



Cutting edge health technologies; ethical considerations

Prof. Effy Vayena

Health Ethics and Policy Lab

effy.vayena@hest.ethz.ch

@EffyVayena

1. Trends and convergence

NEW SCIENTIFIC BREAKTHROUGHS, TREATMENTS, AND CURES

Genetics and stem cell research

- Single-cell analysis
- Gene and stem cell therapies
- Genetic engineering and editing including CRISPR technology

Nanotechnology

- Swallowable small devices

Biologics

- Development and manufacture of complex biologics

Brain research, neurology, and neurosurgery

- Characterization of the brain's major circuits
- New brain imagery for mental disorders
- Migraine treatment

New generation of vaccines and immunotherapy

- HIV and universal flu vaccine
- Cancer vaccine
- Immunotherapy
- New vaccine delivery methods

Pain management

- Effective, non-addictive medicines for pain management

Mental health treatments

- Pre-symptomatic diagnosis and treatment of Alzheimer's disease and other cognitive declines

NEW MEDICAL TECHNOLOGIES

Medical devices

- 3D printing
- Cardiac devices
- Implants and bionics

Medical imaging and diagnostics

- Optical high-definition imaging and virtual anatomic models
- Biosensors and markers
- 4D human charting and virtual reality
- Screening for diseases

Precision and personalized medicine

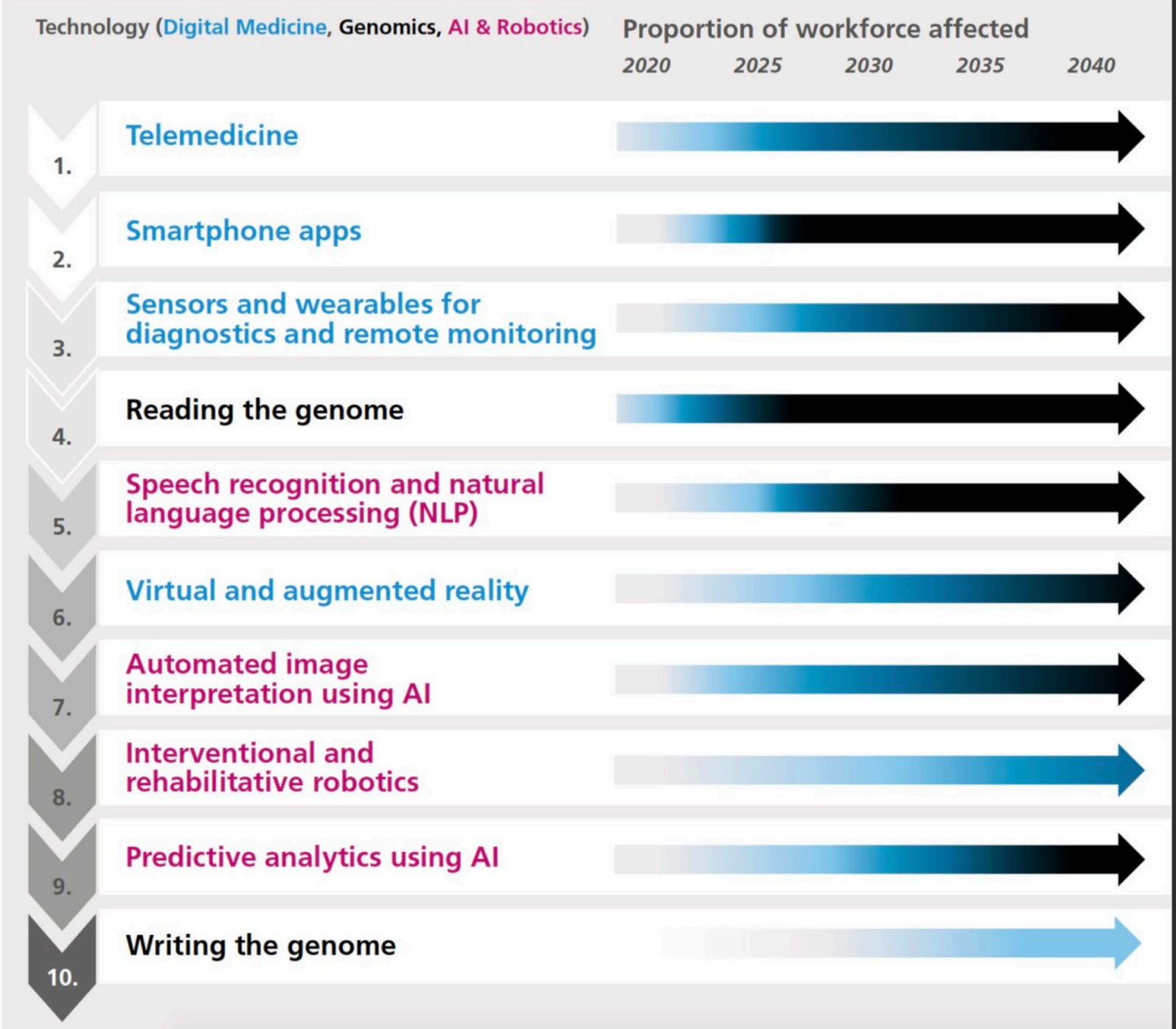
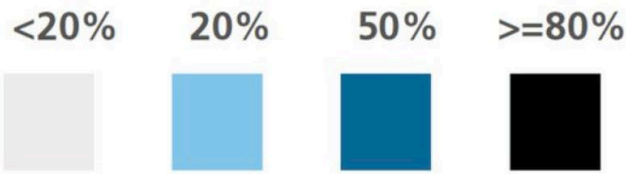
- Computer-assisted surgery
- Surgical robots
- Personalized medicine

Regenerative medicine

- Tissue engineering
- Effective bioartificial pancreas

Global Innovation Index 2019

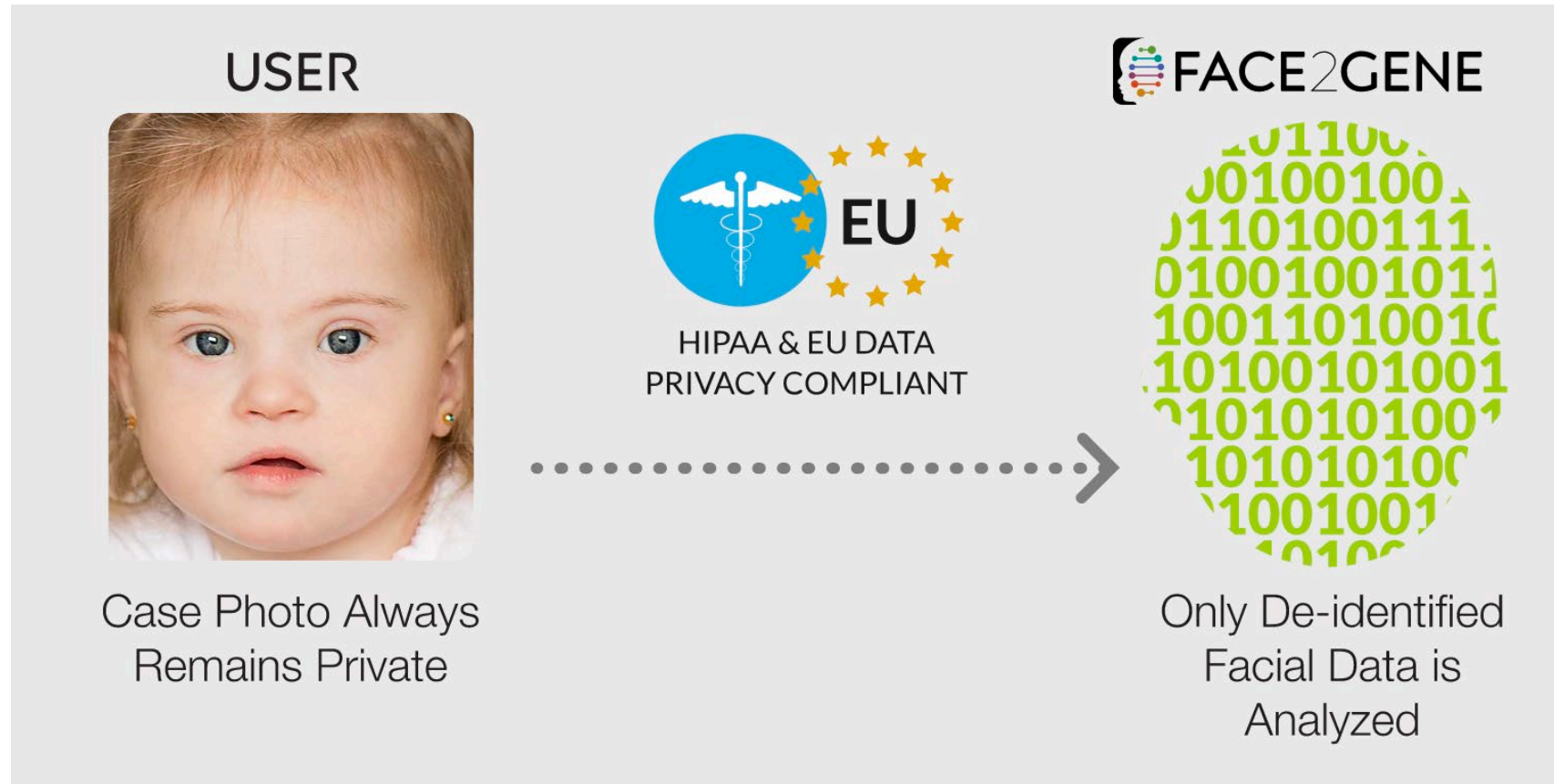
Our Rating of the Top 10 Technologies, Their Penetrance from Now to 2040



