The Democratization of Medicine:
How Patient Empowerment, The Open Access Movement, Social Media, & Digital Health are Transforming Clinical Trials & Set The Stage for the First "Giga Trial"

SLIDES BY **C. MICHAEL GIBSON, M.S., M.D.**

HARVARD MEDICAL SCHOOL **PROFESSOR**

BETH ISRAEL LAHEY HEALTH **INTERVENTIONAL CARDIOLOGIST**

BAIM INSTITUTE **CHIEF EXECUTIVE OFFICER**

BETH ISRAEL LAHEY HEALTH **CHIEF CLINICAL RESEARCH CARDIOVASCULAR DIVISION**

PERFUSE STUDY GROUP **FOUNDER & CHAIRMAN**

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PERFUSE

Wiki Doc

Disclosure

- **Dr. Gibson has received Research Grant Support & consulting monies from Apple and Johnson and Johnson for the HEARTLINE Trial**

- **The slides were prepared by C. Michael Gibson, M.S., M.D. and / or were under the editorial control of C. Michael Gibson, M.S., M.D.**

Slide by C. Michael Gibson, M.S., M.D.

EDITORIAL

The Democratization of Medical Research and Education Through Social Media

The Potential and the Peril

C. Michael Gibson, MS, MD

JAMA Cardiology

Crescat scientia; vita excolatur
Let knowledge grow from more to more; and so be human life enriched.
University of Chicago Motto

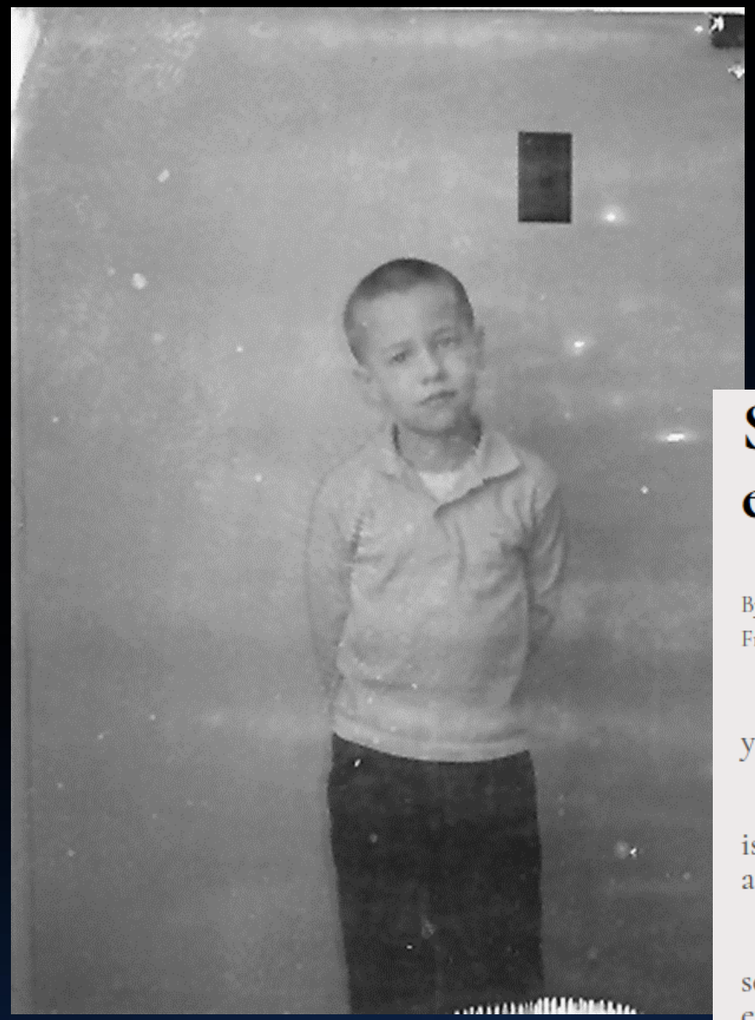
oversight in conformation with the Declaration of Helsinki, as well as ICH-GCP guidance, and be registered on clinicaltrials.gov?

Social media can be used to solicit feedback regarding clinical trial design, and it can also facilitate and speed enroll-

Published Online: December 14, 2016.
doi:10.1001/jamacardio.2016.4933.

Additional Contributions: I would like to thank all of my followers on Twitter and the editors and authors of WikiDoc.org for their valuable comments and insights.

The Internet in Stilwell Oklahoma in the 1960s



Stilwell has the worst life expectancy in the nation

By Leif M. Wright
Friday, September 21, 2018, 9:20 AM

If you're 57 years old in Stilwell, Oklahoma, congratulations, you've beaten the odds.

That's because, according to a Washington Post story, Stilwell is the worst city in the nation for life expectancy, topping out at 56 years old on average.

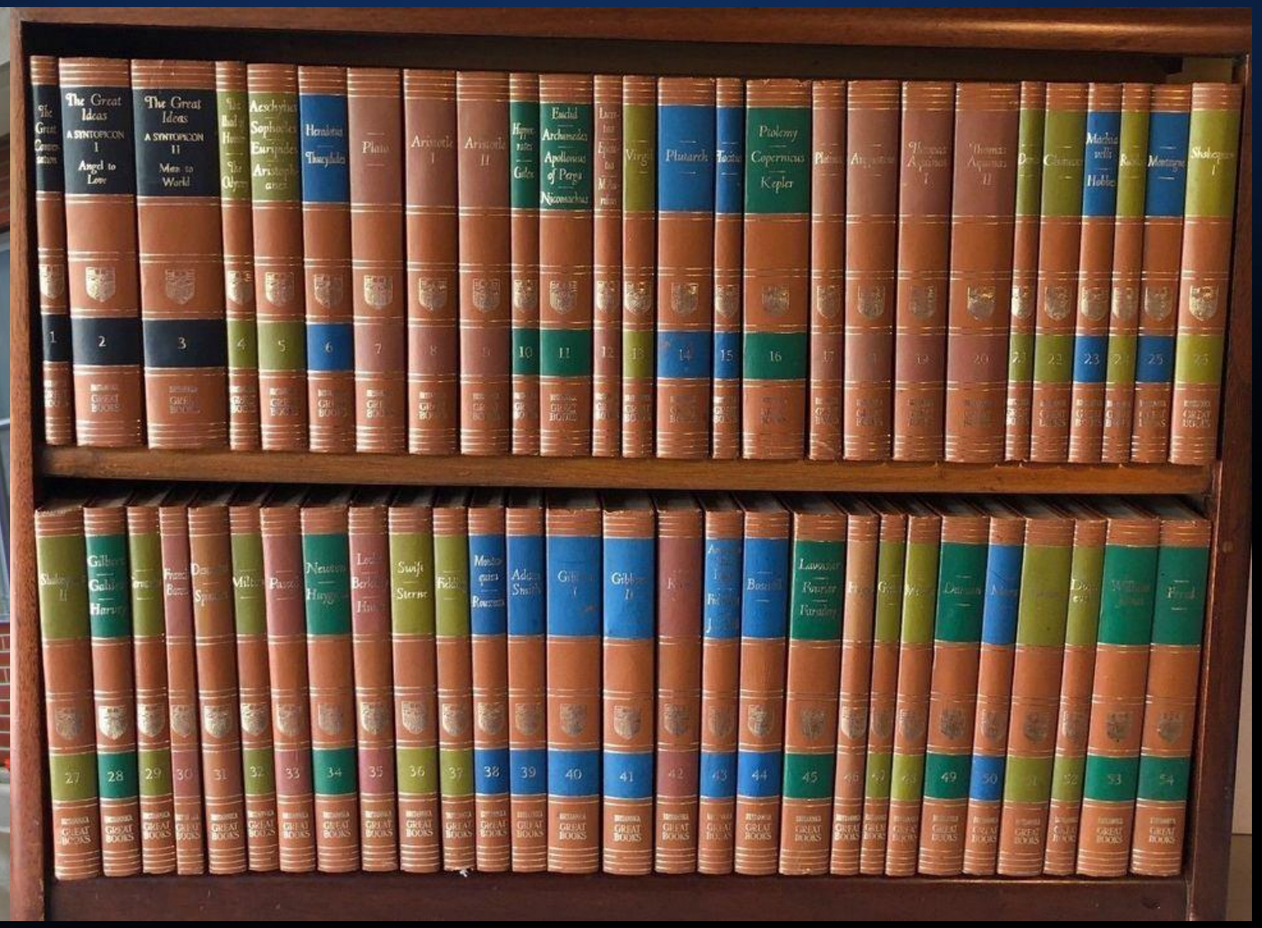
Poverty, poor healthcare availability and obesity are just some of the causes, according to the Post. Nationally, life expectancy averages around 79 years. But don't feel safe just because you aren't living in Stilwell. Oklahoma is the fourth-worst state in the nation for the very same reasons. Only Alabama, West Virginia and Mississippi are worse.

Access …

Kankakee Illinois

In popular culture [edit]

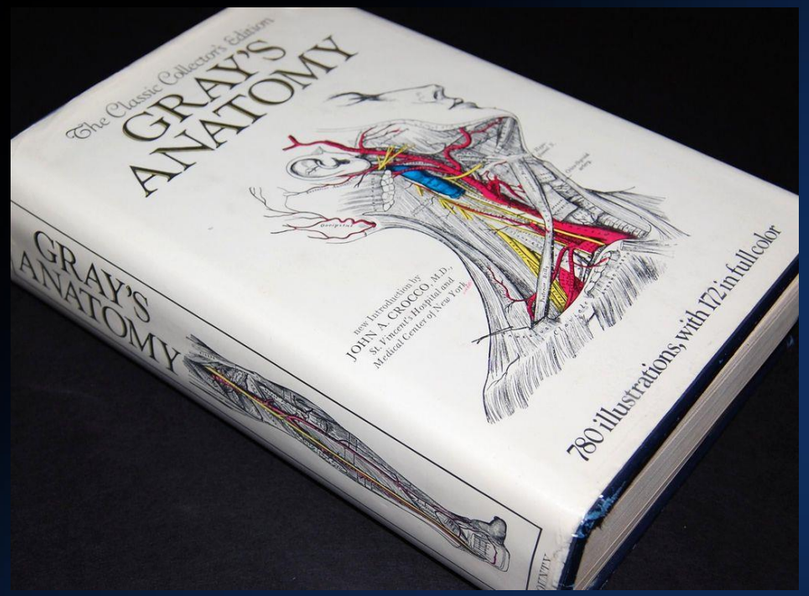
- David Letterman donated two gazebos to Kankakee in 1999 after the city was rated the 354th best metropolitan area in the country to live out of 354 metropolitan areas.[27] The Kankakee, IL Metropolitan Statistical Area is also one of the smallest



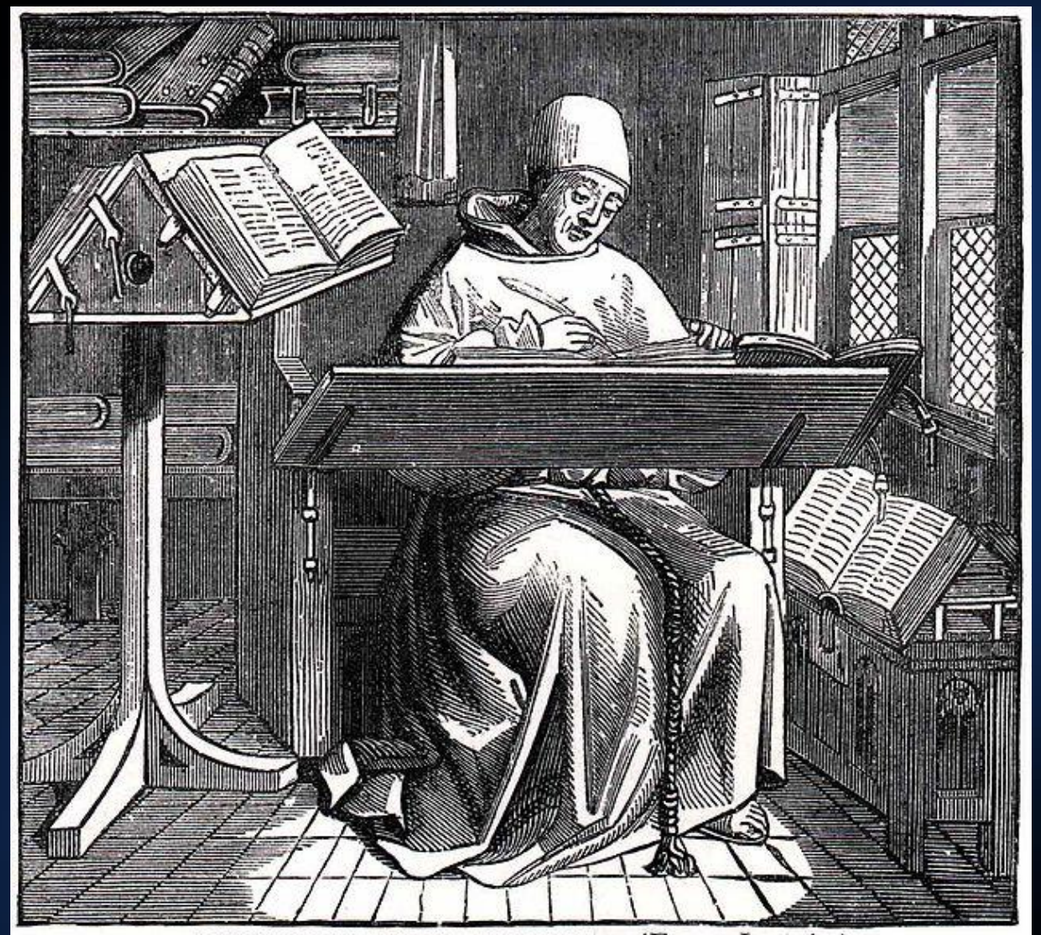
University of Chicago: Science, Culture and Society

