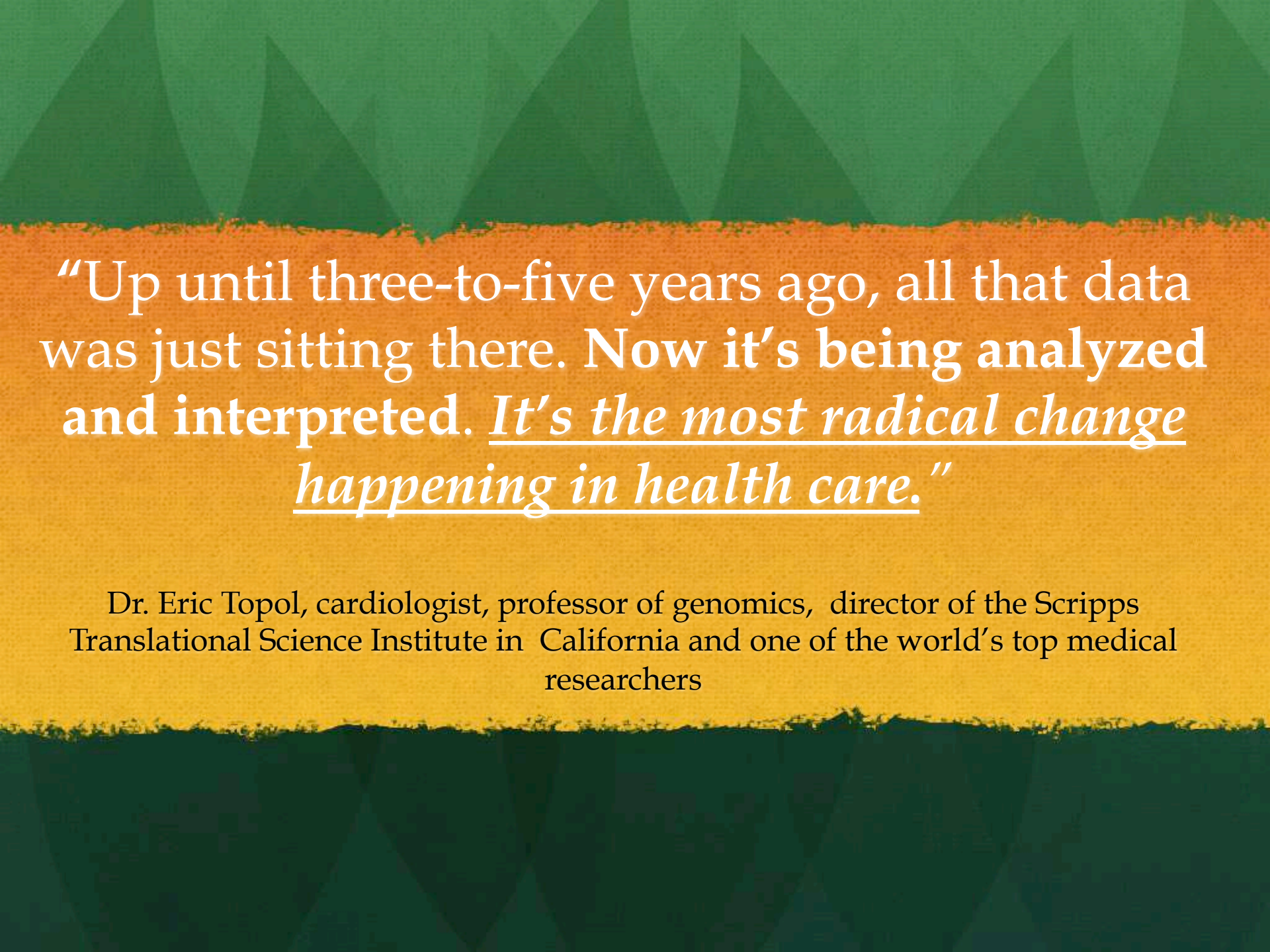
Google's AI "Medical Brain"



Google AI

Reads *handwriting*,
PDFs, other big data
too costly- time consuming to use on
large scale basis *before*

In past, 80% time for predictive models spent
decoding data, making useable format. *No longer*