1. Trends and convergence

- Precision medicine (genomics, omics)
- Digital medicine (data and analytics)
- **Convergence** of the biological and the computational

2. Convergence



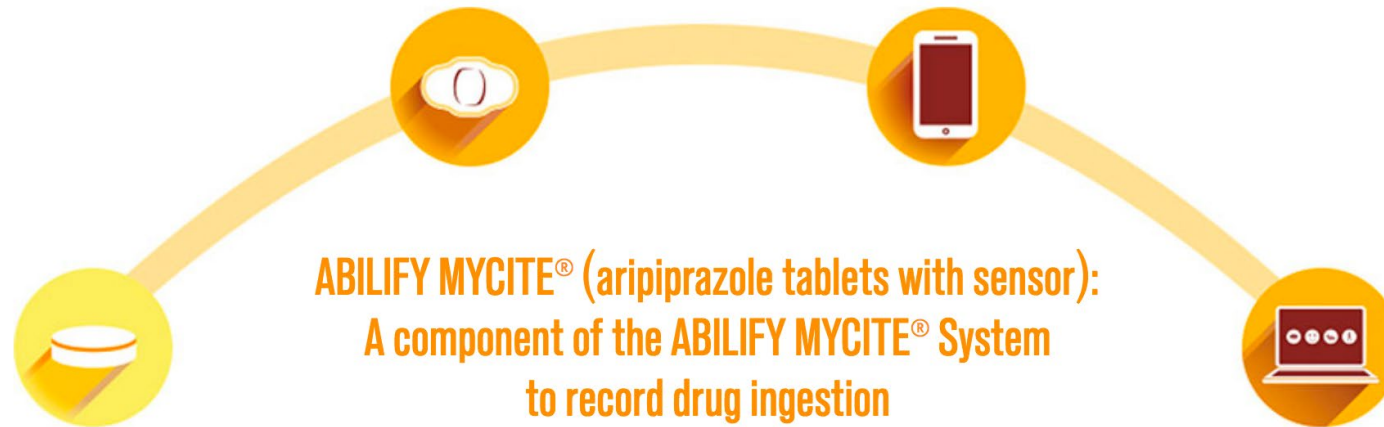


Please see [U.S. FULL PRESCRIBING INFORMATION](#), including **BOXED WARNING**, and [MEDICATION GUIDE](#).

About

Instructions for Use

Initial Rollout



ABILIFY MYCITE is a prescription medicine of an aripiprazole tablet with an Ingestible Event Marker (IEM) sensor inside it used in adults for the:

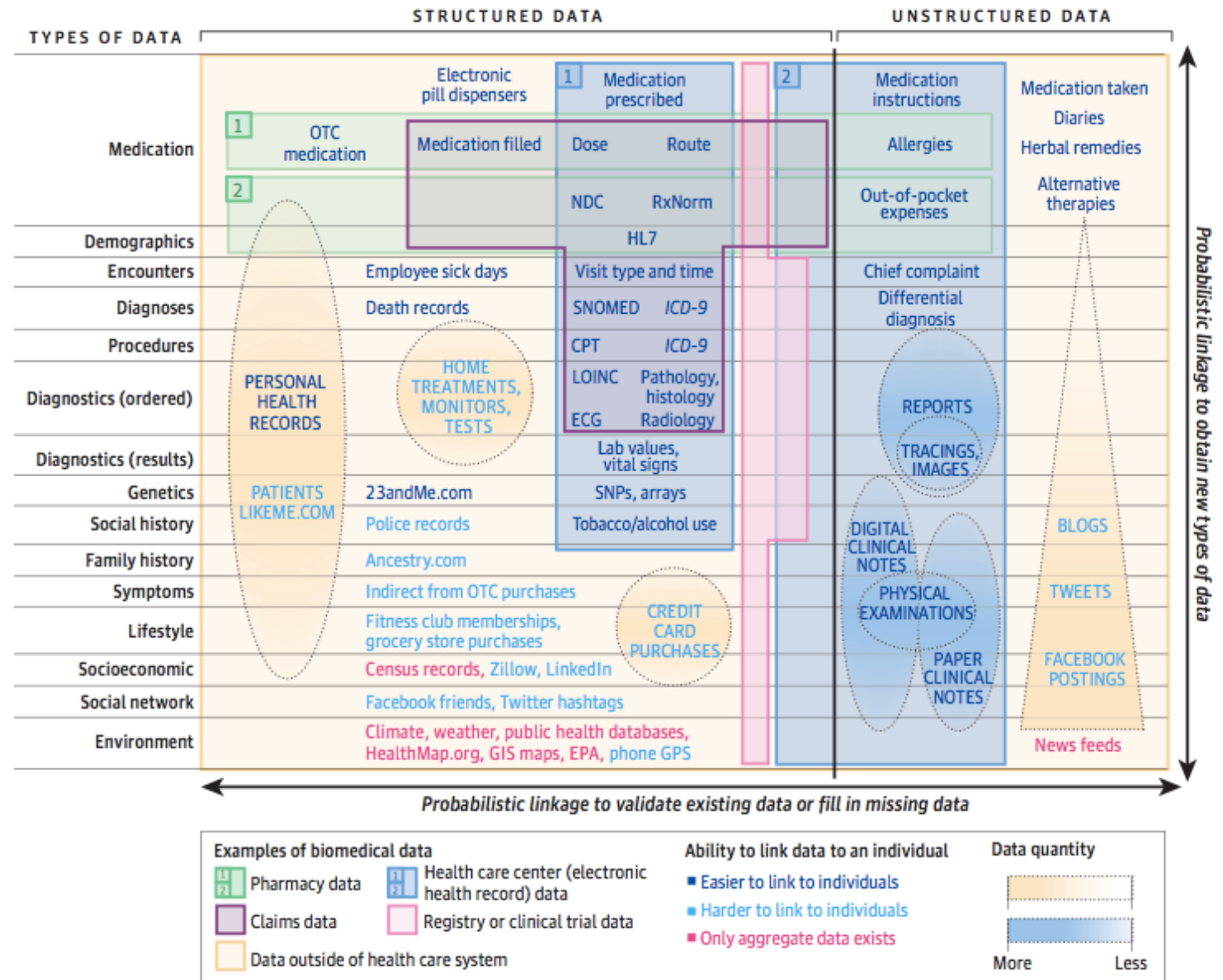
Treatment of
schizophrenia

Treatment of bipolar I disorder
alone or when used with the
medicine lithium or valproate for:

- acute (short-term) treatment of
manic or mixed episodes
- maintenance treatment

Treatment of major depressive
disorder (MDD) along with other
antidepressant medicines

Figure. The Tapestry of Potentially High-Value Information Sources That May be Linked to an Individual for Use in Health Care



Weber et al.2014
JAMA

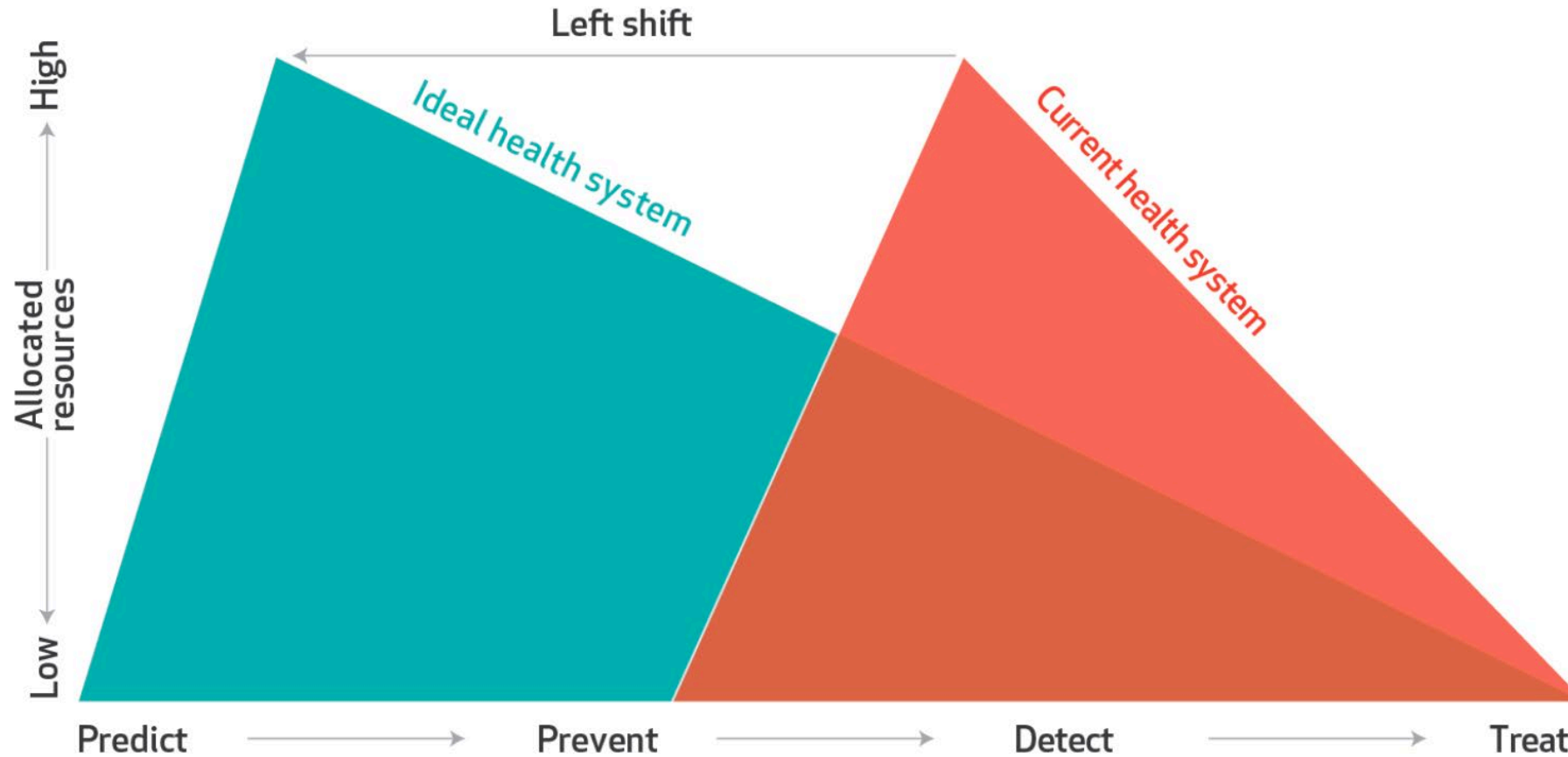
Paradigm shift

“The patient is an enormous repository of information that needs to be harvested as a partnership not only in clinical care but in discovery as well.

It is the only way we will **define wellness and its progression to disease**, rather than **traditional medicine that defines disease and its progression to death.**”

- Dennis Ausiello , Nature Biotech, 2015

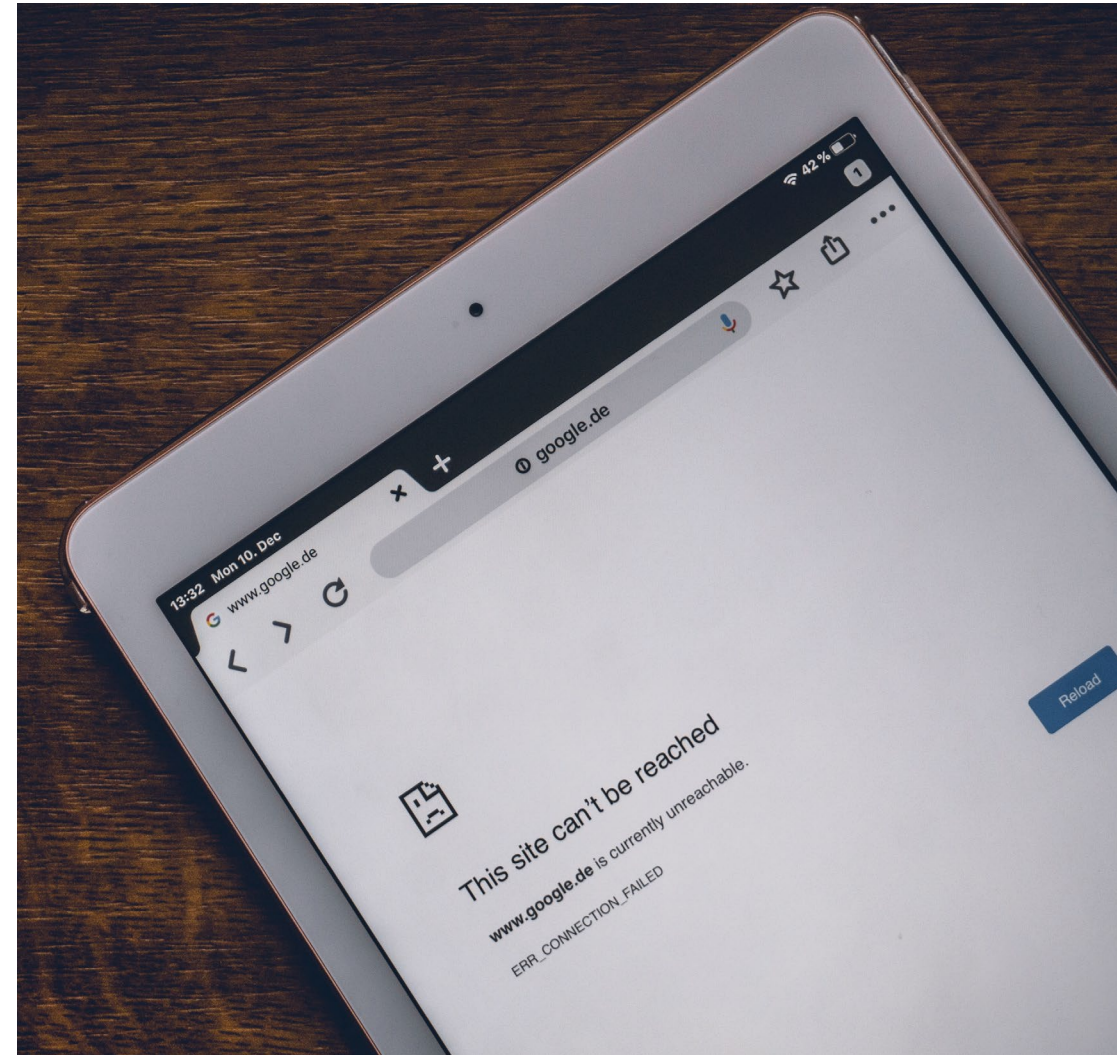
Promise for health



Source: "The Oversell And Undersell Of Digital Health," Health Affairs Blog, February 27, 2019. DOI: 10.1377/hblog20190226.63748

