Perils of Digital Health

Controversies & Advances in the Treatment of Cardiovascular Disease

11-15-19

John Mandrola, MD
Baptist Health Louisville
@drjohnm
Disclosures:

- None

- Staci Mandrola, MD is a hospice and palliative care physician
• A 95-year-old man who lives independently presents to the hospital with shortness of breath due to AF and HFpEF
• He has not seen a doctor in 5 decades.

Q: Why did he live to 95 years?
What is your favorite medical app?

#Meded
#EPeeps
#Dontdisthehis
#CardioTwitter
#RadialFirst
#FOAMed
#POCUS
#AHA19
Remote Monitoring of Implantable Cardioverter-Defibrillators
A Systematic Review and Meta-Analysis of Clinical Outcomes

9 RCTs, including 6,469 patients,
Remote Monitoring vs In-Office follow-up

Symptom Monitoring With Patient-Reported Outcomes During Routine Cancer Treatment: A Randomized Controlled Trial

Ethan Basch, Allison M. Deal, Mark G. Kris, Howard J. Scher, Clifford A. Hudis, Paul Sabbatini...

Show More

Relative to control...

- RCT w/ 766 patients w/ advanced solid tumors undergoing chemoRx
- 12 symptoms recorded on tablet transmitted e-mail vs SC
- PEP – QOL change

- HRQL improved (34% v 18%)
- Fewer ED visits
- Fewer hospitalized
- 75% vs 69% alive at one year (P =0.05)

https://ascopubs.org/doi/10.1200/JCO.2015.63.0830
To be clear, POCUS is a true stethoscope, not stethophone. And seeing the heart on physical exam is the future. #meded #foamed #disruption

Anthony Wald @antwaldecho - Nov 11, 2016
AoV destruction IE. IVDU. 3/7 unwell, hypotension, initial dx by PoCUS.

John Mandrola, MD @drjohnm
Here comes the future. Love #POCUS

Matthew Herper @matthewherper - Sep 27, 2018
Unicorn alert! Jonathan Rothberg’s handheld ultrasound company, Butterfly Network, raises $250 million at a $1.25 billion valuation. forbes.com/sites/matthewh...
QTC intervals can be assessed with the AliveCor heart monitor in patients on dofetilide for atrial fibrillation

Eugene H. Chung MD, FACC, FAHA, FHRS, Kimberly D. Guise MSN, ANP

Using a novel wireless system for monitoring patients after the atrial fibrillation ablation procedure: The iTTransmit study

Khalidoun G. Tarakji MD, MPH, FHRS, Oussama M. Wazni MD, FHRS, Thomas Callahan MD, FHRS, Mohamed Kanj MD, Ali H. Hakim, Kathy Wolski MPH, Bruce L. Wilkoff MD, FHRS, Walid Saliba MD, FHRS, Bruce D. Lindsay MD, FHRS
Telehealth – Is better than no health
What’s the common thread of all these (positive) examples?
New stuff is used on sick people

People who are asking for our help
Sontag’s Dual Citizenship

Kingdom of the Well

Kingdom of the Sick

Circa 1978
Sontag’s Kingdoms

circa 2019

Kingdom of the Well

- Good intentions
- Wishful thinking
- Vested interests

Kingdom of the Sick

- HTN
- T2D
- SCAF
- DCIS
- Depression
- ADHD
- Genetic risks
- Anxiety
Contingent Knowledge and Looping Effects — A 66-Year-Old Man with PSA-Detected Prostate Cancer and Regrets

Robert Aronowitz, M.D., and Jeremy A. Greene, M.D., Ph.D.

**Social medicine perspective**—in which society’s culture shapes the notion of health, disease, and recovery.
- Lead-time-bias – perception that screening has improved survival
- Overdiagnosis -- perception that interventions work

**Looping effects**: feedback patterns among diagnosis, therapeutic interventions, and health behaviors influence the natural history and prognosis of diseases.

Clinicians can strive to reduce the “evidence-free” spread of purportedly risk-reducing interventions.