Culture ⇄ **Science**

Medical School 1982



The Monk



SCRIPTORIUM MONK AT WORK. (From *Lacroix.*)

Boston 1986

Definition of an Expert: A Person With Two Slide Carousels From Boston
Then Came PowerPoint and the Internet

- Presenter “owned” their slides
- No one could copy them

- Then came PowerPoint & the Internet

- You could now make your own slides using Harvard Graphics and PowerPoint, no need for a draftsman, photographer, someone to develop the slides

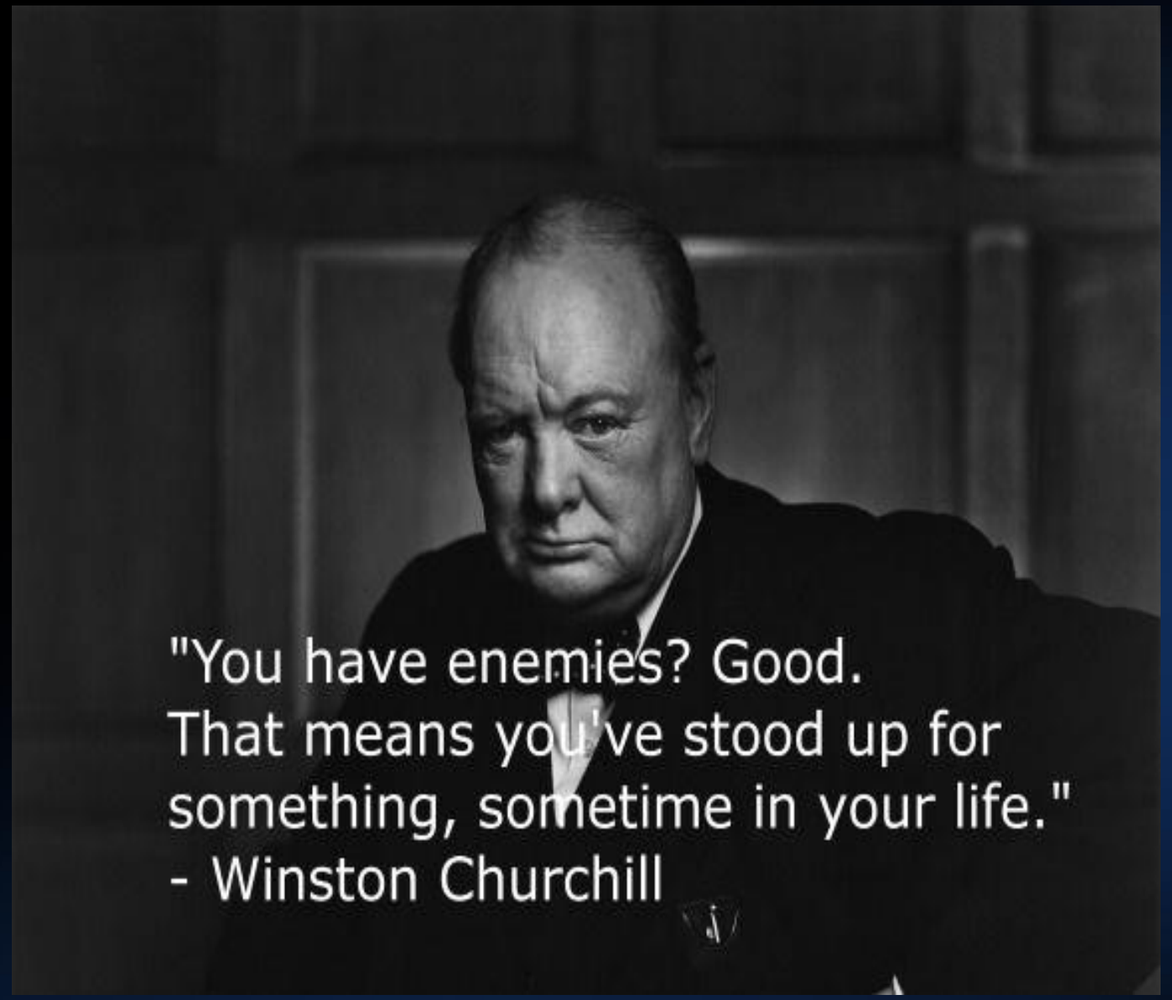
- Anyone could share their ideas and research and then people could download your slides on this thing called the internet

- Key Opinion Leader no longer “owned” their slides once they shared them

- I developed slides sharing site in the 90s in San Francisco (www.clinicaltrial results.org)

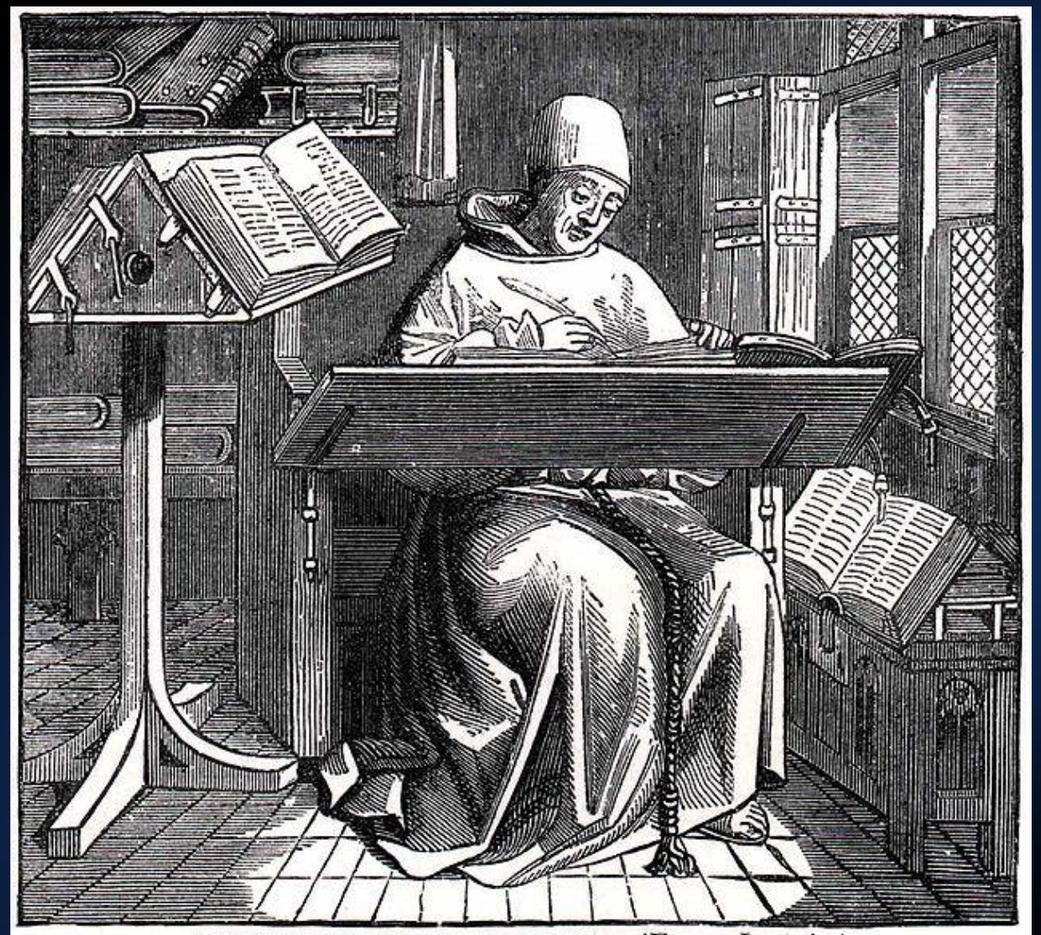
- 10,000 slidesets downloaded on first day!

People Were Angry so I Must Have Been on the Right Track



- "You can't take data from tables, make a bar graph and display it on a slide. (Famous Journal) owns not only the data, but also the mode of display of the data. The data must be displayed as it was published"
- Professional Society claimed ownership of slides displayed at meetings (including slides of my own work) and threatened to sue me for distributing slides.
- Research fellow: "I can't afford the $450 to download the pdfs of our publications."

The Monk



SCRIPTORIUM MONK AT WORK. (From *Lacroix.*)

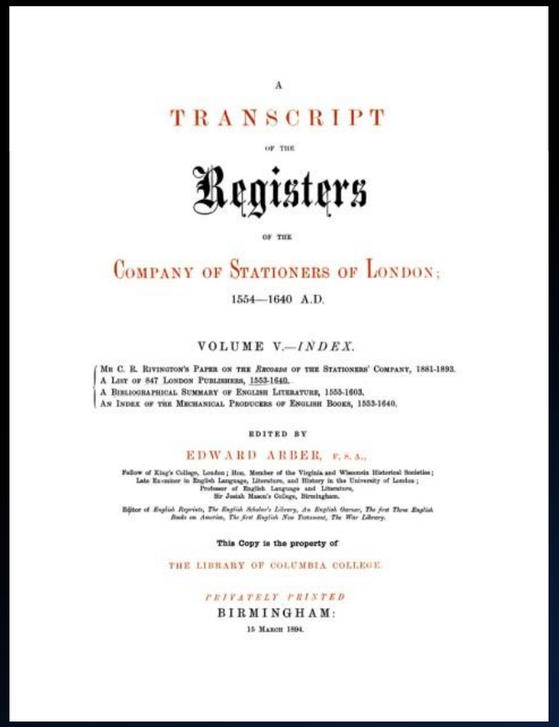
Copyright Law was Born as Essentially A Censorship Law Along Side The Printing Press

For the first time, the printing press allowed ***rapid*** distribution of ***large volumes*** of printed work, some of which could be critical of English government

Copyright originated out of English government's need to **control and censor** the new flood of seditious printed matter

Government permitted only certain people the **"Right to Copy"** work, the original copyright law was actually a **censorship law**

Copyright Law Established Control of the Government and Owners of the Printing Press, the Means of Distribution



A

TRANSCRIPT

OF THE

Registers

OF THE

COMPANY OF STATIONERS OF LONDON;

1554—1640 A.D.

VOLUME V.—*INDEX.*

MR C. R. RIVINGTON'S PAPER ON THE *RECORDS* OF THE STATIONERS' COMPANY, 1881-1893.
A LIST OF 847 LONDON PUBLISHERS, 1553-1640.
A BIBLIOGRAPHICAL SUMMARY OF ENGLISH LITERATURE, 1555-1603.
AN INDEX OF THE MECHANICAL PRODUCERS OF ENGLISH BOOKS, 1553-1640.

EDITED BY

EDWARD ARBER, F.S.A.,

Fellow of King's College, London; Hon. Member of the Virginia and Wisconsin Historical Societies; Late Examiner in English Language, Literature, and History in the University of London; Professor of English Language and Literature, Mr Josiah Mason's College, Birmingham.

Editor of *English Reprints*, *The English Scholar's Library*, *An English Garner*, *The first Three English Books on America*, *The first English New Testament*, *The War Library*.

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PRIVATELY PRINTED

BIRMINGHAM:

15 MARCH 1894.

- Government allowed a **private company** (the London Company of Stationers) to oversee censorship. Company had
  - Exclusive **right to print**
  - Right to **confiscate** unauthorized presses and books
  - Right to **burn** illegally printed books
- **Only books that had passed the "Crown's censor" were entered in the company's Register**
- **Books were entered into the Registry under a publishing company's name, not the author's name**
- **The company who registered the book held the "copyright" which provided exclusive rights to publish the book over other companies**
- ***Early copyright law was clearly designed to protect the government (establish control) and the publishing companies (establish ownership), not the authors or creators of work***

The Internet is Replacing the Paper Printing Press and Copyleft is Replacing Copyright in the New Open Access Era

Old World

High cost of creation & distribution of content on paper

Knowledge flowed slowly only to those at the top and those who could afford access

Copyright ©

New World

Low cost of creation & distribution of content on internet

Knowledge flows rapidly to and from all and is freely accessible

Copyleft

Gibson CM, JAMA Cardiology 2016

General Practitioner and Specialist’s Income

Country	GDP per capita USD ($)	Population (million)	GP's Monthly Salary (USD $)	Specialist's Monthly Salary (USD $)
Tajikistan	1,300	7.1	35	50
India	3,800	1128.2	637	1274
Azerbaijan	7,500	8.5	130	155
China	7,800	1323.6	133 - 160	170 - 230
Russia	12,200	142.3	210	290 - 320
Poland	14,400	38.2	580	750
United States	43,800	301.1		

Old World vs New World: Collaboration

Old World	New World
John is the brightest child in kindergarten	John plays well with others in kindergarten
Physician as a “individual player”	Physician as a “team player”
Promotion depends on first/last author publications	Promotion depends upon more broadly conceived contributions and collaboration
Publish or perish	Collaborate or perish

Gibson CM, JAMA Cardiology 2016

Copyleft Medical Textbook(s): WikiDoc and WikiPatient:

- **Copyleft** a legal doctrine that safeguards against information being controlled by any one person, and ensures that it remains freely accessible forever; all of the information is free for anyone to copy, modify for their own purposes, and redistribute or use as they see fit, as long as the new version grants the same freedoms to others and acknowledges the authors of the original article
- **Free** no pharmaceutical or device company support, viewer supported
- **Continuously updated** leverage social media, moderated crowdsourcing by experts
- **Accessible on mobile** devices, which many MDs in developing countries have
- **Doctor and patient** content linked (57% of pts use internet for medical information)
- **CME and board review**
- **Living guidelines** (polling and suggested edits to guidelines)
- **Integrate into EMR / HER** if desired

Gibson CM, JAMA Cardiology 2016

Copyleft Medical Textbook(s): WikiDoc and WikiPatient:

- **Creator:** C. Michael Gibson, M.S., M.D. in 2005
- **Authors:** > 2,200 physicians
- **MD Chapters:** 135,000
- **Patient Chapters:** > 1,200
- **Edits:** > 1.5 million
- **“Copyleft” images uploaded:** 65,152
- **Board review:** > 16,000 free questions
- **Full time volunteer staff:** 140

Gibson CM, JAMA Cardiology 2016

Wiki Doc

The Living Textbook of Medicine

Search for a Topic on WikiDoc:

Search WikiDoc

Search | Try Exact Match

Or Click on an Icon to Browse the Topic You Are Interested In:


Allergology


Anesthesiology


Basic Sciences


Cardiolology


COVID-19


Dermatology


Ear, Nose & Throat


Emergency Medicine


Endocrinology


Family Medicine


Gastroenterology


General Surgery


Genetics


Geriatrics


Gynecology & Obstetrics


Hematology


Infectious Diseases


Intensive Care Medicine


Musculoskeletal / Orthopedics


Nephrology


Neurology


Nutrition


Oncology


Ophthalmology


Overdose & Toxicology


Pathology


Pediatrics


Plastic Surgery


Primary Care


Psychiatry


Pulmonology


Radiology


Rare Diseases


Rheumatology / Autoimmune


Transplant


Urology

COVID-19

For COVID-19 frequently asked outpatient questions, click here.
For COVID-19 frequently asked inpatient questions, click here.
For COVID-19 patient information, click here.