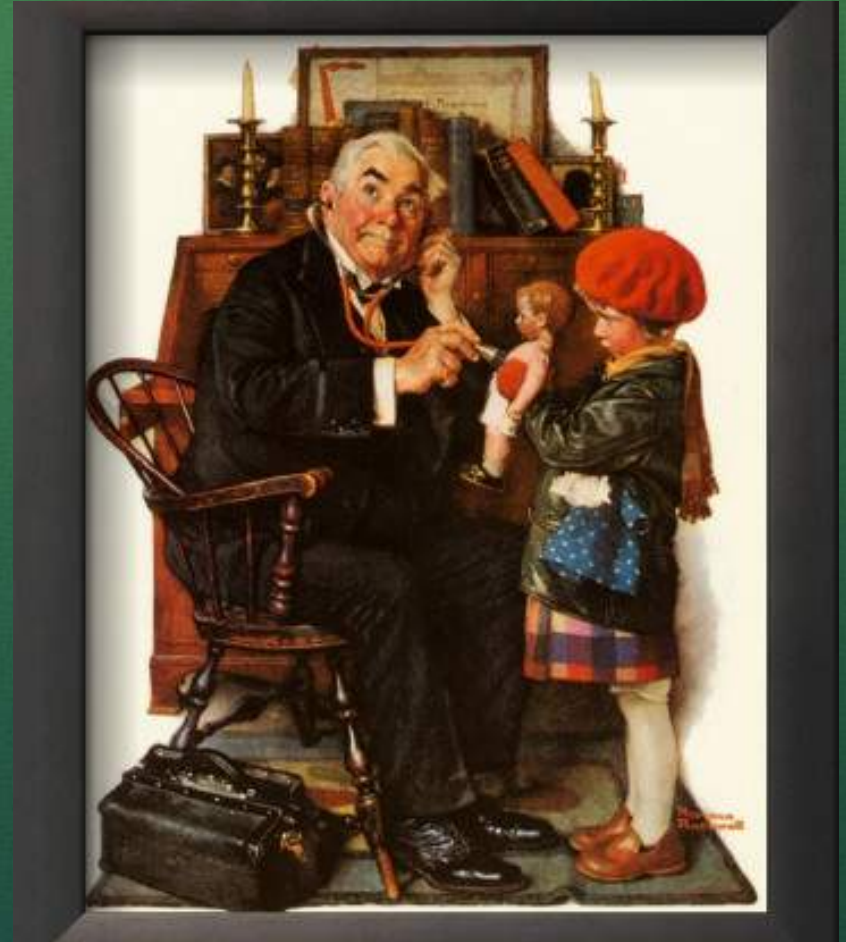


“Up until three-to-five years ago, all that data was just sitting there. Now it’s being analyzed and interpreted. It’s the most radical change happening in health care.”

Dr. Eric Topol, cardiologist, professor of genomics, director of the Scripps Translational Science Institute in California and one of the world’s top medical researchers

Precision Medicine *vs.* *Traditional Medicine*

- Traditionally, treatment tailored for the “**average patient**”
- While “average patient’s” treatment benefits some, *it proves ineffective other patients*



What is Goal of Digitizing Humans???

Identify our *specific differences* in big health data to :

1. Create *universal personal medicine* tailored to each patient
2. Prevent disease
(*not just cure it*)



In 2011...

First Documented Life Saved from big data*

- 13 year old rushed to Stanford University's Emergency Room
- **History lupus (immune system attacking organs)**
- Lab results show *high risk of stroke*
- **One specialist says anti-coagulate and one says do not anticoagulate**

What to do?

- Treating doctor unlawfully uses Watson, identifying other lupus teens with similar lab results.
- **100 other teens found. Vast majority anti-coagulated safely.**
- Patient anti-coagulated and recovers.

* Jennifer Frankovich, Christopher A. Longhurst, *Evidence-Based Medicine in the EMR Era* 365 New Eng. J. Med 1758 (2011)

ARTIFICIAL INTELLIGENCE (“AI”)

Not only digests big health data...

**IBM’s AI Watson digests
libraries of medical
journals and textbooks**

10,000’s of clinician
hours and training cases

**Uses advanced analytics
and predictive “deep
learning”**



Can AI Cure Cancer ...?