Aronowitz Green NEJM 2019
Software as a Medical Device

Digital Health Software Precertification (Pre-Cert) Program

Sim 2019 NEJM

“Companies that demonstrate a “culture of quality and organizational excellence” for streamlined review of their applications.”

“Products of precertified companies do not have to be associated with improved clinical outcomes before market release …”
Now for some reality

How is technology doing?
Digital Revolution begins
Life expectancy vs. health expenditure, 1970 to 2015

Health financing is reported as the annual per capita health expenditure and is adjusted for inflation and price level differences between countries (measured in 2010 international dollars).
Prevention and the Dubious Cartesian Frame

Will the search for one problem lead to health?
Disease-specific mortality vs Overall mortality

The vast majority of deaths are from non-screened-for-diseases
reductions in all-cause mortality are very rare or non-existent.
W.H.O. 1968

- In theory, screening is an admirable method of combating disease...
- In practice, there are snags.

J.M.G. Wilson (London) and G. Jungner (Gothneburge, Sweden) WHO
Facebook will now remind you to get flu shots and medical checkups

PUBLISHED MON, OCT 28 2019-1:00 PM EDT

Christina Farr
@CHRISyFARR

Facebook on Monday is debuting a new tool, called Preventive Health, that reminds users to get medical checkups, vaccines and tests.
### Medical Check Ups

**Cochrane Database of Systematic Reviews**

**General health checks in adults for reducing morbidity and mortality from disease**

Cochrane Systematic Review - Intervention | Version published: 31 January 2019  | see what's new

https://doi.org/10.1002/14651858.CD005000.pub3

**17 trials**

- **150K individuals**

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<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Illustrative comparative risk* (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>No of participants (studies)</th>
<th>Certainty of the evidence (GRADE)</th>
</tr>
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<tr>
<td><strong>Total mortality</strong></td>
<td>Without health checks</td>
<td>With health checks</td>
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<tr>
<td>Follow-up: 4-30 years</td>
<td>68 per 1000</td>
<td>68 per 1000</td>
<td>215,298 (1)</td>
<td>high</td>
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<tr>
<td></td>
<td>(64 to 72)</td>
<td>(64 to 72)</td>
<td>(1)</td>
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<td></td>
<td>RR: 1.00 (0.97 to 1.03)</td>
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<tr>
<td>Follow-up: 4-22 years</td>
<td>36 per 1000</td>
<td>24 per 1000</td>
<td>139,298 (8)</td>
<td>high</td>
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<td>(32 to 39)</td>
<td>(24 to 34)</td>
<td>(8)</td>
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<td>RR: 1.40 (1.19 to 1.63)</td>
<td>RR: 1.40 (1.19 to 1.63)</td>
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<tr>
<td>Follow-up: 4-30 years</td>
<td>52 per 1000</td>
<td>44 per 1000</td>
<td>170,227 (9)</td>
<td>moderate</td>
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<td>(48 to 56)</td>
<td>(40 to 49)</td>
<td>(9)</td>
<td></td>
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<tr>
<td></td>
<td>RR: 1.20 (1.04 to 1.39)</td>
<td>RR: 1.20 (1.04 to 1.39)</td>
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Krogsboll Cochrane Library 2019
Who Does Screening Like This Benefit?
Identifies Three Big Challenges of Remote / Digital Health
Recruited 419k individuals in 8 months

Incredible and Novel
Challenge 1: Looking for AF in Young Apple Watch Users

bullseye wrong target

The Young

The Old
N = 100 million adults live with multiple chronic conditions

https://www.rand.org/pubs/tools/TL221.html
Multiple Chronic Conditions in the United States
by Christine Butterff, Teague Ruder, Melissa Bauman
Related Topics: Chronic Diseases and Conditions, Health Care Costs, Health Disparities, United States

Cognitive Impairment

1 in 4 adults age ≥ 65 w/ five or or more chromic conditions have cognitive limitations

https://www.rand.org/pubs/tools/TL221.html
Who Does Screening Benefit?
Large-Scale Assessment of a Smartwatch to Identify Atrial Fibrillation