Editor-In-Chief: C. Michael Gibson, M.S., M.D. [1]; **Associate Editor(s)-in-Chief:** Sabawoon Mirwais, M.B.B.S, M.D.[2], Syed Hassan A. Kazmi BSc, MD [3]

Synonyms and Keywords: Novel coronavirus, covid-19, COVID-19, SARS-CoV-2, Wuhan coronavirus

Overview

Historical Perspective

Classification

Pathophysiology

Causes

Differentiating COVID-19 from other Diseases

Epidemiology and Demographics

Risk Factors

Screening

Natural History, Complications and Prognosis

Cardiovascular Complications

- COVID-19-associated myocardial injury
- COVID-19-associated myocarditis
- COVID-19-associated myocardial infarction
- COVID-19-associated heart failure
- COVID-19-associated arrhythmia and conduction system disease
- COVID-19-associated cardiogenic shock
- COVID-19-associated cardiac arrest
- COVID-19-associated pericarditis
- COVID-19-associated spontaneous coronary artery dissection
- COVID-19-associated stress cardiomyopathy

Dermatologic Complications

- COVID-19-associated dermatologic manifestations

Gastrointestinal and Hepatic Complications

- COVID-19-associated digestive symptoms
  - COVID-19-associated anorexia
  - COVID-19-associated diarrhea
  - COVID-19-associated nausea and vomiting
  - COVID-19-associated abdominal pain
- COVID-19-associated hepatic injury

Hematologic Complications

- COVID-19-associated coagulopathy
- COVID-19-associated cytokine storm
- COVID-19-associated hematologic symptoms
  - COVID-19-associated anemia
  - COVID-19-associated lymphopenia
  - COVID-19-associated neutrophilia
  - COVID-19-associated thrombocytopenia

Infectious Disease Complications

- COVID-19 and influenza co-infection

Nephrologic Complications

- COVID-19-associated acute kidney injury
- COVID-19-associated hemodialysis
- COVID-19 Infection in Transplant Patients

Neurologic Complications

- COVID-19-associated CNS manifestations
  - COVID-19-associated encephalitis
  - COVID-19-associated encephalopathy
  - COVID-19-associated headache
  - COVID-19-associated meningitis
  - COVID-19-associated seizure
  - COVID-19-associated stroke
- COVID-19-associated PNS manifestations
  - COVID-19-associated anosmia
  - COVID-19-associated Guillain-Barre syndrome
  - COVID-19-associated Miller-Fischer syndrome
  - COVID-19-associated myelitis
  - COVID-19-associated polyneuritis cranialis

Pulmonary Complications

- COVID-19-associated acute respiratory distress syndrome
- COVID-19-associated hypoxemia
- COVID-19-associated pneumonia
- COVID-19-associated pulmonary embolism
- COVID-19-associated pulmonary hypertension
- COVID-19-associated respiratory failure

Endocrine Complications

- COVID-19-associated diabetes mellitus

Pediatric Complications

- COVID-19-associated multisystem inflammatory syndrome
- COVID-19 associated pediatric complications

Diagnosis

Diagnostic study of choice | History and Symptoms | Physical Examination | Laboratory Findings | Electrocardiogram | X-Ray Findings | Echocardiography and Ultrasound | CT-Scan Findings | MRI Findings | Other Imaging Findings | Other Diagnostic Studies

Treatment

Medical Therapy | Interventions | Surgery | Primary Prevention | Secondary Prevention | Cost-Effectiveness of Therapy | Future or Investigational Therapies

Plan S: All Funded Scientific Works to be Free in Europe as soon as Published

NEWS · 04 SEPTEMBER 2018

Radical open-access plan could spell end to journal subscriptions

Eleven research funders in Europe announce 'Plan S' to make all scientific works free to read as soon as they are published.

Shifts costs to funders of work, away from subscribers. Participants include French, British and Dutch funders, national agencies in Austria, Ireland, Luxembourg, Norway, Poland and Slovenia, research councils in Italy and Sweden.

https://www.nature.com/articles/d41586-018-06178-7

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

Sharing Data from Cardiovascular Clinical Trials — A Proposal

The Academic Research Organization Consortium for Continuing Evaluation of Scientific Studies — Cardiovascular (ACCESS CV)

N Engl J Med 2016; 375:407-409 | August 4, 2016 | DOI: 10.1056/NEJMp1605260

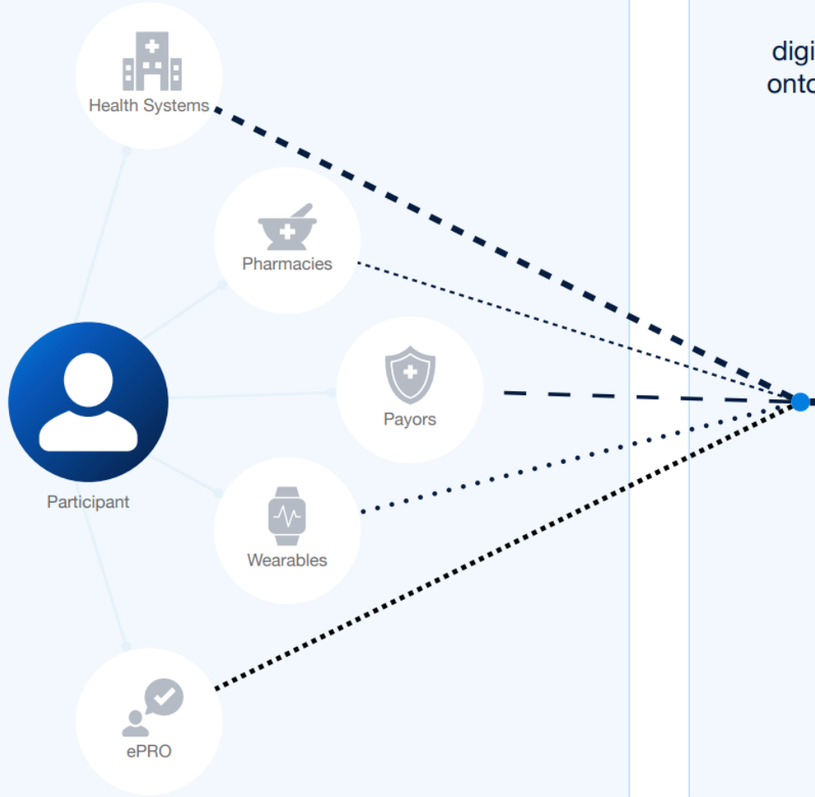
The authors, who are initial partners in ACCESS CV, are Manesh R. Patel, M.D., Paul W. Armstrong, M.D., Deepak L. Bhatt, M.D., M.P.H., Eugene Braunwald, M.D., A. John Camm, M.D., Keith A.A. Fox, M.B., Ch.B., Robert A. Harrington, M.D., William R. Hiatt, M.D., Stefan K. James, M.D., Ph.D., Ajay J. Kirtane, M.D., Martin B. Leon, M.D., A. Michael Lincoff, M.D., Kenneth W. Mahaffey, M.D., Laura Mauri, M.D., Roxana Mehran, M.D., Shamir R. Mehta, M.D., Gilles Montalescot, M.D., Stephen J. Nicholls, M.B., B.S., Ph.D., Vlado Perkovic, M.B., B.S., Ph.D., Eric D. Peterson, M.D., M.P.H., Stuart J. Pocock, Ph.D., Matthew T. Roe, M.D., M.H.S., Marc S. Sabatine, M.D., M.P.H., Mikkael Sekeres, M.D., Scott D. Solomon, M.D., Ph.D., Gabriel Steg, M.D., Gregg W. Stone, M.D., Frans Van de Werf, M.D., Ph.D., Lars Wallentin, M.D., Ph.D., Harvey D. White, D.Sc., and C. Michael Gibson, M.D. The institutional affiliations of the partners and the full list of ACCESS CV participants are provided in the Supplementary Appendix, available at NEJM.org.

Hugo as a Platform to Share Data

A Participant-As-Partner, Real-World Data Platform

Participant Data Collection

With over **25,000** integrated sites, health data collection is easy



The Hugo Harmony Engine

Data normalized
improved integrity, ready for analysis

Data harmonized
digital de-duplication, automated term/ ontology mapping, multi-site integration

Hugo

Seamless Data Sharing

With participant permission

Data accessible to researchers & clinicians through dashboards, local applications, and integrations with existing databases and systems

Participants can view their data with the mobile app

Source: Harlan Krumholz

Evolution of the Internet to Give Everyone a Voice on Social Media

Old World

Internet 1.0

Website with *one direction of flow* of information

New World

Internet 2.0

Participatory community with *bidirectional flow of information* through social media

Gibson CM, JAMA Cardiology 2016

Old World vs New World: Media

Broadcast one show to millions

Broadcast millions of shows to one

Patients are looking to physicians for curation / criticism of this content

Gibson CM, JAMA Cardiology 2016

Boston Marathon Coverage on Twitter: More Up to Date Than Traditional News

After marathon, my son texted me "I'm OK"

I texted "You must be tired"

He texted "No dad a bomb just went off about 10 minutes after I crossed the finish line"

I was on call and in the ER; provided updates

Set up a communications center where families could call & check if relative was in ER

Told people to Tweet #ImOk on twitter

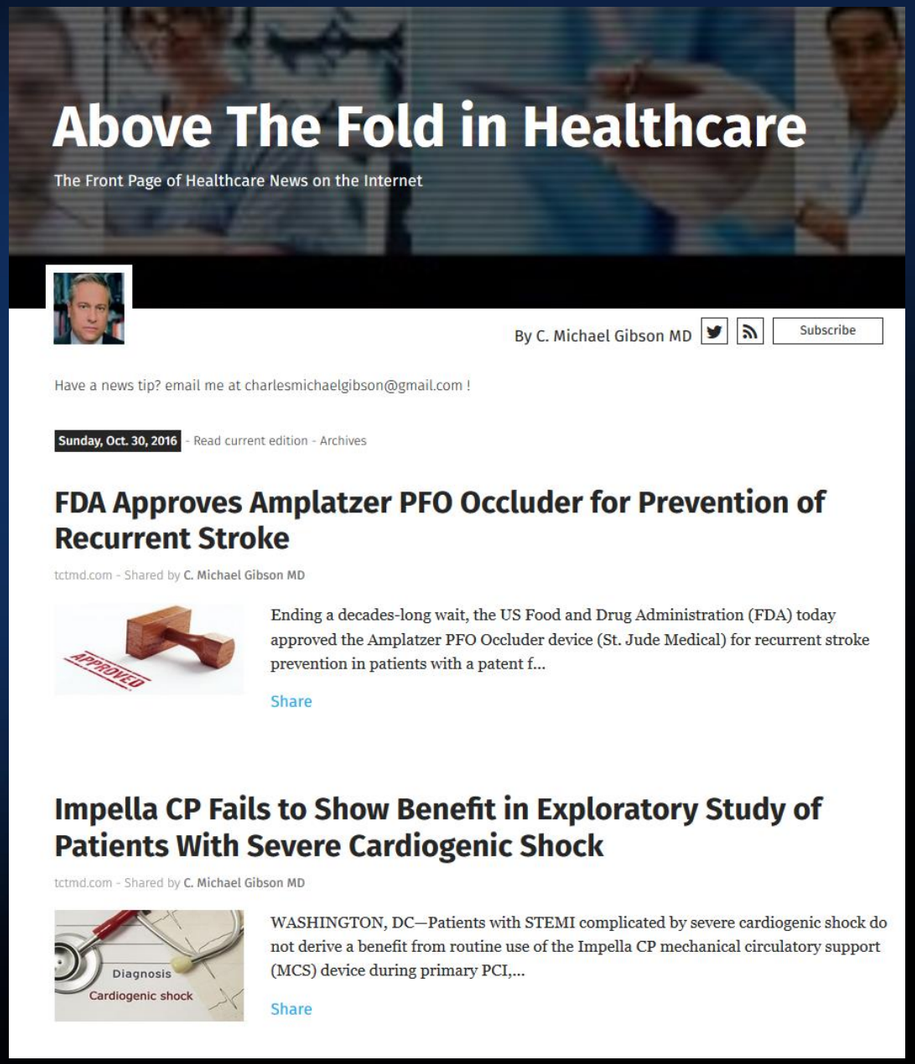
Power of the Citizen Reporter in images, narrative, and power to take control & react

Gibson CM, JAMA Cardiology 2016

Become A “Citizen Journalist”: Use Twitter to Drive Content for A Daily Newsfeed For Your Patients

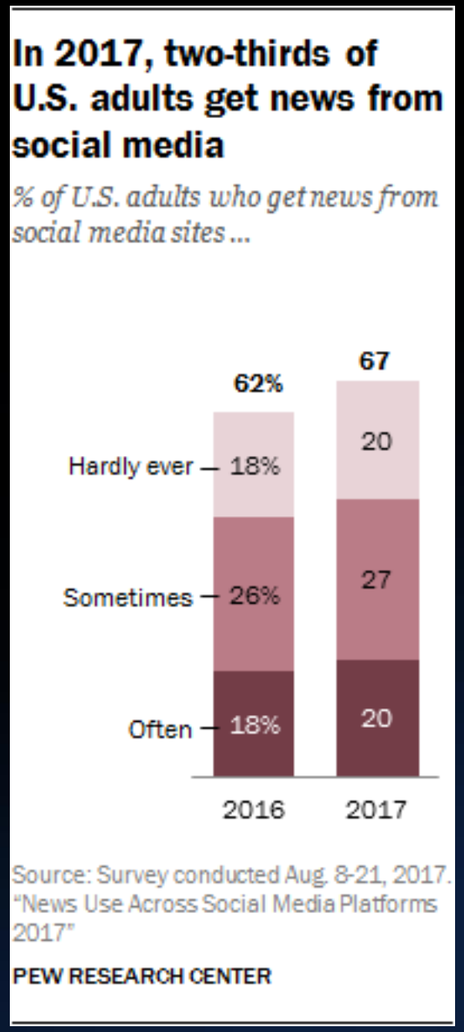
Camera-Phones are at the root of the Citizen-Journalism revolution.