3. Data Quality and Data Aggregation

- Data collection and interoperability
- Data quality
- Data sharing



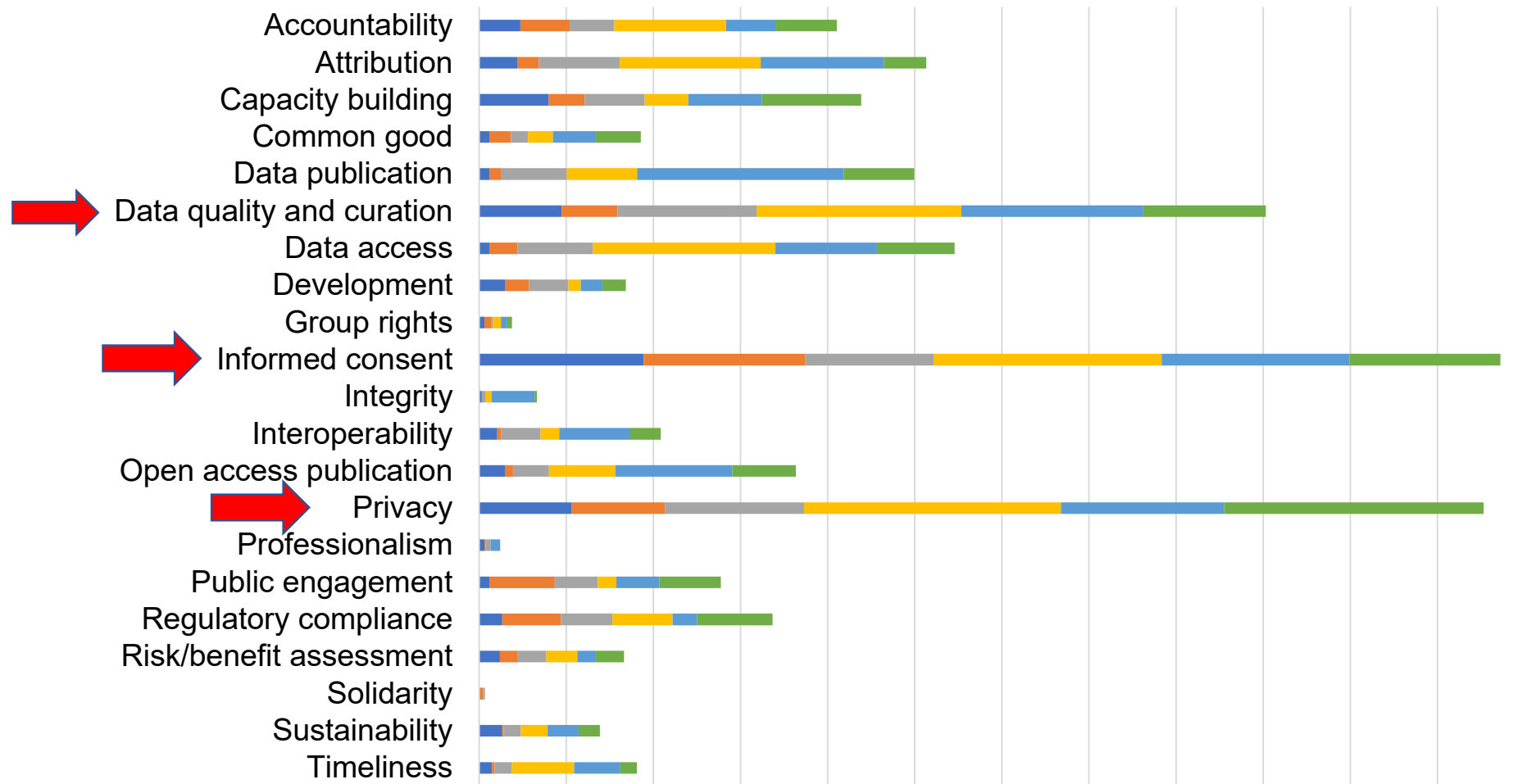
4. Data sharing

PRECISION MEDICINE

By Alessandro Blasimme, Marta Fadda, Manuel Schneider, and Effy Vayena

DOI: 10.1377/hlthaff.2017.1558
HEALTH AFFAIRS 37,
NO. 5 (2018): 702-709
©2018 Project HOPE—
The People-to-People Health
Foundation, Inc.

Data Sharing For Precision Medicine: Policy Lessons And Future Directions



- International public policy organization
- National public policy organization
- Scientific society/professional organization/expert group
- Public research funder
- Scientific consortium/institute
- Government/governmental organization

5. Consent



NATURE | NEWS FEATURE



Informed consent: A broken contract

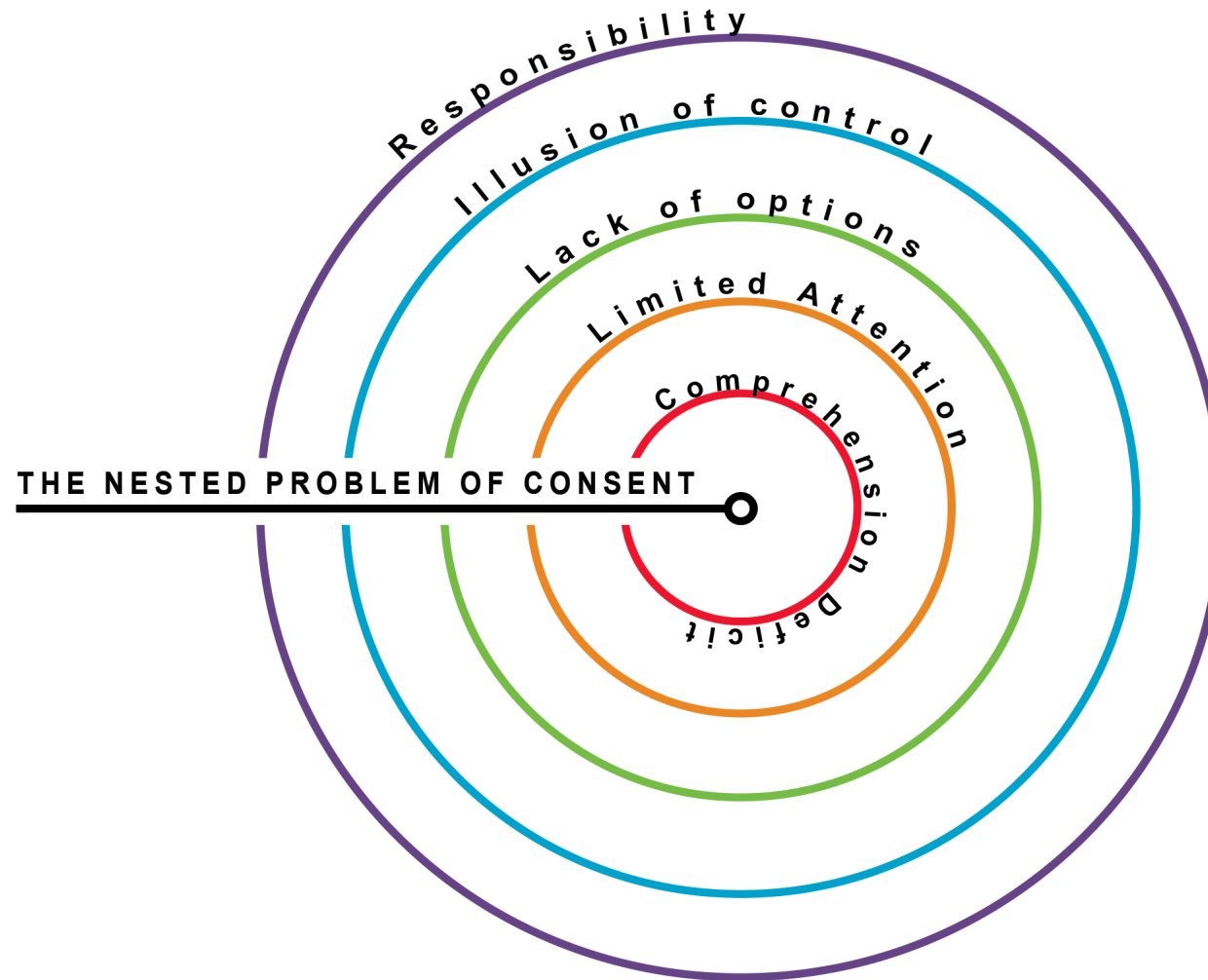
As researchers find more uses for data, informed consent has become a source of confusion. Something has to change.