For patient's individual tumor, AI looks for:

- Specific clinical trials
- Weighs treatments success rate

In one test on 1,000 cancer patients:

- AI matched doctors treatment 99%
- Advised *additional* treatment options for 30% patients

AI *predicting* heart disease...and soon *treating*

AI - 600 variables to ID patient's risk vs. doctors' 27 variables +

AI more accurate than doctors ? In one study*, AI ID 355 more patients who *later* developed heart disease *doctors missed !!!*

In 5 years, expect AI to go from *predicting risk* *to treating heart disease* based on success of other patients with similar characteristics

Some Big Health Databases Are For Profit

“Surveillance Capitalism”*

Surveillance capitalism
= making profit from
captured data.

*Phrase coined by social scientist
Shoshana Zuboff



+ 5 million people
paid US\$100 each
to have saliva
analyzed for DNA
related relatives.



Drug giant GlaxoSmithKline *paid* 23andMe
US\$300,000,000. for *exclusive rights* to
customer data to create new drugs for profit

*Not all big data
about surveillance
or making a profit...*

Use Big Data and
technology to
improve global
medicine by:

~Giving patients
control to self-
manage care

~Providing universal
accessible and
affordable healthcare

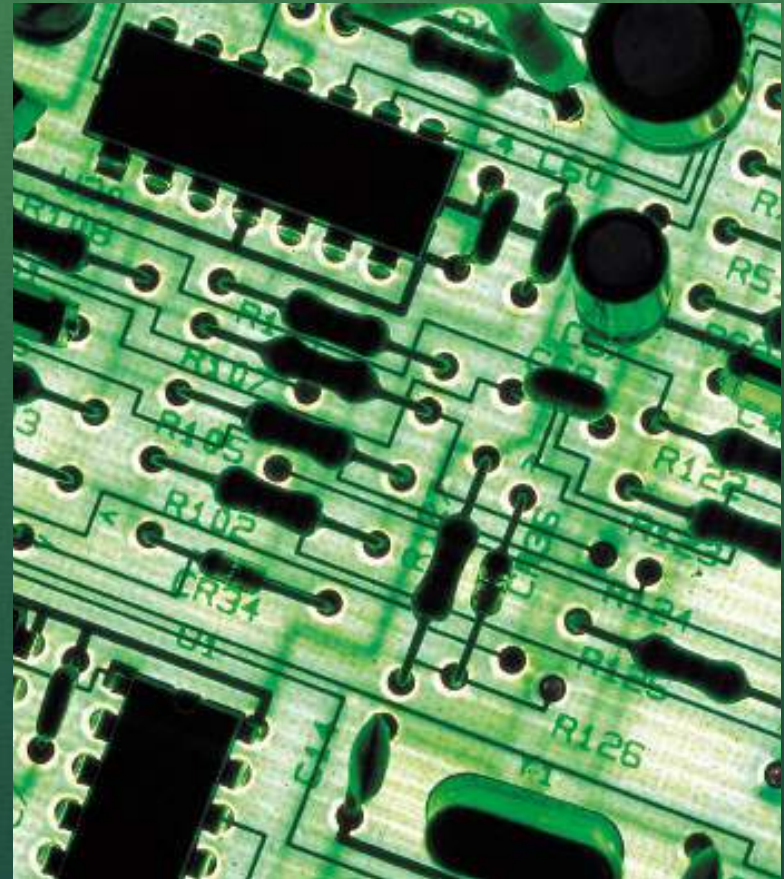
“iMedicine Galaxy”*



* Eric Topol MD

What does it take to change the future of medicine?

- Big health data
- Smartphone
- Wifi/cellular data connection
- Combined with electrical engineering & sensors (*"synthetic biology"*)



Smartphone = “Guttenberg of Health Care”?*

Printing press changed
the world – made masses
literate

Smartphone changing the
world - *rapidly* giving
patients medical
information to take control
of own health



Continuing challenge of digitizing people:

- ✓ Synch all data with mobile apps, social data in *real time*
- ✓ Make affordable
- ✓ Make safe and secure
- ✓ Make universal

Medical Sensors + Labs on a Chip

- Takes electronic devices used in hospitals to measure:
 - ✓ Blood pressure
 - ✓ Temperature,
 - ✓ oxygen saturation, etc.
- Expanding to cheap, worldwide use of **wearable sensors on watches, smartphones**



Smartphone + *cheap attachments*
= costs drop dramatically:

+ High powered microscope
diagnoses malaria+ TB

+ Treated paper
processes urine, blood, sputum for molecular diagnoses (*similar to home pregnancy testing kits*)