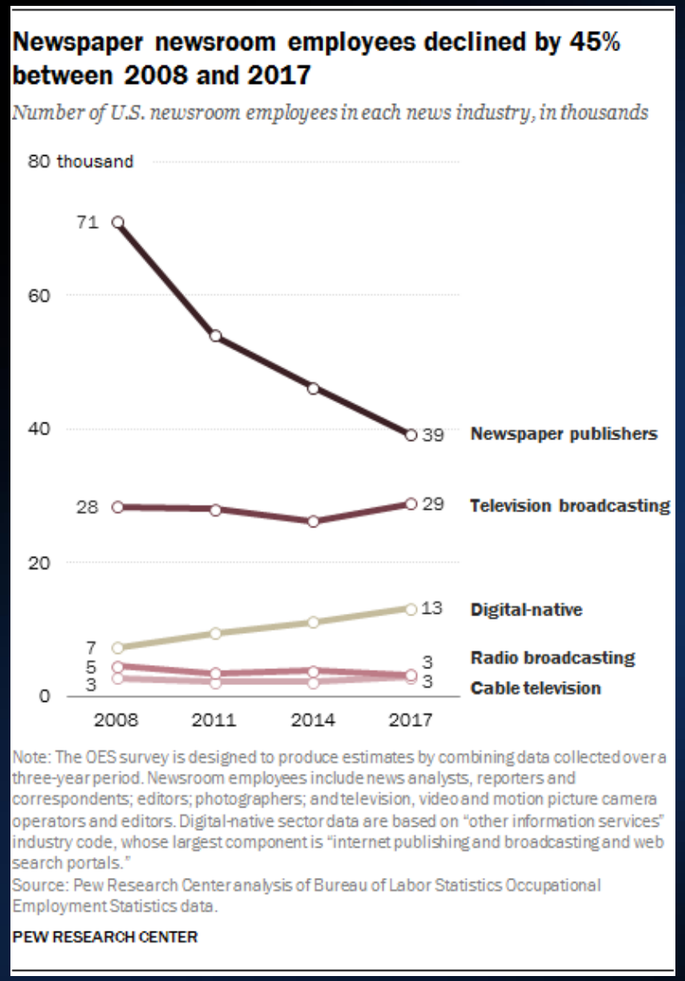
(Philippe Kahn)

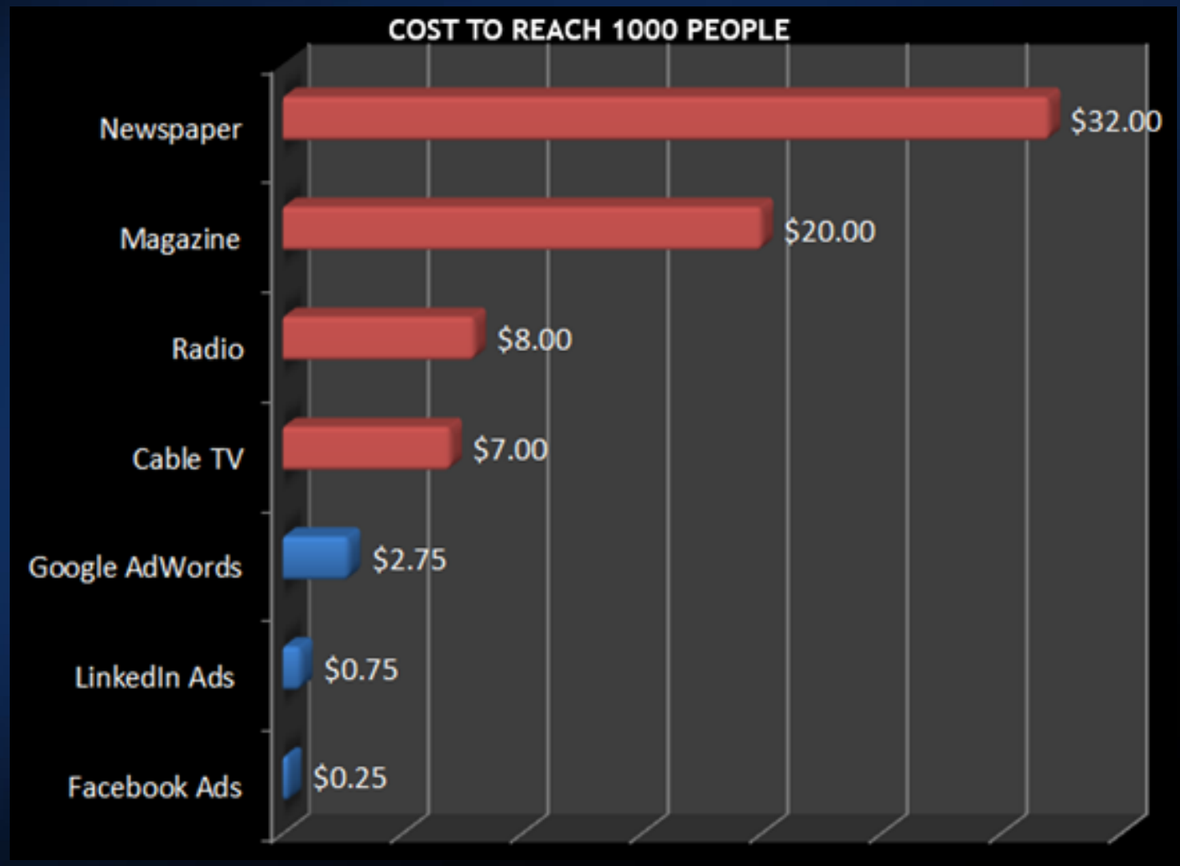


Gibson CM, JAMA Cardiology 2016

Decline in Traditional Media; Lower Costs of Reaching People Via SoME



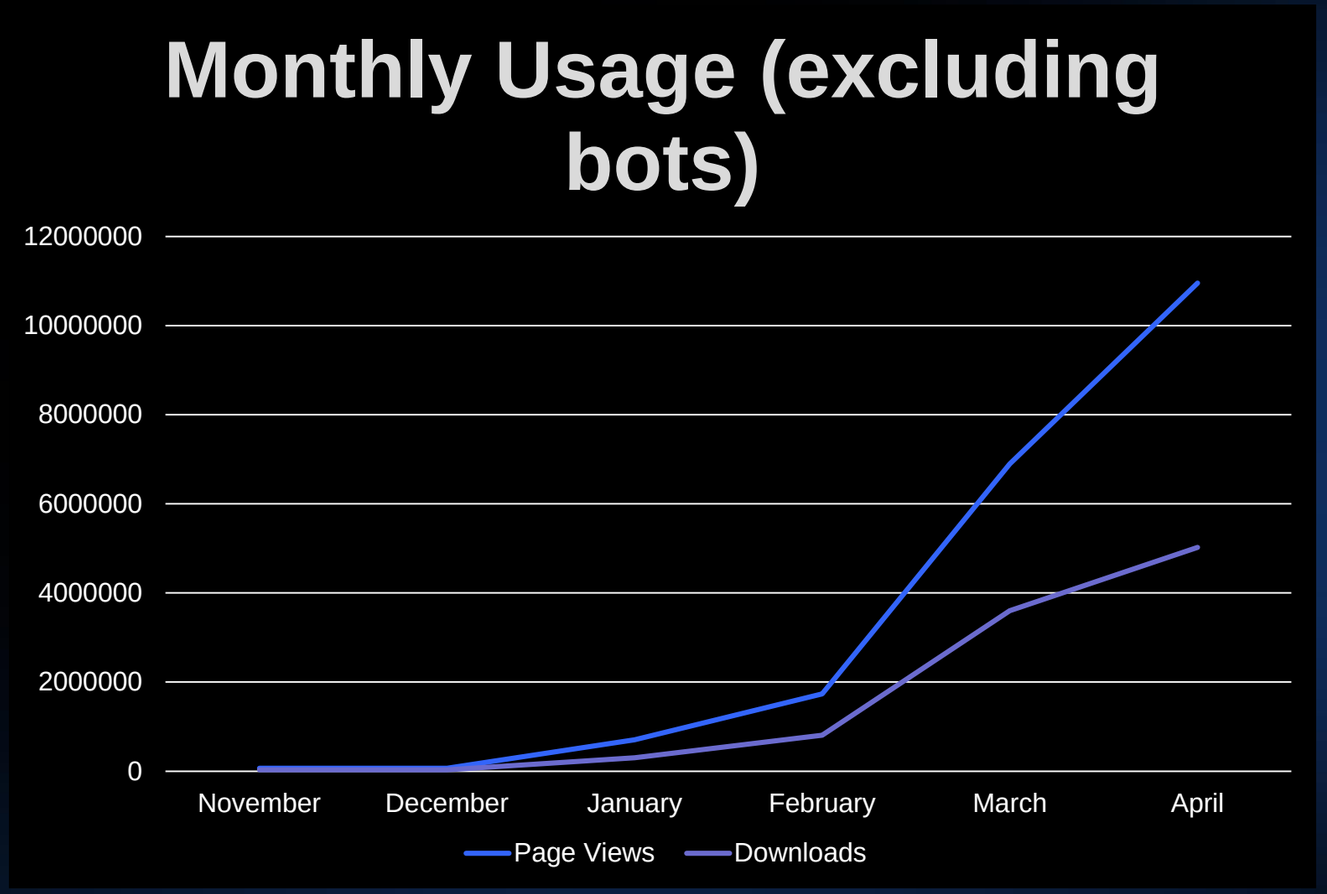


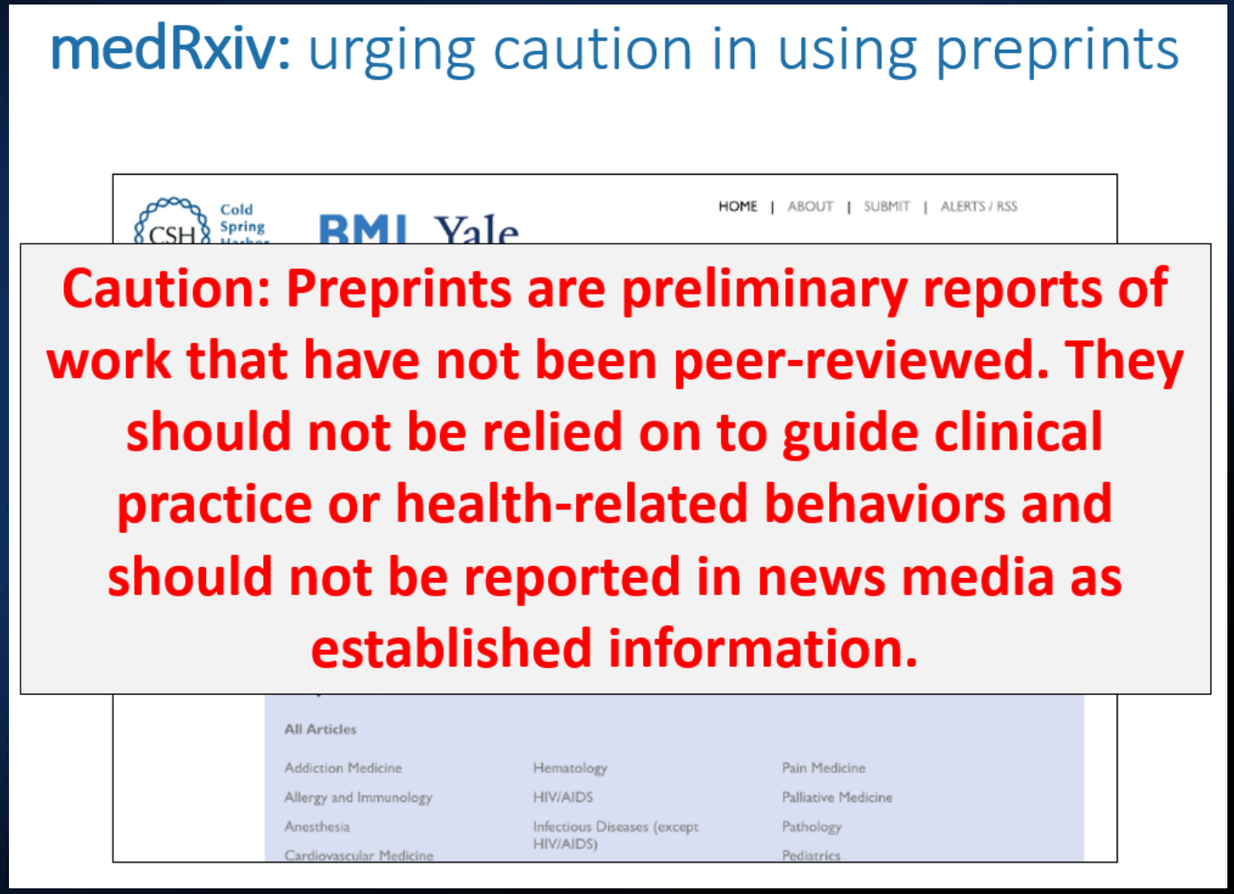


Social Media and Open Access During The Pandemic

- The physician as citizen journalist
- The physician & citizen scientist as innovator
- The physician & citizen as activist
- The physician as educator