Erika Check Hayden

20 June 2012

Koenig, B. Have We Asked Too Much of Consent? *Hastings Center Report* 44, no. 3 (2014):33-34

5. Consent



5. Consent

Consent Innovation

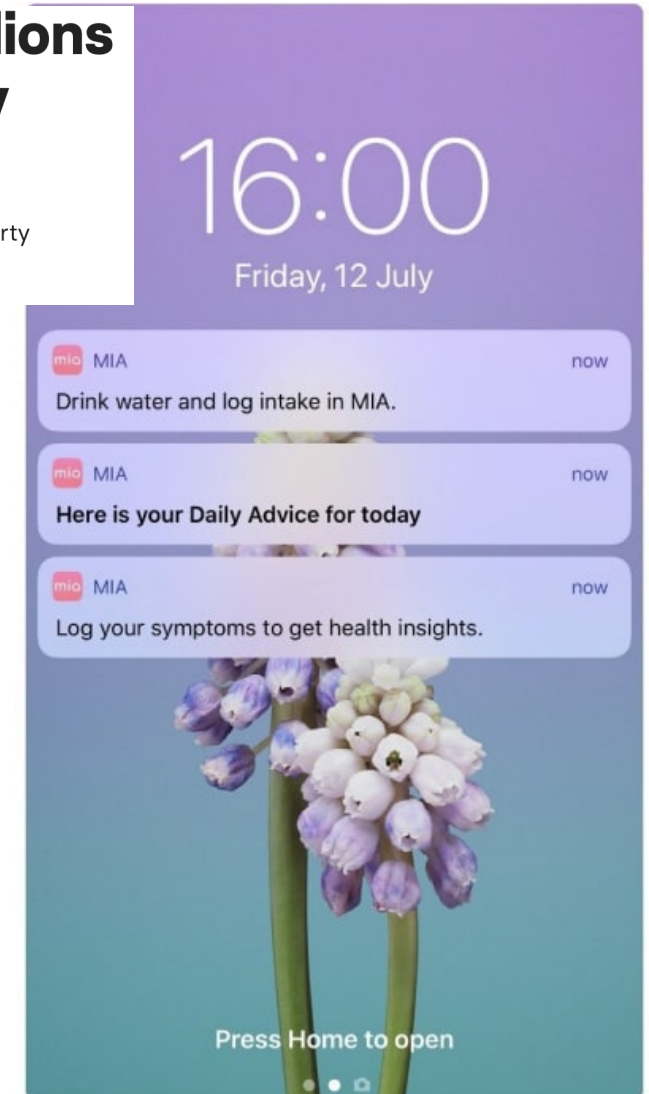
Least onerous - info-control + data availability	Midway		Most onerous + info-control - Data availability
	Overseen	Choice-based	
No consent Presumed consent (Gill 2004) Presumed consent with opt-out (Wendler and Emanuel 2002) Blanket consent (UNESCO 2001) (Tomlinson 2013) Open consent (Lunshof et al. 2008) Portable legal consent (Hayden 2012; Vayena, Mastroianni, and Kahn 2013) Broad consent 1 = blanket + limitations (as defined in Grady et al. 2015)	Broad consent 2 = blanket consent + safety + withdrawal + access review (Hansson et al. 2006) Broad consent + ongoing oversight and communication (Grady et al. 2015) Broad consent + governance (O'Doherty et al. 2011) Broad consent + trusted governance system (Koenig 2014; Garrett, Dohan, and Koenig 2015)	Authorization model (Caulfield, Upshur, and Daar 2003) Tiered consent (McGuire and Beskow 2010; Mello and Wolf 2010; Bunnik, Janssens, and Schermer 2013) Electronic informed Consent (FDA and DHHS 2016; Sage Bionetworks 2017) Dynamic consent (Kaye et al. 2012; Kaye et al. 2015; Budin-Ljøsne et al. 2017)	Informed consent (Faden and Beauchamp 1986; Manson and O'Neill 2007) Consent for de-identified samples and data

6. Privacy

- Data provenance
- Secondary uses of data
- Re-identification
- Inferences

Period Tracker Apps Used By Millions Of Women Are Sharing Incredibly Sensitive Data With Facebook

Data including when women last had sex was sent to Facebook and other third-party services, according to new research shared exclusively with BuzzFeed News.



7. Quality assurance

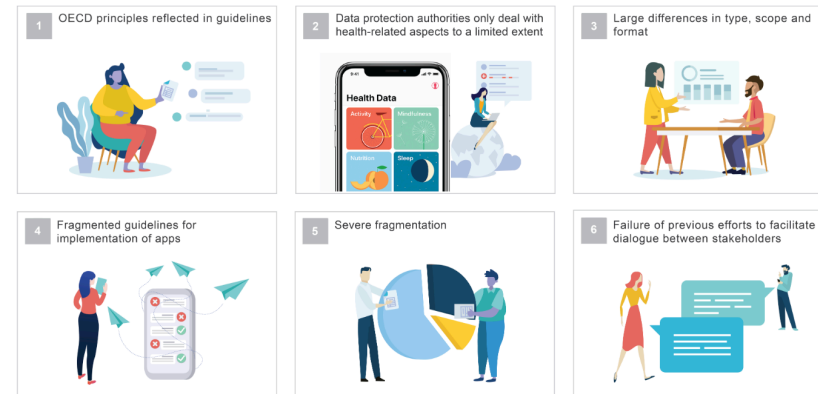
Health Apps: Quality Assurance? Evaluation of existing guidelines

Effy Vayena,
Health Ethics & Policy Lab, Departement für Gesundheitswissenschaften und Technologie

Which guidelines already exist?



Findings from the analysis of existing guidelines:



→ No generally applicable guidelines for quality assurance in health apps

Conclusion:

There is an urgent need for systematic quality assurance through the development of new frameworks at international level that will enable harmonisation and the targeted implementation of guidelines.

Ferretti, A., Ronchi, E., & Vayena, E. (2019). From principles to practice: benchmarking government guidance on health apps. *The Lancet Digital Health*.
[https://doi.org/10.1016/s2589-7500\(19\)30027-5](https://doi.org/10.1016/s2589-7500(19)30027-5)

7. Quality assurance

Classic [#HeartAttack](#) symptoms in a FEMALE, results in a diagnosis of [#PanicAttack](#) or [#Depression](#).