Marco V. Perez, M.D., Kenneth W. Mahaffey, M.D., Haley Hedlin, Ph.D., John S. Rumsfeld, M.D., Ph.D., Ariadna Garcia, M.S., Todd Ferris, M.D., Vidhya Balsubramanian, M.S., Andrea M. Russo, M.D., Amol Rajmane, M.D., Lauren Cheung, M.D., Grace Hung, M.S., Justin Lee, M.P.H., et al., for the Apple Heart Study Investigators

- 2,161 participants notified of an irregular pulse
- 450 follow-up and returned ECG patches

79% drop out rate

Barriers to and Facilitators of Engagement With Remote Measurement Technology for Managing Health: Systematic Review and Content Analysis of Findings

Sara Simblett¹, PhD, DClinPsych; Ben Greer¹, BSc; Faith Matcham¹, PhD, CPsychol; Hannah Curtis¹, BSc; Ashley Polhemus², MSE; José Ferrão², PhD; Peter Gamble², MBA; Til Wykes³, DBE, PhD

¹Institute of Psychiatry, Psychology and Neuroscience, Psychology, King’s College London, London, United Kingdom

- Systematic Rev
- N = 33 studies
- Barriers to Remote Measurement Tech

Up to 44% Dropout Rate

Perez NEJM 2019
Simblett J Med Internet Res 2018
Challenge #2 – Do people stick with remote measurement tools?

Fitbit has 28 million active users, but it has sold more than 100 million devices.

So most people that bought one aren't using it. Can Google fix the all important engagement problem? 75% churn is high, from what I understand.
This study of 711 fitbit users found retention of 74% at day 100 and 16% at day 320.

Top predictors: age, goal (stop smoking), smartphone model, multi-person sports, household.

Note: From http://mhealth.jmir.org/2017/10/e164
Challenge 3 – Is it a good idea to send more people into the healthcare system?
RCTs showing that Rx of screen-detected AF reduces stroke

- Click to add text
Medical Error – 251,000 deaths
Percent of physicians who reported cascades caused their patients

- **Psychological harm (68.4%)**
- **Financial burden (57.5%)**
- **Physical harm (15.6%)**
- **Anxiety (45.4%)**
Everyday Banal Decisions – Unstudied

- Troponin ➔ ???
- ECG ➔ ???
- Stress test ➔ ???
- Echo ➔ ???

https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2752986
A 95-year-old man who lives independently presents to the hospital with shortness of breath due to AF and HFpEF.

He has not seen a doctor in 5 decades.

Q: Why did he live to 95 years?
“The pursuit for health is a symptom of unhealth.”

Petr Skrabanek, The Death of Humane Medicine, 1994
The Moral Core of Medicine

The relief of suffering

I don’t see digital medicine, big data or biometric sensors relieving the subjective experience of fear and distress.

Heath BMJ 2017
Thank You

- John.Mandrola@gmail.com

- Twitter -- @drjohnm
1. Clinical iatrogenesis
   Direct Harm done by us

2. Social iatrogenesis
   1. Medicalization of life

3. Cultural iatrogenesis
   (Insidious)

https://www.rcpe.ac.uk/sites/default/files/jrcpe_46_2_omahony_0.pdf
George Bernard Shaw --

- Shaw compared doctors to tradesmen and shopkeepers, with a pecuniary interest in people being ill.

- Shaw’s health philosophy
  - Do not try to live forever, you will not succeed
  - Use your health, even to the point of wearing it out. That is what it is for
  - Spend all you have before you die and do not outlive yourself
  - Take utmost care to get born well, and well brought up.
What is medicine for?