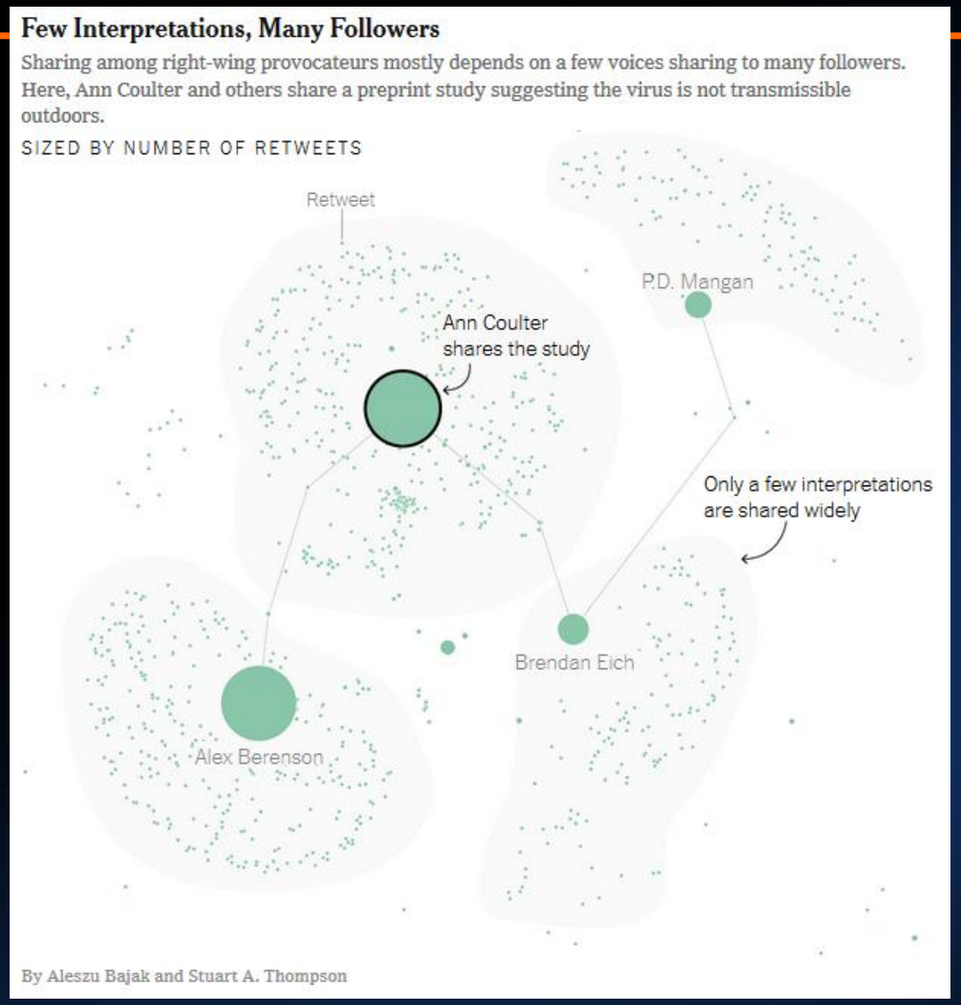
Ascent of the Pre-Print Server During the Pandemic





Source: Harlan Krumholz

Sharing of Pre-Print Data: Media Celebrity vs Research Groups



Source: Bajak A. and Howe J., https://www.nytimes.com/2020/05/14/opinion/coronavirus-research-misinformation.html.

Pre-Print Servers During the Pandemic Critical

Transmission Potential of SARS-CoV-2 in Viral Shedding Observed at the University of Nebraska Medical Center

Authors: Joshua L. Santarpia[1,2*], Danielle N. Rivera[2], Vicki Herrera[1], M. Jane Morwitzer[1], Hannah Creager [1], George W. Santarpia[1], Kevin K. Crown[2], David M. Brett-Major[1], Elizabeth Schnaubelt[1,3], M. Jana Broadhurst[1], James V. Lawler[1], St. Patrick Reid[1], and John J. Lowe[1]

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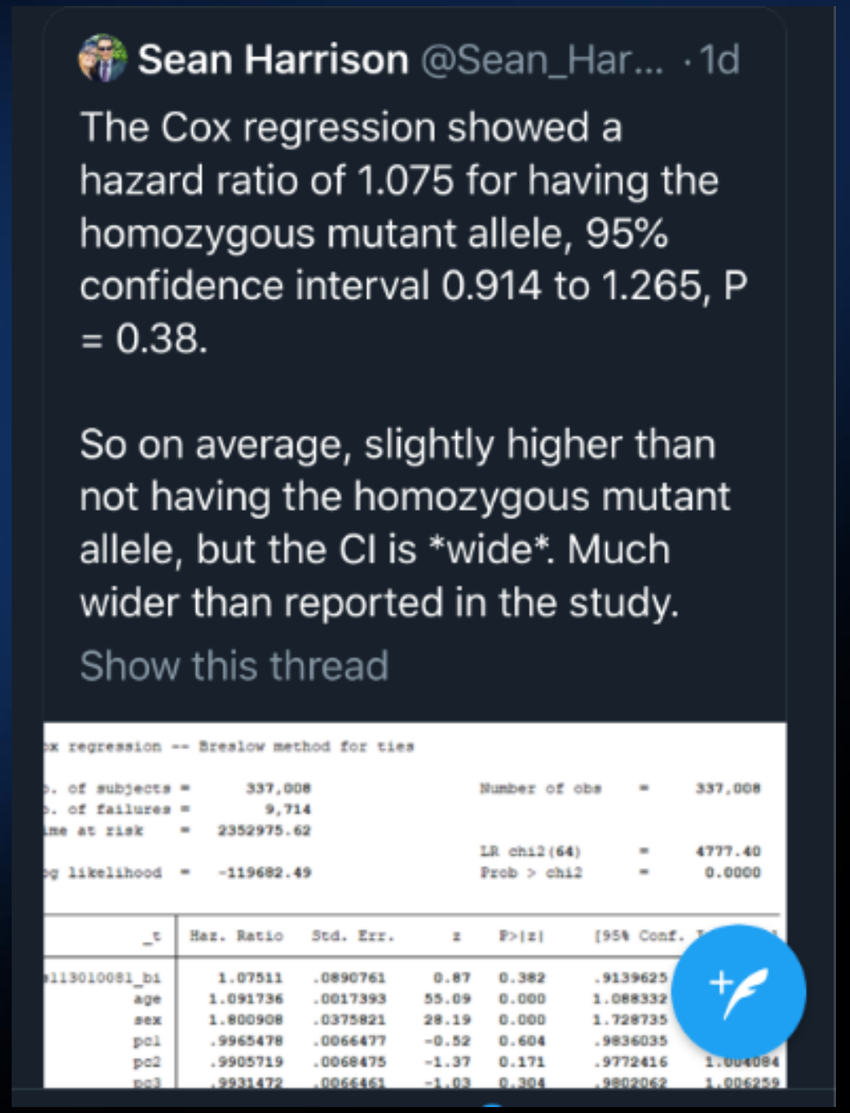
JAMA Internal Medicine

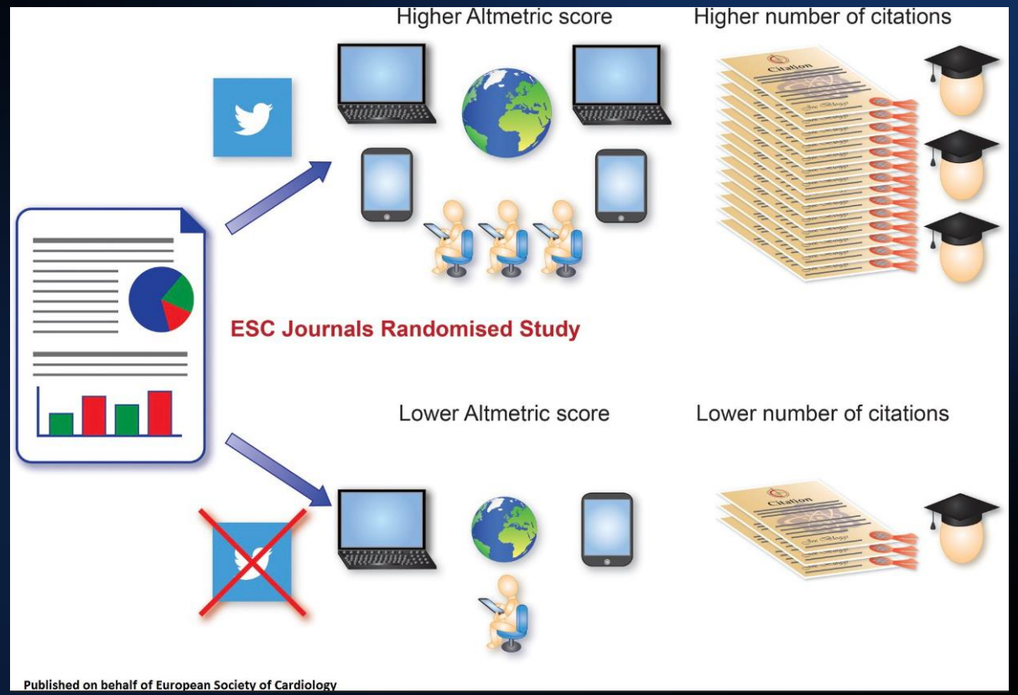
Twitter: Rapid, Transparent, Global Peer Review



Twitter promotion predicts citation rates of cardiovascular articles: a preliminary analysis from the *ESC Journals Randomized Study* FREE

Ricardo Ladeiras-Lopes ✉, Sarah Clarke, Rafael Vidal-Perez, Michael Alexander, Thomas F Lüscher,
the ESC (European Society of Cardiology) Media Committee and European Heart Journal
Author Notes

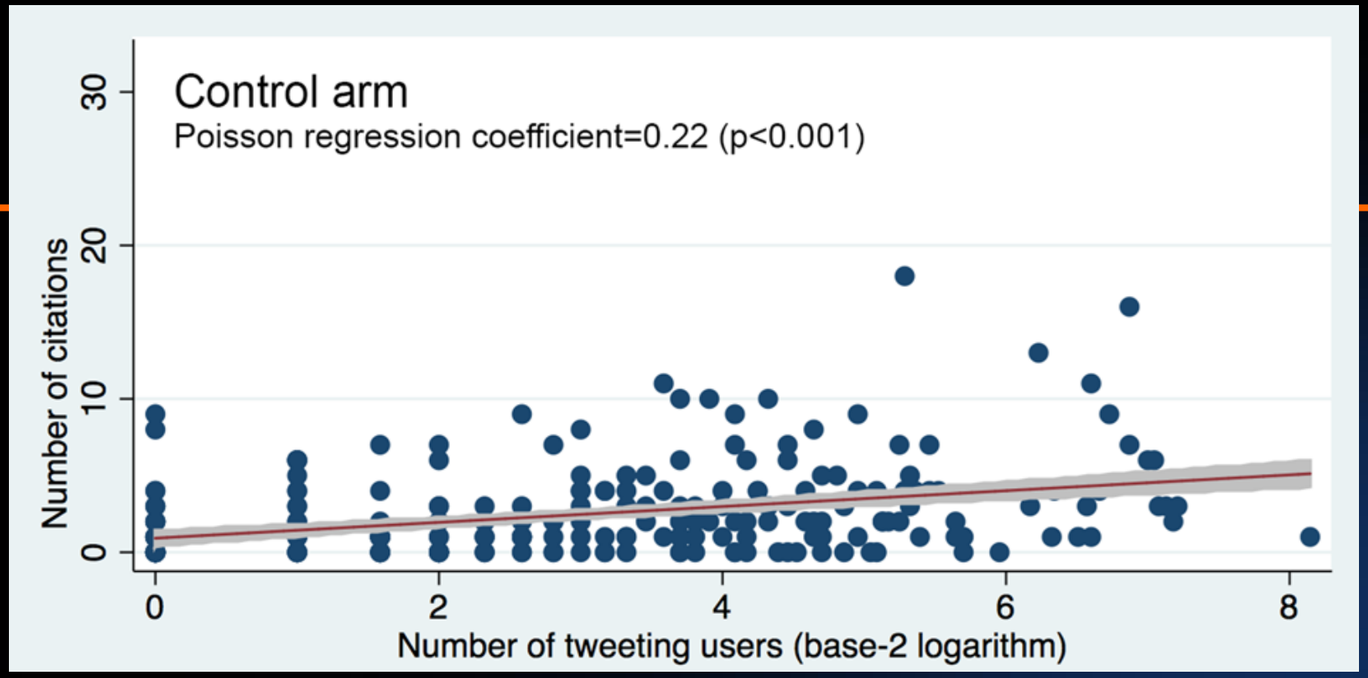
European Heart Journal, ehaa211, https://doi.org/10.1093/eurheartj/ehaa211
Published: 19 April 2020 **Article history** ▾