It's hysteria, not a heart attack, GP app Babylon tells women

Shanti Das

October 13 2019, 12:01am,
The Sunday Times

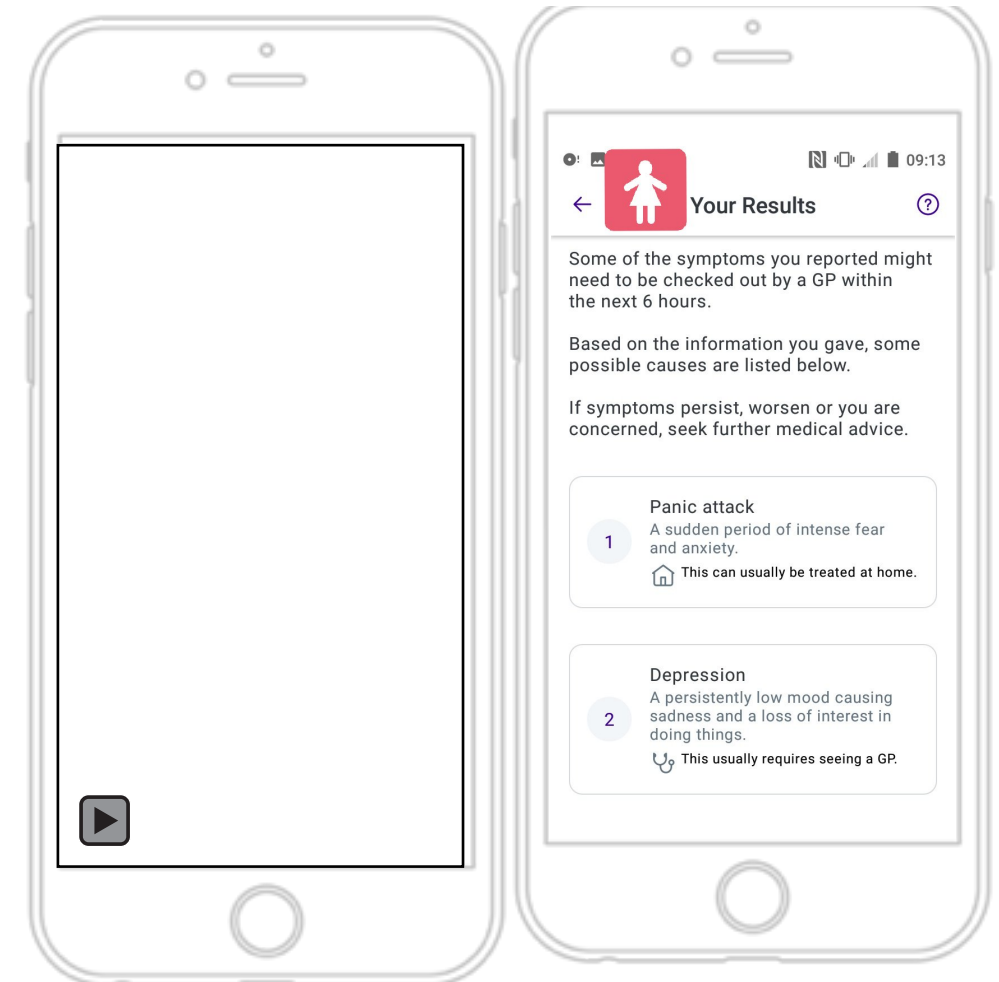
NHS

Conservative Party

Politics

UK politics

Health



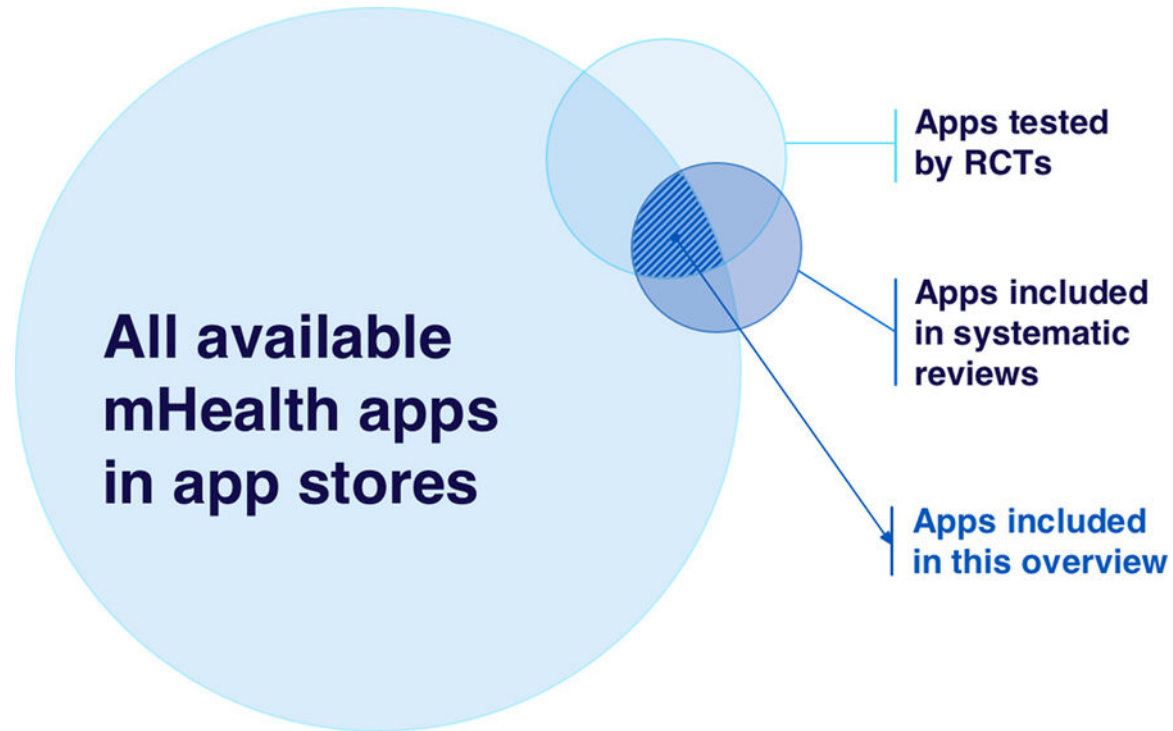
8. Evidence

Coding element	n (%) of apps
§3. Positive claims	59 (81)
§3.a. Claims of effectiveness	47 (64)
§3.a.i. Detection or diagnosis	7 (10)
§3.a.ii. Improvement in symptoms or mood	22 (30)
§3.a.iii. Improvement in self-management	26 (36)
§3.b. Claims of acceptability	33 (45)
§4. Supporting statements	47 (64)
§4.a. Scientific language	32 (44)
§4.a.i. Specific technique described	24 (33)
§4.a.ii. Evidence from study using app	2 (2.7)
§4.a.iii. Citation to scientific literature	1 (1.4)
§4.b. Technical expertise	23 (32)
§4.b.i. Certification or accreditation	0
§4.b.ii. Prizes or awards	2 (2.7)
§4.b.iii. Credible developers	18 (25)
§4.b.iv. Credible endorsements	3 (4.1)
§4.c. Lived experience design	10 (14)
§4.c.i. Lived experience involvement	6 (8.2)
§4.c.ii. Lived experience developer	5 (6.8)
§4.d. "Wisdom of the crowd"	14 (19)
§4.d.i. Download, usage or popularity statistics	11 (15)
§4.d.ii. User testimonials	8 (11)
§4.d.iii. Press endorsements	6 (8.2)
§5. Negative claims	22 (30)
§5.a. Medical disclaimer	20 (27)
§5.b. Legal disclaimer	8 (11)

All percentages are reported based on n = 73

*Larsen, et al. Using science to sell apps:
Evaluation of mental health app store quality claims
npj Digital Medicine 2, :18 (2019)*

8. Evidence



“At present, anyone can create and publish health and medical apps in the app stores without having to test them, and patients must experiment with apps by trial and error.