- Keep the entire adult population under permanent surveillance?
- Does longevity trump all other considerations?
- What if we won the war on Cancer?
Interactions with the Healthcare System
Multiple Chronic Conditions in the United States
by Christine butterf, Teague Ruder, Melissa Bauman
Related Topics: Chronic Diseases and Conditions, Health Care Costs, Health Disparities, United States

N = 100 million adults live with multiple chronic conditions

https://www.rand.org/pubs/tools/TL221.html
• Death rates have not budged in years

• What has risen is the numbers of people living with chronic conditions, dementia, frailty and loneliness
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Related Topics: Chronic Diseases and Conditions, Health Care Costs, Health Disparities, United States

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ADL Limitations

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- N = 33 studies
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Challenge #2 – Do people really stick with Remote Measurements?

Christina Farr (@chrissyfarr)

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1:26 PM · Nov 1, 2019 · Twitter Web App

195 Retweets 951 Likes
• Attacker modified 3d medical imagery using deep learning
• Could inject or remove lung CA from CT scans using free medical imagery from the Internet
• Manipulation easily fooled radiologists and state of the art AI

“Machine learning is very accessible to the public these days; it is almost like plug and play.”

-- PI Yisroel Mirsky
Racial Bias
Dissecting racial bias in an algorithm used to manage the health of populations

Ziad Obermeyer\textsuperscript{1,2,*}, Brian Powers\textsuperscript{3}, Christine Vogeli\textsuperscript{4}, Sendhil Mullainathan\textsuperscript{5,6,†}
+ See all authors and affiliations

Science 25 Oct 2019;
Vol. 366, Issue 6464, pp. 447-453
DOI: 10.1126/science.aax2342
The expanding **digital health landscape** includes products such as:

**Digital Therapeutics**
Digital therapeutics deliver evidence-based therapeutic interventions to patients to prevent, manage, or treat a medical disorder or disease.

*Examples provided on page 6.*

**Mobile Health (mHealth)**
- Wellness, fitness trackers, and nutrition apps
- Consumer health information
- Medication adherence apps

*Examples include:*

**Health Information Technology (HIT)**
- Electronic medical record systems
- Electronic prescribing and order entry
- Consumer health IT applications

**Devices, Sensors, and Wearables**
- Wearable and wireless devices
- Biometric sensors
- Diagnostic products

*Examples include:*

**Personalized Healthcare**
- Patient reported outcomes
- Predictive analytics
- Clinical decision support

**Telehealth**
- Telemedicine virtual visits
- Remote patient monitoring
- Remote care programs

*Examples include:*
Retention of Wearables?
For tech companies, heart disease is the “holy grail of disease management.”

Apple hires another prominent cardiologist as it makes heart health a big ar...
Medicalization -- Can Normal be Saved?
The Luddites, shown here hammering away in a textile mill in 1812, were not the first protesters to smash technology. And many were skilled at using machines. (Tom Morgan / Mary Evans Picture Library)
How one feels about digital/mobile health turns on this question?
His Corrective Pacing or Biventricular Pacing for Cardiac Resynchronization in Heart Failure

Gaurav A. Upadhyay, Pugazhendhi Vijayaraman, Hemal M. Nayak, Nishant Verma, Gopi Dandamudi, Parikshit S. Sharma, Moeen Saleem, John Mandrola, Davide Genovese, Roderick Tung and on behalf of the His-SYNC Investigators

On-treatment comparison between corrective His bundle pacing and biventricular pacing for cardiac resynchronization: A secondary analysis of His-SYNC

Gaurav A. Upadhyay, MD, FHRSGlobal, Pugazhendhi Vijayaraman, MD, FHRSGlobal†, Hemal M. Nayak, MD, FHRSGlobal*, Nishant Verma, MD, MPH†, Gopi Dandamudi, MD, FHRSGlobal‡, Parikshit S. Sharma, MD, FHRSGlobal‡, Moeen Saleem, MD†, David Genovese, MD*, Jess W. Oren, MD‡, Faiz A. Subzposh, MD†, Zaid Aziz, MD†, Andrew Beaser, MD†, Dalise Shatz, BA*, Stephanie Besser, MSAS*, Roberto M. Lang, MD*, Richard G. Trohman, MD, FHRSGlobal‡, Bradley P. Knight, MD, FHRSGlobal†, Roderick Tung, MD, FHRSGlobal‡ on behalf of the His-SYNC Investigators