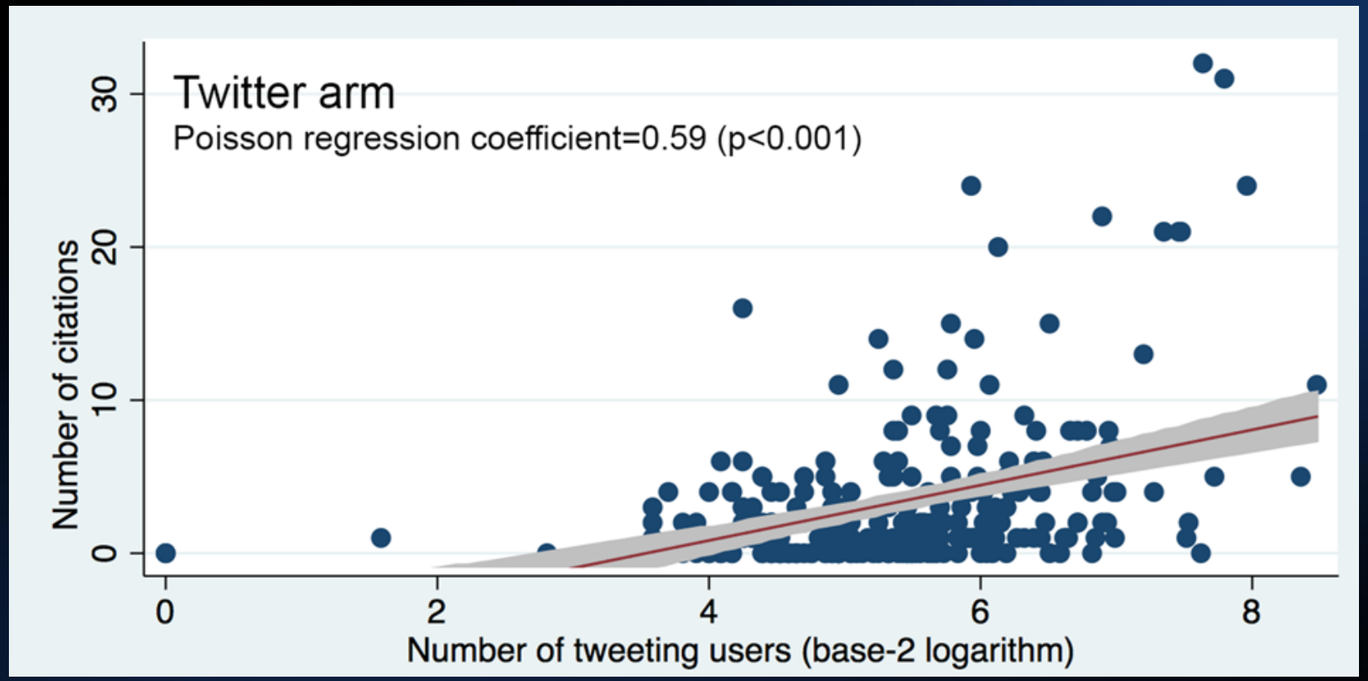


Methods and Results

The ESC Journals Study randomized 696 papers published in the ESC Journals family (March 2018–May 2019) for promotion on Twitter or to a control arm (with no active tweeting from ESC channels) and aimed to assess if Twitter promotion was associated with an increase in citation rate (primary endpoint) and Altmetric score. This is a preliminary analysis of 536 articles (77% of total) published until December 2018 (therefore, papers published at least 6 months before collecting citation and Altmetrics data). In the analysis of the primary endpoint, Twitter promotion of articles was associated with a 1.43 (95% confidence interval 1.29–1.58) higher rate of citations, and this effect was independent of the type of article. Both Altmetric score and number of users tweeting were positively associated with the number of citations in both arms, with evidence of a stronger association (interaction) in the Twitter arm.

https://doi.org/10.1093/eurheartj/ehaa211





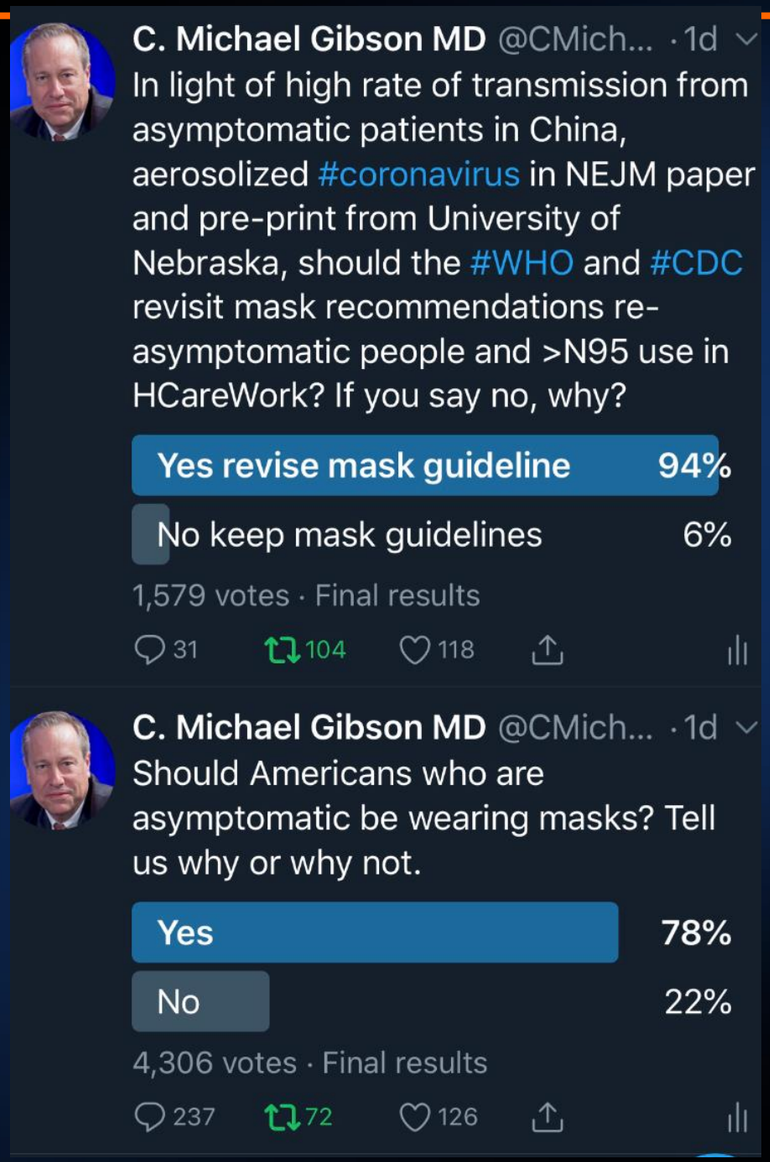
Twitter arm:	**Median tweeters 24**
	Altmetric score of 24
Control arm:	**Median tweeters 5**
	Altmetric 4

Scatter plot showing the association between the number of tweeting users and number of citations.

The number of tweeting users was a positive predictor of number of citations in both arms *with a significant positive interaction between the control and twitter arm.*

https://doi.org/10.1093/eurheartj/ehaa211

Patient and Physician Advocacy During A Pandemic



Educating Patients & Promoting Grass Roots Innovation: #MacGyverCare

Testing the Efficacy of Homemade Masks: Would They Protect in an Influenza Pandemic?

Anna Davies, BSc, Katy-Anne Thompson, BSc, Karthika Giri, BSc, George Kafatos, MSc, Jimmy Walker, PhD, and Allan Bennett, MSc

ABSTRACT

Objective: This study examined homemade masks as an alternative to commercial face masks.

Methods: Several household materials were evaluated for the capacity to block bacterial and viral aerosols. Twenty-one healthy volunteers made their own face masks from cotton t-shirts; the masks were then tested for fit. The number of microorganisms isolated from coughs of healthy volunteers wearing their homemade mask, a surgical mask, or no mask was compared using several air-sampling techniques.

Results: The median-fit factor of the homemade masks was one-half that of the surgical masks. Both masks significantly reduced the number of microorganisms expelled by volunteers, although the surgical mask was 3 times more effective in blocking transmission than the homemade mask.

Conclusion: Our findings suggest that a homemade mask should only be considered as a last resort to prevent droplet transmission from infected individuals, but it would be better than no protection. (*Disaster Med Public Health Preparedness.* 2013;0:1–6)

Key Words: homemade facemasks, respirators, airborne transmission, microbial dispersion, pandemic prevention

TABLE 3

Median Colony-Forming Units by Sampling Method Isolated From Volunteers Coughing When Wearing a Surgical Mask, a Homemade Mask, and No Mask

Sampling Method	Median Interquartile Range: No Mask		Homemade Mask		*P*
Air	6.0	(1.0, 26.5)	1.0	(0.5, 6.5)	.007
Settle plates	1.0	(0.0, 3.0)	1.0	(0.0, 2.0)	.224
Total	2.0	(0.0, 12.3)	1.0	(0.0, 3.0)	.004

Sampling Method	Median Interquartile Range: No Mask		Surgical Mask		*P*
Air	6.0	(1.0, 26.5)	1.0	(0.5, 3.0)	.002
Settle plates	1.0	(0.0, 3.0)	0.0	(0.0, 0.0)	.002
Total	2.0	(0.0, 12.3)	0.0	(0.0, 1.0)	<.001

#MacGyverCare Hashtag was Used >3,000 times in 86 countries on 6 continents in 2 weeks

	3 Days	1 Week	2 Weeks
Retweets	1,316	2,476	3,460
Countries	53	79	86
Continents	6	6	6

TABLE 1

Filtration Efficiency and Pressure Drop Across Materials Tested with Aerosols of *Bacillus atrophaeus* and Bacteriophage MS2 (30 L/min)[a]

Material	*B atrophaeus*		Bacteriophage MS2		Pressure Drop Across Fabric	
	Mean % Filtration Efficiency	SD	Mean % Filtration Efficiency	SD	Mean	SD
100% cotton T-shirt	69.42 (70.66)	10.53 (6.83)	50.85	16.81	4.29 (5.13)	0.07 (0.57)
Scarf	62.30	4.44	48.87	19.77	4.36	0.19
Tea towel	83.24 (96.71)	7.81 (8.73)	72.46	22.60	7.23 (12.10)	0.96 (0.17)
Pillowcase	61.28 (62.38)	4.91 (8.73)	57.13	10.55	3.88 (5.50)	0.03 (0.26)
Antimicrobial Pillowcase	65.62	7.64	68.90	7.44	6.11	0.35
Surgical mask	96.35	0.68	89.52	2.65	5.23	0.15
Vacuum cleaner bag	94.35	0.74	85.95	1.55	10.18	0.32
Cotton mix	74.60	11.17	70.24	0.08	6.18	0.48
Linen	60.00	11.18	61.67	2.41	4.50	0.19
Silk	58.00	2.75	54.32	29.49	4.57	0.31

[a] Numbers in parentheses refer to the results from 2 layers of fabric.

TABLE 2

Median and Interquartile Range Results from Respirator Fit Testing of Homemade and Surgical Masks

Condition	Median Interquartile Range: Homemade Mask		Surgical Mask	
Normal breathing	2.0	(2.0, 2.5)	6.0	(2.5, 9.0)
Heavy breathing	2.0	(2.0, 3.0)	7.0	(2.5, 13.5)
Head moving side to side	2.0	(1.0, 2.0)	5.0	(3.0, 7.0)
Head moving up and down	2.0	(1.5, 2.0)	5.0	(3.0, 7.0)
Bending over	1.0	(1.0, 2.0)	3.0	(2.0, 9.0)
Talking	2.0	(1.0, 2.0)	6.0	(3.0, 12.0)
Normal	2.0	(1.0, 2.0)	5.0	(2.0, 8.5)
All data	2.0	(1.0, 2.0)	5.0	(3.0, 9.0)

The influencers of #Coronavirus

World Health Organization (WHO)
@WHO
100

CDC @CDCgov
69

C. Michael Gibson MD
@CMichaelGibson
60

Patient Access & Advocacy During A Pandemic

FEATURE

How New Jersey's First Coronavirus Patient Survived

James Cai's case was completely new to his doctors. When he grew severely ill, he tapped a network of Chinese and Chinese-American medical colleagues who helped save his life.

Within 12 hours, half a million people had watched the video. C. Michael Gibson, the founder of the open-source textbook WikiDoc and a top cardiologist with nearly a half a million followers, helped by quickly

terrorpanda @terrorpandaz · 9m
Replying to @CMichaelGibson @BertGoldPhD and @FYang_EP

Thanks dr Gibson, they told us the medicine will be there by tomorrow. Grateful

You Retweeted

Felix Yang @FYang_EP · 22h
Replying to @CMichaelGibson @netta_doc and 7 others

@CMichaelGibson you are THE MAN. Thanks so much for helping out!! Just heard from their end. And thanks everyone else on this twitter feed. This is modern medicine fueled by social media at its best!!!