If GPs are to prescribe health apps, then they must be confident that the apps are shown to work, have fair privacy and data safety policies, and are usable at the very least.”

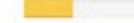
9. Bias

Biased datasets:

- Biased tools
- Risk of perpetuating existing prejudices and exacerbating disparities in healthcare

Genome-wide association studies (GWAS)

78% European,
10% Asian,
2% African,
1% Hispanic,
<1% all other ethnic groups.

Gender Classifier	Darker Male	Darker Female	Lighter Male	Lighter Female	Largest Gap
 Microsoft	94.0% 	79.2% 	100% 	98.3% 	20.8% 
 FACE++	99.3% 	65.5% 	99.2% 	94.0% 	33.8% 
 IBM	88.0% 	65.3% 	99.7% 	92.9% 	34.4% 



10. Discrimination

nature
medicine

PERSPECTIVE

<https://doi.org/10.1038/s41591-019-0534-z>

Genetic testing, insurance discrimination and medical research: what the United States can learn from peer countries

Jean-Christophe Bélisle-Pipon¹, Effy Vayena², Robert C. Green³ and I. Glenn Cohen^{1*}

While genetic testing may be the gateway to the future of medicine, it also poses challenges for individuals, especially in terms of differentiated treatments on the basis of their genetic characteristics. The fear of unwanted disclosure to insurers and the possibility of genetic discrimination can hamper the recruitment of individuals for clinical research that involves genetic testing. Precision medicine initiatives, such as All of Us, are proliferating in the United States. In order to succeed, however, they must ensure that the millions of Americans recruited to share their genetic data are not penalized with regard to life, disability and long-term insurance coverage. In this Perspective, we discuss several initiatives adopted by countries around the world, such as the United Kingdom and France, that better balance the interests of insurers and research subjects, and explain how the United States might learn from them. We call for regulatory and industry leadership to come together to establish a voluntary moratorium on insurance pricing with the aim of protecting research participants.

NATURE MEDICINE

PERSPECTIVE

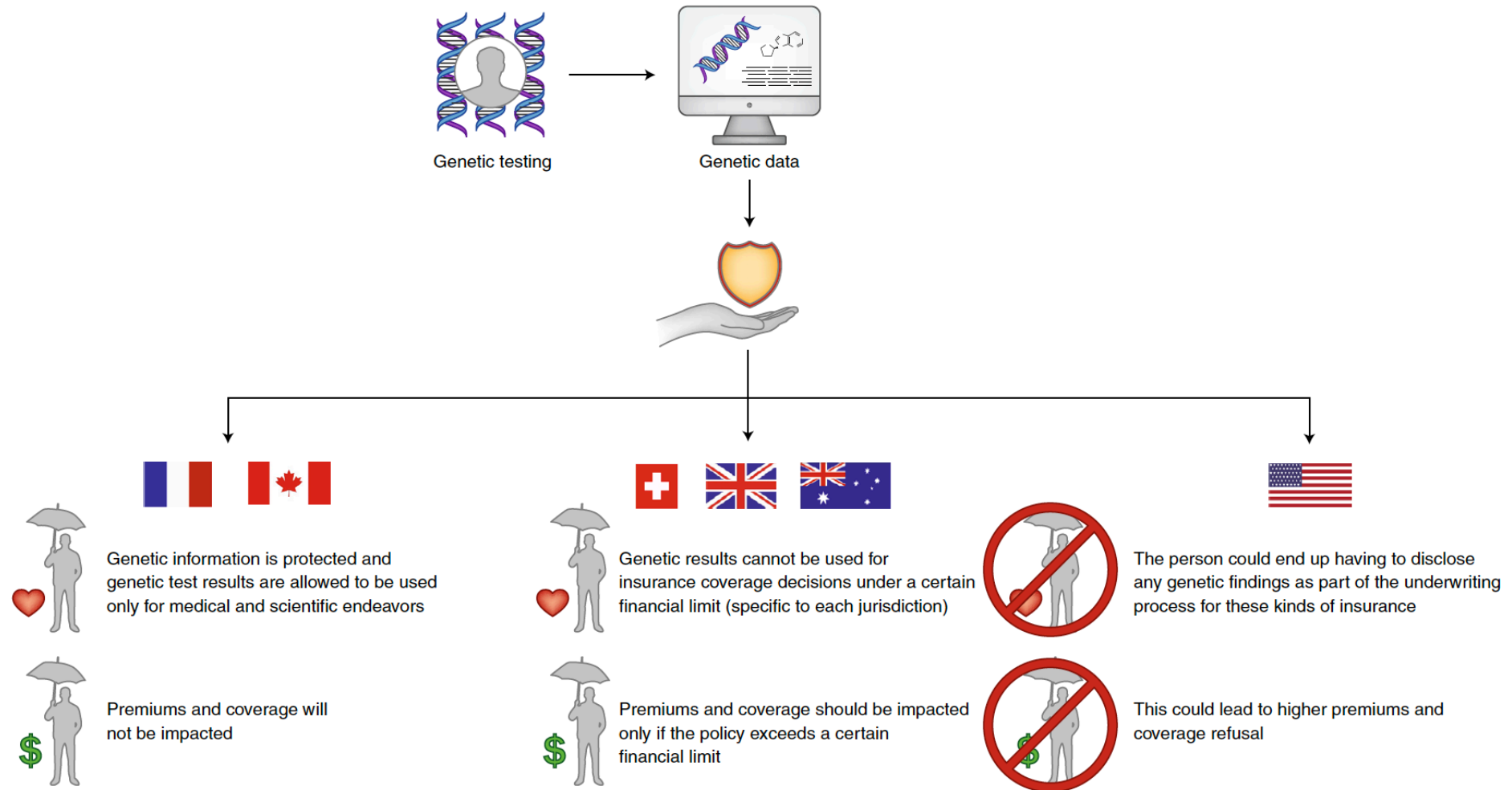


Fig. 1 | Potential impact of genetic data for insurance by jurisdiction.

NEWS • 29 AUGUST 2019

No 'gay gene': Massive study homes in on genetic basis of human sexuality

Nearly half a million genomes reveal five DNA markers associated with sexual behaviour – but none with the power to predict the sexuality of an individual.

[Jonathan Lambert](#)

NEWS • 29 OCTOBER 2019

Controversial 'gay gene' app provokes fears of a genetic Wild West

Debate highlights broader concerns about tools that use the results of direct-to-consumer genetic testing.

11. Transparency and Trust

The image shows two news articles side-by-side. The top article is from BBC News, titled "ONE STEP TOO FAR FOR LEGENDARY DANISH TRANSPARENCY" by Jens Degett, dated 25 March 2015. The bottom article is from the Financial Times, titled "Fears raised over Google's DeepMind deal to use NHS medical data" by Nick Triggle, dated 19 February 2014. The Financial Times article includes a sub-headline: "Academics concerned over company's access to private records for mobile app".

BBC NEWS

Home | Video | World | UK | Business | Tech | Science | Magazine | Entertainment & Arts

Health

Care.data: How did it go so wrong?