Phone apps increasing *powers of perception* with natural *language processing* + *computer vision*

Examples when combined with big health data:

Apps track *how we walk* + our *speech patterns* =
MEASURES EARLY MENTAL DECLINE

Apps “*see*” via cameras with computer vision
algorithms=

DETECTS SKIN CANCER

- With imbedded biosensors, know *what* disease exists and *when* it needs treatment

Apple iPhone apps: *Worldwide Research /Self-help Platform*

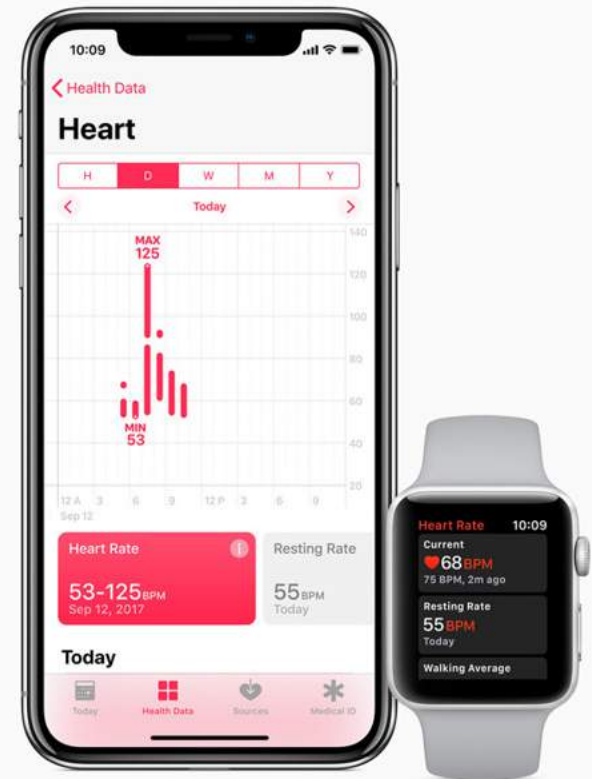
<https://www.apple.com/researchkit/>

Examples:

Parkinson's app: Gyroscope collects data gait, tremor, voice.
Since 2015, 10,000 people=
LARGEST PARKINSON'S STUDY IN HISTORY

Autism app: Videocam & facial recognition app analyzes emotional reactions for treatment

PRIVACY? People choose what to join, control what info to give to which apps and can see data being shared.



Empowering Personal Healthcare:

Qualcomm Tricorder global competition



Modeled after Star Trek Tricorder, handheld device diagnoses diseases

Goal: Give consumers *independent* medical care without health professionals

Criteria:

- * <5 lbs (2.3 kg)
- * Diagnose +13 conditions
- * Continuously record, stream 5 vital signs
- * Diagnose patients as good as team of docs

Millions US \$ already awarded top finalists

The Sensor Project

www.thesensorproject.org

“Make vital sign monitoring available to everyone everywhere”

1st project- fund oxygen saturation sensors screening 20,000 pregnancies in 4 low income countries to ID deadly high blood pressure (pre-eclampsia)

Infant deaths dramatically decreased in two years

“Helping Babies Survive” healthychildren.org

Initiated by World Health Organization and global consortium

Smartphone monitoring
reduced infant mortality
from asphyxia,
infections, preterm
complications

**Example: Tanzania-
newborn mortality
dropped 47% in 2 years**

Reaches 400,000 health
care providers in 77
countries

EVERY NEWBORN
An Action Plan To End Preventable Deaths



"Imaging the World"

imagingtheworld.org

Software transmits ultrasounds over cellphone signal :

Pilot program: Eight sites in rural Uganda identifies:

- ✓ High risk pregnancies
- ✓ **Breast cancer**
- ✓ Liver, kidney thyroid disease
- ✓ **Trauma triage**
- ✓ Heart disease



“Abilify MyCite”

Your Pills Will Spy on You

- New anti-psychotic drug
- First U.S. FDA-approved drug with *tracking mechanism*-digital sensor alerts if pill not taken by patient
- Like other medical devices has data reporting (insulin pumps, pacemakers)



Up Next? **IMBED Pills**

(Ingestible Micro-Bioelectronic Device)

Made to explore *inside* the body:

Swallow pill, passes into stomach

- ✓ **When inflammation or infection found, wireless signal sent**

Tested on pigs:

- ✓ **Finds stomach inflammation**
- ✓ Finds intestinal infections
- ✓ **@ 52 minutes to find excess bleeding**
- ✓ *Correctly* identifies pigs with bleeding and ones without



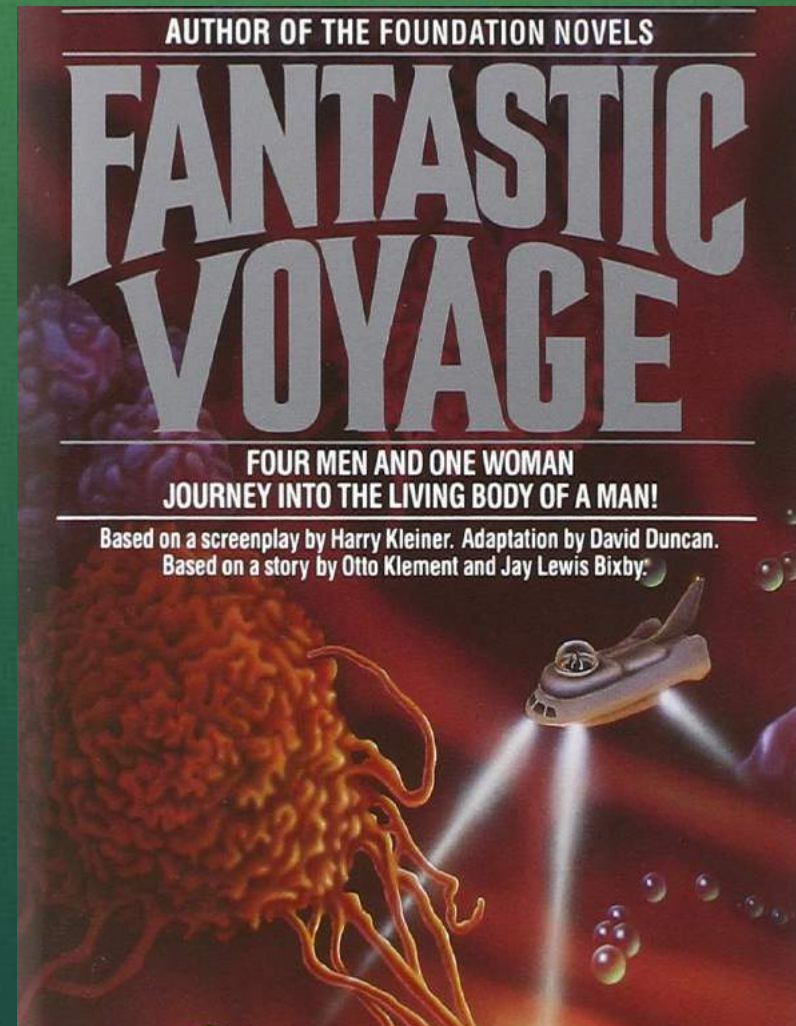
“The day before something is truly a breakthrough, it’s a crazy idea.”

Peter Diamandis

1960’s Science Fiction

PLOT: Submarine crew shrunk so small they can squeeze inside human and travel to brain + help inside body

IMBED works like this *without shrinking people!*



Plans for IMBEDs:

Now 30ml (1") : Plans for *Imbeds* 1/3 smaller

Unlock information about body's functions + impact of disease and treatment

- Treatment on horizon:

- Replace colonoscopies**

- Diagnose circulatory system.

- **Remove blood clots in organs(like brain)**

Is This All Too Good to be True?



Is Big Health Data, technology Promising More Than it Can Achieve?

**May overstate potential and ignore serious
challenges**

Is Technology Driving Hypochondria???

- ✓ "False alarm" calls to doctors?
- ✓ Risk of misdiagnosis
- ✓ Risk of over-treatment

Is Privacy Doomed to Die?

Most systems do not delete identifiers only de-identify

Re-identification available (*how lupus teen treated*)

Easily re-identified if genetic data cross-referenced with online data (Social Media)

Are We all at risk for e-Theft?

Stolen health data= *stolen identity*

Health data worth more than stolen credit card

Children's health data/identity worth most:

- Rarely check kids' credit reports
- With no debt, kids have excellent credit!

Too Much “Red Tape” and Ethical Problems?

Will AI and government have too much power?

Will AI make its own decisions?