25 64 649

C. Michael Gibson MD @CMic... · 22h
This is tremendous news! Let's hope he gets better! 🙏🙏🙏

You Retweeted

James Cai @JamesCaiNJNYC · 1d
Replying to @CMichaelGibson and @GileadSciences

Dr Gibson. Thank you again for saving my life. And I hope that my story and message can save more lives

2 8 49

C. Michael Gibson MD @CMich... · 1d
I am glad that the @GileadSciences compassionate use program helped you and that you are recovering 🙏🙏🙏

Donated “The Last Shift” to Charity for PPE Raised > $25,000

Old World vs New World: Information Flow

Old World	New World
Insular and Secretive	Open Source
Innovate from within	Innovate from without
Knowledge flowed only to those at the top	Knowledge flows to and from all
Medium: Paper	Medium: Internet
Copyright 	Copyleft 

Gibson CM, JAMA Cardiology 2016

Surveillance Capitalism

Myth

- Digital services are a free commodity
- You search Google
- We use SoMe to connect
- I signed a Privacy Policy
- I own my picture on Facebook
- Division of Labor
- You know more about you than them
- You have more knowledge & power
- Knowledge of you is for your well being
- Earning Inequality
- Ownership of means of production
- Cambridge University & News
- Human virus
- Military warfare

Reality

- You are the free commodity
- Google searches us
- That connection is how SoMe uses us
- You signed a Surveillance Policy
- Your picture is used for surveillance
- Division of knowledge
- Know more about you than you
- They have more knowledge and power
- Knowledge of you is for them for profit
- Learning Inequality
- Ownership of the production of meaning
- Cambridge Analytica & Fake News
- Information virus
- Information warfare

https://www.nytimes.com/2020/01/24/opinion/sunday/surveillance-capitalism.html

Surveillance Capitalism

Myth

- Compete on products
- You buy an airborne drone

- Data collected
- What we can do
- You are Playing Pokémon Go

- Online privacy protection

- Innovation created technology with goal of enriching lives

Reality

- Compete on Predictions (on line ads)
- You are a drone armed with a cell phone to give data about your location, images, and your biometrics
- Data to predict & data to cause you to act
- What can be done to us (acuation)
- Pokémon Go is playing you to go to sponsors establishments like McDonalds, Starbucks, & local Pizza places for "Footfall"
- "Surveillance exceptionalism", complete informational awareness post 911
- Created a technocracy, vast capital & computational power dedicated to prediction & actuation of human behavior for profit, not for enrichment

https://www.nytimes.com/2020/01/24/opinion/sunday/surveillance-capitalism.html

Old World vs New World: Organizations

Old World	New World
Symbol: The silo	Symbol: The Globe
Organization: Vertical	Organization: Horizontal
“Command and Control”	“Cocreation” “Collective genius” “Peering” “Online collectivism”
The corner office	Open space no walls

The Patient Now Has A Seat At The Table

Gibson CM, JAMA Cardiology 2016

Access to Medical Information and a Voice on the Internet has Empowered Patients Lowering Physician / Patient Power Gradient

Old World

Trusted provider conveys paternalistic, proscriptive information to uninformed patient in a one-way conversation

New World

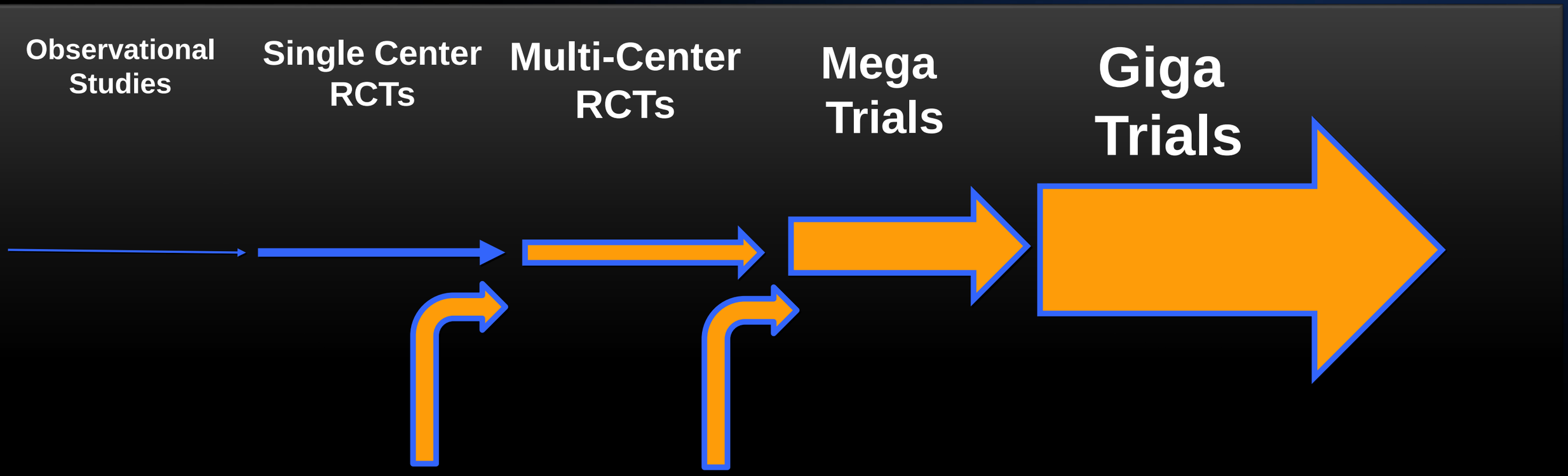
We must now earn the trust of relatively informed & knowledgeable patients through a two-way conversation

Gibson CM, JAMA Cardiology 2016

The Heartline Giga Trial is the Culmination of all These Changes

Open access of patients to participation irrespective of geography and provider
& open access of patients to their data
Social media features: family members alerted to outcomes
Use of electronic health records +
Patient reported outcomes
Patient empowerment &
Patient Compensation
Wearables
Big data
Apps

Evolution of the Giga Trial



The HEARTLINE Trial of the Apple Watch to Detect Atrial Fibrillation in Participants ≥ 65: Entering the Era of the Giga Trial

A randomized trial of up to 180,000 patients to test whether the new Apple watch (with a built-in single lead EKG) can detect new onset atrial fibrillation in participants ≥ 65

Does this reduce the risk of all cause death and all cause stroke?

This virtual trial will cost 1% of what it costs to do a traditional RCT

HEARTLINE™

Objective 1: Atrial Fibrillation Detection / Treatment

OBJECTIVE ONE

Atrial Fibrillation Detection / Treatment

INCLUSION

≥65 years of age who do not have a diagnosis of AF at study entry

PRIMARY OBJECTIVE

Determine whether a broad health-focused engagement program* paired with the heart arrhythmia alert (PPG) and an ECG sensor via the Apple Watch® in participants ≥65 years of age with undiagnosed symptomatic or asymptomatic AF can increase the clinically confirmed diagnosis rate of AF vs standard of care (ie, control group) *Health engagement program: broad heart and AF education, challenges, and electronic PRO surveys through the Apple Watch and/or iPhone® app, with rewards for their engagement with these study-related tasks

PRIMARY ENDPOINT

The number (%) of clinically confirmed diagnoses of AF at a defined timepoint with validation obtained from a claims database. Time to receiving an alert and a confirmed diagnosis from a physician will also be considered as endpoints for analysis. Key Secondary Endpoint: CV outcomes defined as MACE (All cause death, stroke)

Slide by C. Michael Gibson, M.S., M.D.

Patient Empowered Trials Will Replace Bricks and Mortar

Old World

Hospital Based Trial

Patients enrolled, consented on paper & randomized in hospital or clinic

Patients followed up in hospital or clinic using paper or eCRFs

New World

Virtual Trial

Patients enrolled via app on-line

Patients followed-up on-line by apps for Patient Reported Outcomes (PROs) and claims databases

Consent

Old World	New World
Paper	Electronic
Institution specific	Global
Local IRB	Central IRB

Patient Empowered Trials will Provide More Generalizable Results

Old World

Single center studies, multicenter studies, International **Mega** trials of 10,000 to 20,000 patients

Includes only a ***highly select target population*** with greatest modifiable risk to reduce sample size

Limited generalizability

New World

HEARTLINE is a **Giga** trial of 180,000 patients

Includes ***real world*** *patients* with a broad range of modifiable risk and limited exclusion criteria

Broader generalizability

Ability to Definitively Test Primary Hypothesis

Old World

Possibly *underpowered*

Depending upon event rates, *may not test primary hypothesis definitively*

May not be powered to assess secondary hypotheses

New World

Well *powered*

Definitive test of primary hypothesis

Likely well powered to assess secondary hypotheses

Significance of Results

Old World

If treatment effect robust enough to be statistically significant, generally clinically significant

New World

Trial so large that treatment effect may be statistically significant but not clinically significant

Patient Empowered Trials will Enroll Rapidly

Old World

0.3 (US) to 1.0 (Rest of World) patient per site per month yielding enrollment of **hundreds** of patients per month worldwide

New World

50,000 patients enrolled per month

Direct to Patient Recruitment

- Social Media
- Facebook ads
- Twitter influencers
- At the time of launch interviews with all major print/electronic outlets
- Local TV: 35 local TV & radio interviews in a day
- National TV: Went on “The Talk” to promote the study
- Targeted advertising to demographic group: AARP for instance
- Insurance companies: Not cost effective
- Physicians
- Electronic Health Records

Costs

Old World

$30,000 to $150,000 per patient

Hundreds of millions of dollars per phase 3 pharma trial; sometimes a billion dollars +

Cost to track down missing patients: $50,000 / patient

40% of budget spent on monitoring

New World

Small fraction of cost, @1%

No cost to track down missing patients because claims database is used

No monitoring; automatically drops budget 40%

Patient Empowered Trials: Patient and Family Access to Data

Old World

None during trial, limited access at end of trial

No ability to notify family members of an event

New World

Available on app at all times

Via private social networking family members alerted to event (your family member may have atrial fibrillation)

Specificity and Sensitivity of Endpoints

Old World

Independent physician adjudication of events (Clinical Event Committee or CEC) using rigorous trial specific definitions leads to higher specificity, fewer events

Less sensitive in identifying events

New World

Use of International Classification of Disease (ICD 10 codes, not specific to trial) to find events leads to lower specificity, more events

More sensitive in identifying events

Compliance

Old World

Ideal

Calls from and visits with research team and pill counts improve compliance

New World

Moderate

Approximates real world behavior

Exception is if family members alerted to an event in trial

Adjudication of Events

Old World

Physicians adjudicate each case

Based on evolving definitions that vary across trials (TIMI, BARC, GUSTO, ISTH, Plato bleeding etc)

New World

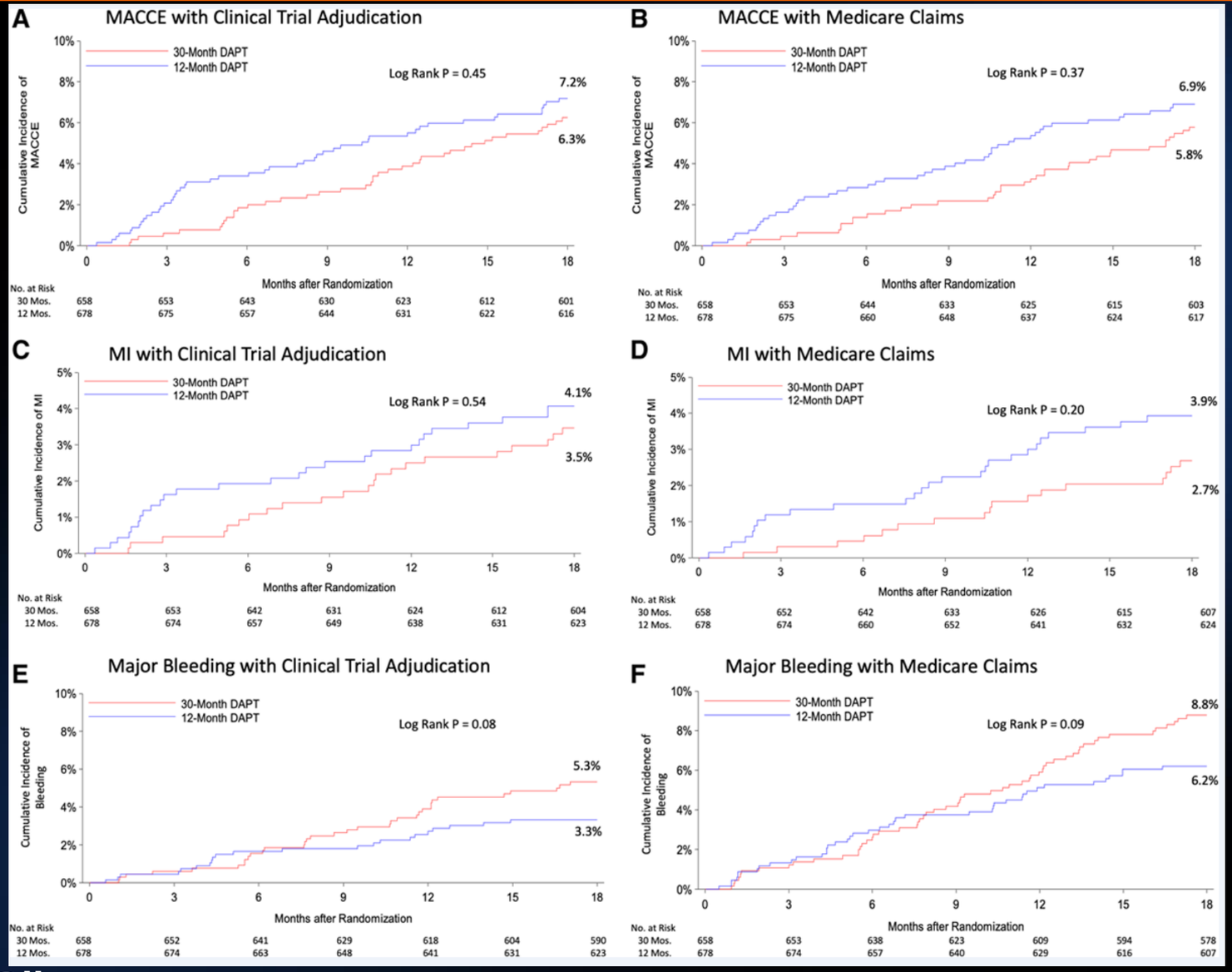
Based on claims data

Worldwide use of ICD 10 codes, peridically updated, single consistent code can be used worldwide

ICD 9 can be translated to ICD 10

CEC vs Claims Database in the DAPT Trial

DAPT Study data linked to the American College of Cardiology's NCDR (National Cardiovascular Data Registry) CathPCI Registry and Medicare fee-for-service claims & CEC c/w claims data



Faridi KF, …Gibson CM, Yeh R. Circulation. 2020;142:306–308

CEC vs Claims Database

- Relative effects of 30 versus 12 months of DAPT on MACCE were similar in magnitude and direction whether based on claims or adjudicated events (claims HR, 0.82 [95% CI, 0.53–1.26] versus trial HR, 0.85 [95% CI, 0.56–1.29]; interaction *P*=0.79). Relative effects for MI (claims HR, 0.67 [95% CI, 0.36–1.24] versus trial HR, 0.84 [95% CI, 0.48–1.47]; interaction *P*=0.29) and bleeding (claims HR, 1.42 [95% CI, 0.95–2.12] versus trial HR, 1.61 [95% CI, 0.94–2.75]; interaction *P*=0.56) were similar in direction with nonsignificant differences in magnitude.
- This study suggests that treatment effects of extended-duration DAPT after PCI using claims-derived events may be similar to those using adjudicated events, with several caveats. We observed some differences that were numerically different but did not reach criteria for statistical significance. Such differences between claims and adjudication could potentially alter conclusions in a larger, adequately powered study. This was also a subgroup of older patients linked to Medicare, and our findings may not apply to other populations. For trials particularly focused on an older US-based population, our data suggest that claims may be cautiously used as a supplement to current adjudication methods or other strategies such as use of electronic health records.