Nick Triggle
Health correspondent

19 February 2014 | Health | 354

ONE STEP TOO FAR FOR LEGENDARY DANISH TRANSPARENCY

25 MARCH, 2015 | JENS DEGETT | 6 COMMENTS

sh regional health authority have
cted data from patients illegally in the
seven years, in a scenario reminiscent
George Orwell's 1984 ★ 1

FINANCIAL TIMES

HOME | WORLD | US | COMPANIES | MARKETS | OPINION | WORK & CAREERS | LIFE & ARTS

Digital health + Add to myFT

Fears raised over Google's DeepMind deal to use NHS medical data

Academics concerned over company's access to private records for mobile app

Read next
Could onli
to predict

There comes a point when the weight of criticism becomes so much that the dam bursts

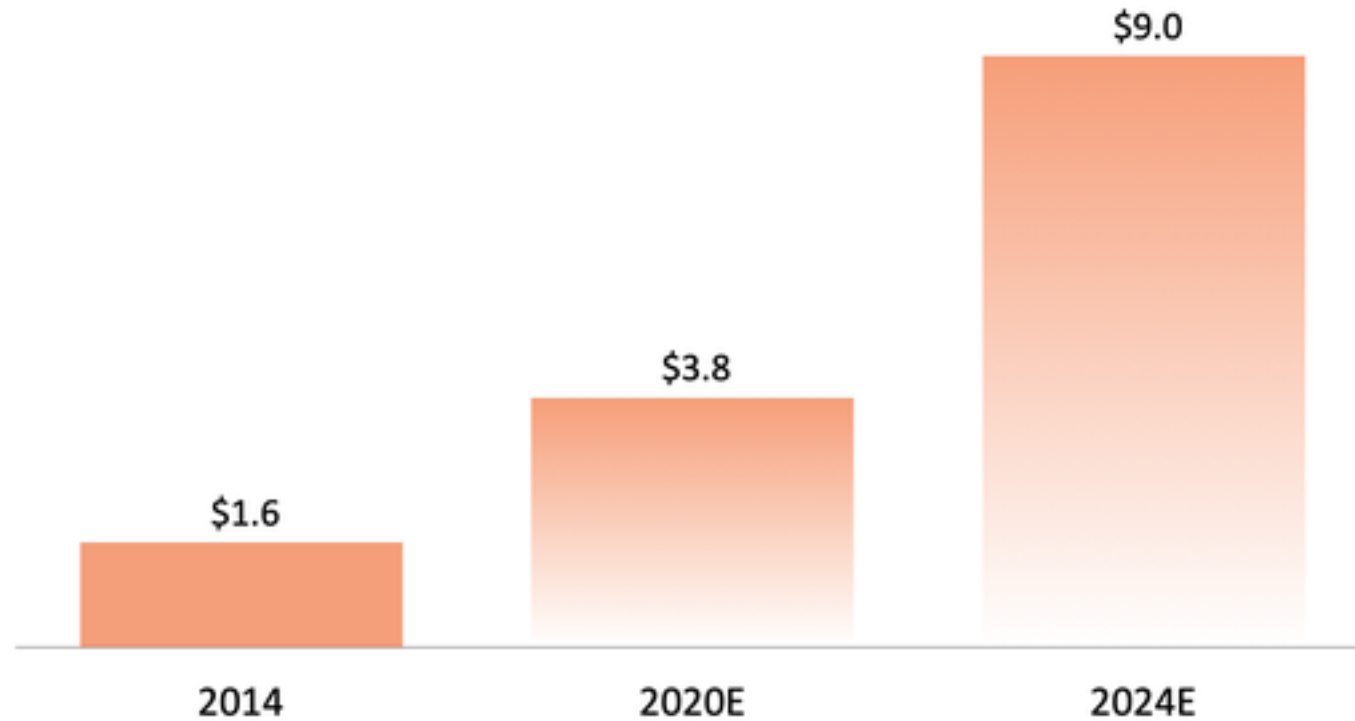
More from Nick

Benefit sharing

Exclusive access to data sources

The Global Smart Pill Market Is Expected To See Fast Growth Through 2024

Billions



Abilify MyCite **\$1,650**

Abilify **\$20**

BUSINESS
INSIDER
INTELLIGENCE

Source: Statista, 2015

New Actors

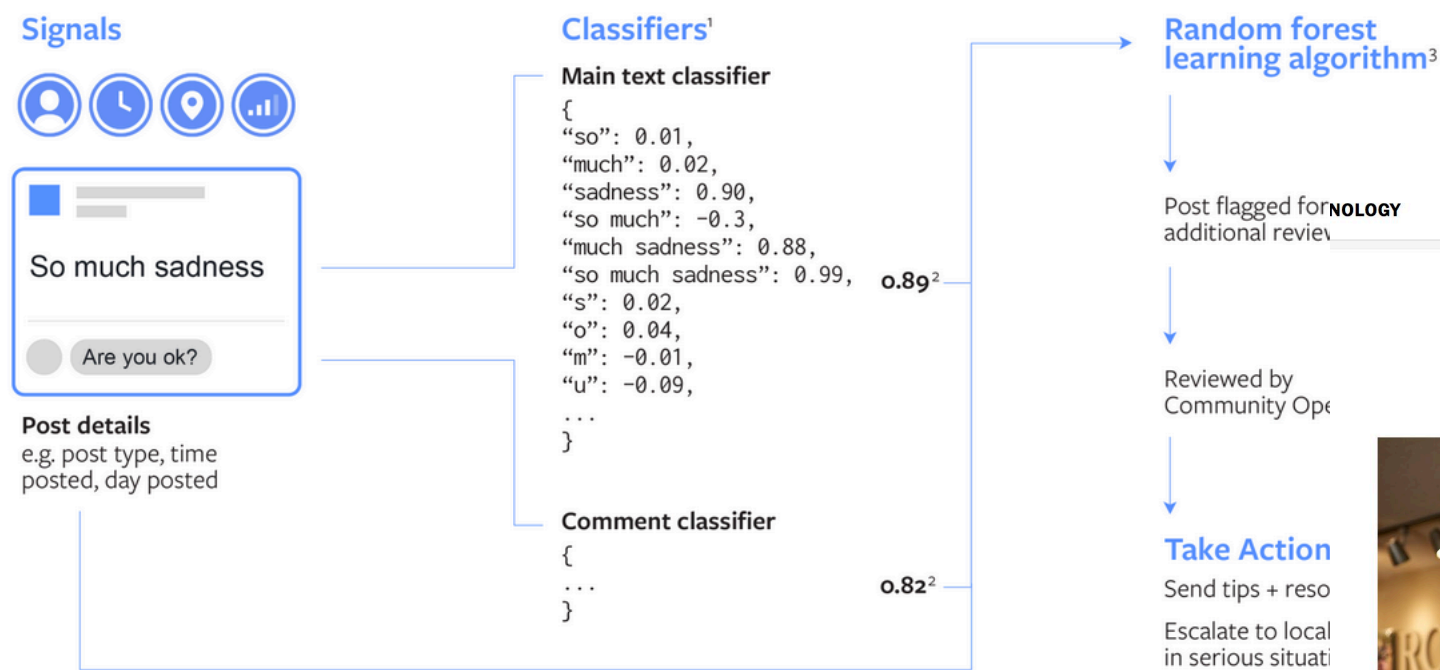
"If you zoom out into the future, and you look back, and you ask the question, 'What was Apple's greatest contribution to mankind,' it will be about health."

Tim Cooke



How Facebook AI Helps Suicide Prevention

How text and comment classifiers work



The New York Times

In Screening for Suicide Risk, Facebook Takes On Tricky Public Health Role



12. Fairness and justice

- Are cutting edge technologies in health going to improve health for all?
- Are they going to help achieve UHC?
- Are they going to decrease health disparities?
- Are they going to contribute to just health and just society?
 - Bias
 - Privacy as luxury
 - Costs associated with new medicines

Tech Trends 2019: Key messages

- Privacy is dead.
- Voice Search Optimization (vs SEO)
- The big Nine (G-MAFIA_{US} +BAT_{CN})
- Personal Data Records are coming.
- China continues to ascend and not only in AI.
- Lawmakers around the world are not prepared to deal with new challenges that arise from emerging science and technology.
- Consolidation continues as a key theme for 2019.

Future of Technology Institute