*Is there a difference between doctor
“diagnosing” and AI predicting?*

What about UNINTENDED CONSEQUENCES?

Information collected
for one authorized purpose is
used for another

Can this lead to
discriminatory profiling...
Good or Bad?

U.S. Serial Killer Caught by Family posting DNA

Looking for lost family, person uploaded DNA data on ancestry website

California police searched ancestry site, comparing old crime scene samples linked to “Golden State Serial Killer”

- This serial killer committed + 50 rapes + 12 murders in 1970s and 80s
- **Police arrested a man for crimes based on DNA match of suspect's family member found in ancestry database**

+1 million Americans DNA data on open ancestry websites

@ 60% Americans can now be ID by name with DNA, age + what region they live

By 2021, once 3 million+ DNA on open websites, *nearly all Americans will be identifiable* by DNA alone with few data points.

Science Journal published October 2018 <https://www.sciencemag.org/news/2018/07/report-advocates-broader-return-research-results>

How is U.S. law keeping pace with privacy concerns?

There is no broad U.S. federal guarantee of a right of privacy



U.S. Supreme Court (*finally*) Places *Some* Limits on Collecting Personal Data

Data kept for one purpose cannot be used for other purposes without warrant

Carpenter v. United States gives privacy of cellphone location records and *Riley v. California* privacy over data if smartphone locked

Unknown how far cases will be applied

Since serial killer caught with data from search warrant, arrests likely okay

U.S. Law on *Health Data*

- **Health Insurance Portability and Accountability Act (HIPAA) + HITECH Act**
- - Federal laws with minimal privacy protection
 - No financial compensation for patients
 - State laws vary
- **California Medical Information Act (CMIA):**
 - Bars medical data disclosure without consent
 - Requires data kept/disposed with confidentiality.
 - Allows financial compensation for the patient including:
 - ✓ Min \$1,000 *even if person had no adverse effects*
 - ✓ All of the out of pocket expenses
 - ✓ Attorneys fees
 - ✓ Class actions allowed

Where does American Law Stand on Big Health Data?

California enacted sweeping privacy laws, 2018 Consumer Privacy Act (CCPA) similar to GDPR

but it was *amended to exclude medical data!*

US Patient has no ownership right
to profits from tissue/cells

Moore v. Regents

Patient treated for cancer at
UCLA. Cancer cells developed
into cell line commercialized
by UCLA

California Supreme Court held
patient's discarded blood and
tissue not his personal
property

U.S. Supreme Court:
Mother Nature Cannot Be Patented

Assoc for Molecular Pathology v. Myriad Genetics

Myriad patented BRCA1 + BRCA 2- associated with breast + uterine cancer, giving them monopoly

Court held patents on *naturally occurring gene sequencing* NOT valid: genetic information produced by nature and not inventive.

Effect of ruling: Open competition for sequencing and human genes, *causing testing prices to drop*

U.S. 21st Century Cures Act

*Broadens access
to patients for own health data*

Bars “information blocking” (not allowing patient to get patient’s own personal health data)

- ✓ Applies to app creators, hospitals and doctors
- ✓ Fines up to US \$ 1 million
- ✓ Problem: Awaiting government regulations since 2016 for implementation
- ✓ Patient still doesn’t exclusively own or control data

What Must Be Done ?

MOOM- Massive Open Online Medicine *
Massive medical data sharing from data

Example: Cystic Fibrosis Foundation all opened patient data led to genomically geared treatment in 1/3 of time usually spent on drug development by finding patterns in the data

*Coined by Dr. Eric Topol

What Must Be Done?

Each person must own their own data- and decide individually how it can be used or sold

Not current culture nor US Law

What Else Must Be Done ?

Ancestry websites should only allow searches related to one's own DNA.

How?

23andMe and others must put special code on raw data files given to people.

Open ancestry sites only upload/access DNA sequence if they have a valid code.

What Must Be Done ?

- ✓ Ban *sale of data* for targeted ads
- ✓ Protect disclosure in legal proceedings
(burden on lawyer filing documents with court to protect privacy)

: *Ethically difficult restrictions*
(effect patients like girl with lupus) :

- | | |
|--|---|
| ✓ Require Multiple tiers of data access
(depending on type, use and user) | ✓ Stop unauthorized re-identification or make <i>anonymous and delete identifiers</i> (will never happen) |
|--|---|

The end...

Thank you.

Questions?

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