Faridi KF, …Gibson CM, Yeh R. Circulation. 2020;142:306–308

Reimbursement for Labor

Old World

Doctors and Nurses and Hospital reimbursed

New World

Patient reimbursed for effort to complete patient reported outcomes and interacting with App

Safety Monitoring

Old World

- Site reports event
- Site collect documents
- Documents sent to CEC
- Documents redacted
- Documents translated
- Queries issued
- Event adjudicated
- Additional queries sent
- Final adjudication

Delay in updated data for DSMB meetings

New World

- Continuous monitoring of ICD 10 diagnoses

Real time data for DSMB meetings as data always caught up (or caught up to the time of discharge or death)

Missing Data

Old World

Missing data may approximate event rates

Risk of informative censoring

Eg: Frail, old people who bleed drop out leaving only young healthy people who passed “bleeding stress test”, lowering the risk of Death / heart attack and stroke in remaining patients

New World

Little to no missing patients (unless patient leaves country in a US only trial)

Big Data / Artificial Intelligence

Old World

Number of patients / events often modest

"Clean data" NOT available in real time for modeling

More covariates

More may not be better or practicable in utilization

Megabytes to Gigabytes of data

New World

Larger number of patients and events

"Clean data" available in real time to guide trial modifications

Fewer covariates though

With wearables can be Terabytes to Pentabytes of data

Patient Empowered Trials Will Yield Patient Specific Predictions

Old World

Guidelines based medicine (one size fits all)

Traditional population statistics

New World

Personalized medicine (tailored to every kind of "ome" & risk factors)

Artificial intelligence to make predictions re individual outcomes

Using Big Data to make Predictions About Individual Patient Outcomes to Allow Shared Decision Making

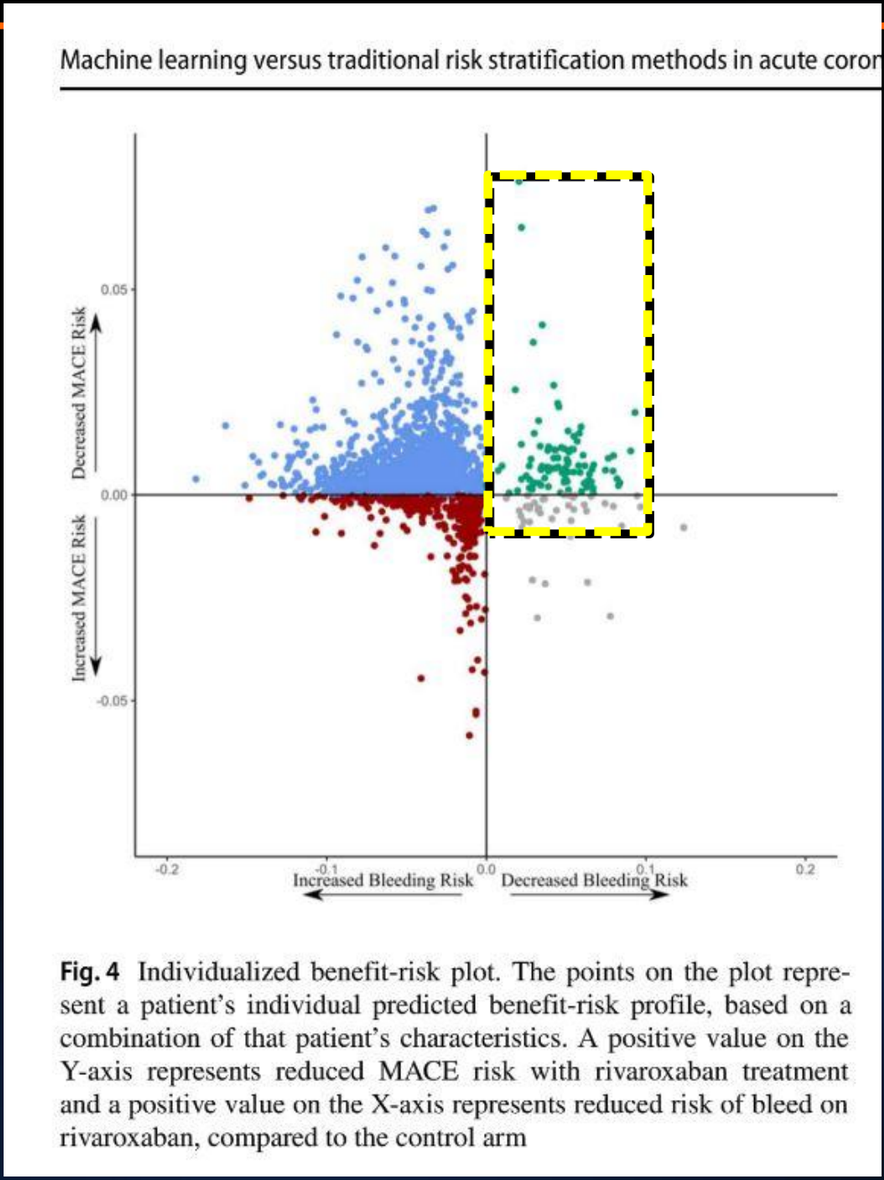


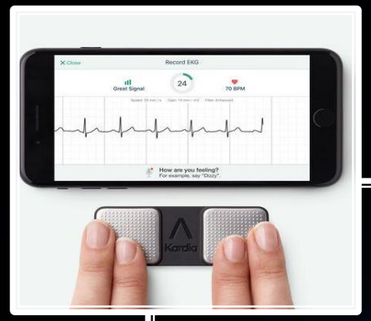
Fig. 4 Individualized benefit-risk plot. The points on the plot represent a patient's individual predicted benefit-risk profile, based on a combination of that patient's characteristics. A positive value on the Y-axis represents reduced MACE risk with rivaroxaban treatment and a positive value on the X-axis represents reduced risk of bleed on rivaroxaban, compared to the control arm

Each dot shows the risk of having a heart attack or stroke and the risk of bleeding for an individual patient

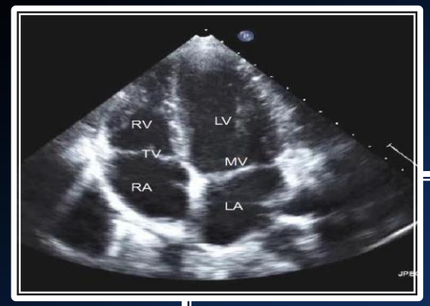
Artificial Intelligence predicts people in the yellow box would have only benefit with no risk of bleeding

Gibson et al Journal of Thrombosis and Thrombolysis in press

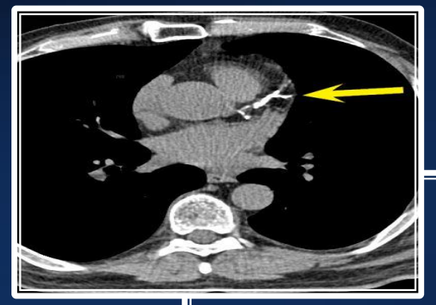
FDA Approved AI Diagnostic and Prognostic Tools in Cardiology



- **ALIVECOR KardiaMobile Heart Monitor**
- **Records, stores and transfers single-channel EKG rhythms**
- **Detects Atrial fibrillation, tachycardia, bradycardia**



- **EchoMD Automated Ejection Fraction Software by Baylabs**
- **Analyzes transthoracic ultrasound images using deep learning**

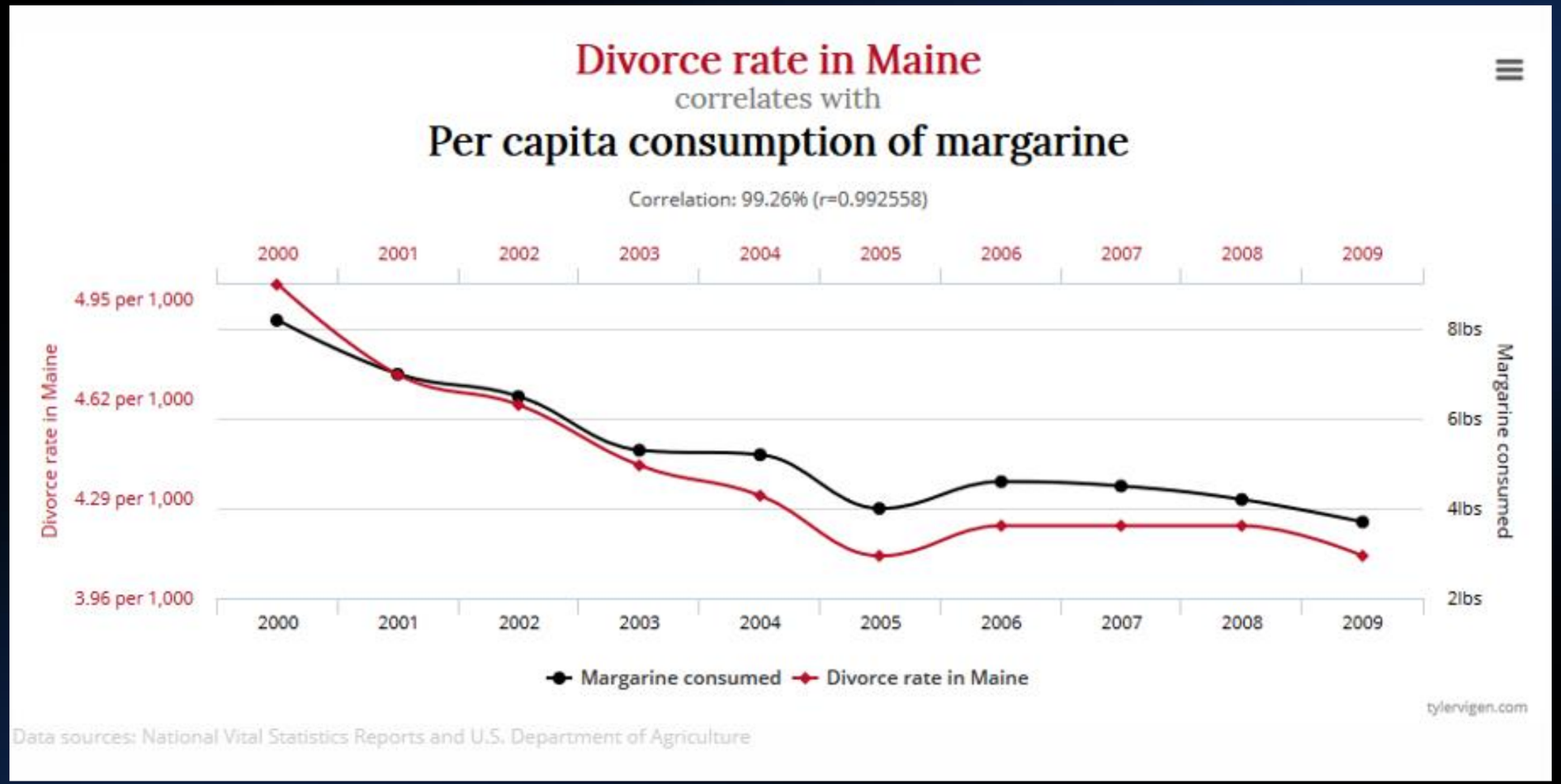


- **Health CCS by Zebra Medical**
- **Analyzes EKG-gated/triggered CT scans and generates a 4-category Agaston-equivalent risk score for evaluation of calcified plaques in coronaries**

Slide by C. Michael Gibson, M.S., M.D.

Reference here

There Can Be Spurious Correlations



Slide by C. Michael Gibson, M.S., M.D.

http://tylervigen.com/spurious-correlations

Artificial Intelligence: The Black Box Problem
AI Diagnosed Melanoma Because Dr. Had Put Ruler Next to Lesion

He and his colleagues had one such problem in their their study with rulers. When dermatologists are looking at a lesion that they think might be a tumor, they'll break out a ruler—the type you might have used in grade school—to take an accurate measurement of its size. Dermatologists tend to do this only for lesions that are a cause for concern. So in the set of biopsy images, if an image had a ruler in it, the algorithm was more likely to call a tumor malignant, because the presence of a ruler correlated with an increased likelihood a lesion was cancerous. Unfortunately, as Novoa emphasizes, the algorithm doesn't know why that correlation makes sense, so it could easily misinterpret a random ruler sighting as grounds to diagnose cancer.

That bias, and others like it, will need to be culled in order for A.I. to truly be a popular approach in medical diagnostics. "These technologies are a bit like the driverless car, in that they have to perform extremely well in order to be available to the general public," Novoa said. People's lives are tied to something that will diagnose cancer."

https://www.thedailybeast.com/why-doctors-arent-afraid-of-better-more-efficient-ai-diagnosing-cancer?source=twitter&via=desktop

https://www.nature.com/articles/nature21056.epdf

The Appropriate Role of Digital Health

"You can't list your iPhone as your primary-care physician."

Technology should work for healthcare

Healthcare should not work for technology

Health information does not equal healthcare

Digital health should not compete with but should compliment Nurses and Doctors

Putting patients at the center of trials will be the future