



AT THE FOREFRONT

**UChicagoMedicine**

Comprehensive Cancer Center



A Cancer Center Designated by the  
National Cancer Institute

# Genomic Testing is Harmful to Individuals and Society

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Center for Clinical Cancer Genetics & Global Health  
The University of Chicago

# Disclosures

- Co-Founder: CancerIQ
- Consultant or Advisory role: Tempus
- Research Collaboration: Myriad, Color, Novartis, Roche, Abbvie
- Advocacy Board: Susan G Komen, V Foundation

I will not discuss of label use of any drugs

# In Chicago....All Politics is Local!



Stephen at his Elite Medical School



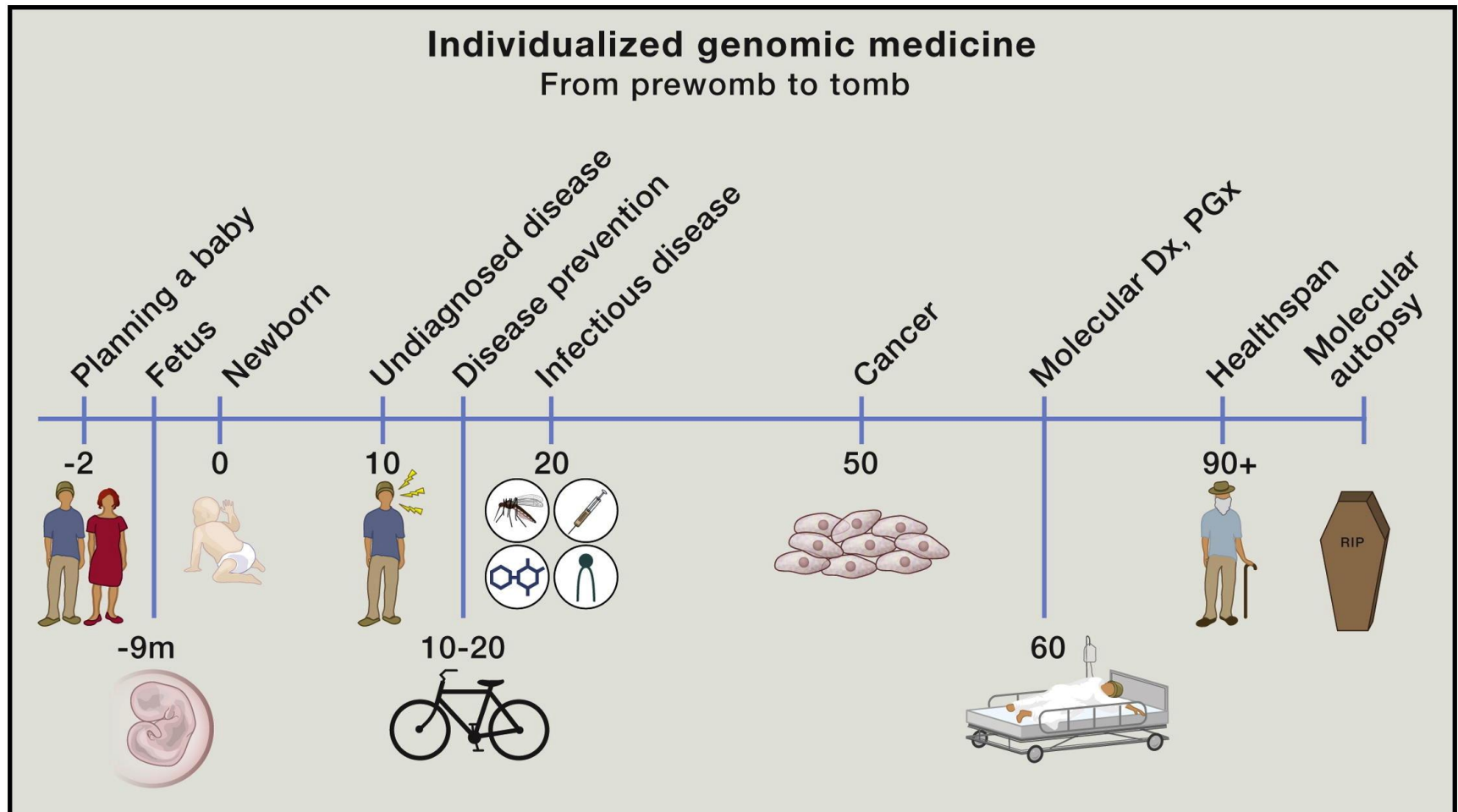
Funmi raising expectations on the Southside  
In her Sunday Best – Obamas totally chill!



President Barack Obama with liver cancer patient Elana Simon at precision medicine event at White House.  
AMERICAN SOCIETY FOR BIOCHEMISTRY AND MOLECULAR BIOLOGY

## Obama gives East Room rollout to Precision Medicine Initiative

# Timeline of DNA Sequencing Applications in Medicine





# Sickle Cell Patients Suffer Discrimination, Poor Care — And Shorter Lives



NeDina Brocks-Capla stands in her living room in San Francisco. She made a shrine filled with memories of son Kareem Jones, who died of sickle cell disease in 2013. (Jenny Gold/KHN)



# The Ethical Principles

- Autonomy
  - Informed consent
- Beneficence
  - Benefit must outweigh risks
- Non-maleficence
  - Do no harm
- Justice
  - Fair distribution of risks

# Winner takes all mentality!

## Breast Cancer

[sciencemag.org/special/breastcancer](http://sciencemag.org/special/breastcancer)

PERSPECTIVE

## "The Race" to Clone *BRCA1*

Mary-Claire King

*Science* **343** (6178), 1462-1465.  
DOI: 10.1126/science.1251900



Henry Lynch commiserating with "Losers"



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# Arc of Justice

- Association for Molecular Pathology vs. Myriad
  - A naturally occurring DNA segment is not patent eligible
  - cDNA which is not naturally occurring is patent eligible

# Implications of Supreme Court Ruling

- Elimination of monopoly on Genetic testing
- Potential reduction in price of genetic testing
  - Rapid expansion of genetic testing for other diseases
  - Expanded panel and discovery of more incidental mutations of unknown significance and with no established standards
- Race for manipulation of DNA and boon for biotechnology companies to expand genetics research
- Strain on limited financial resources for unnecessary testing
- Increase in demand for genetic counseling

# My Medical Choice: Angelina Jolie

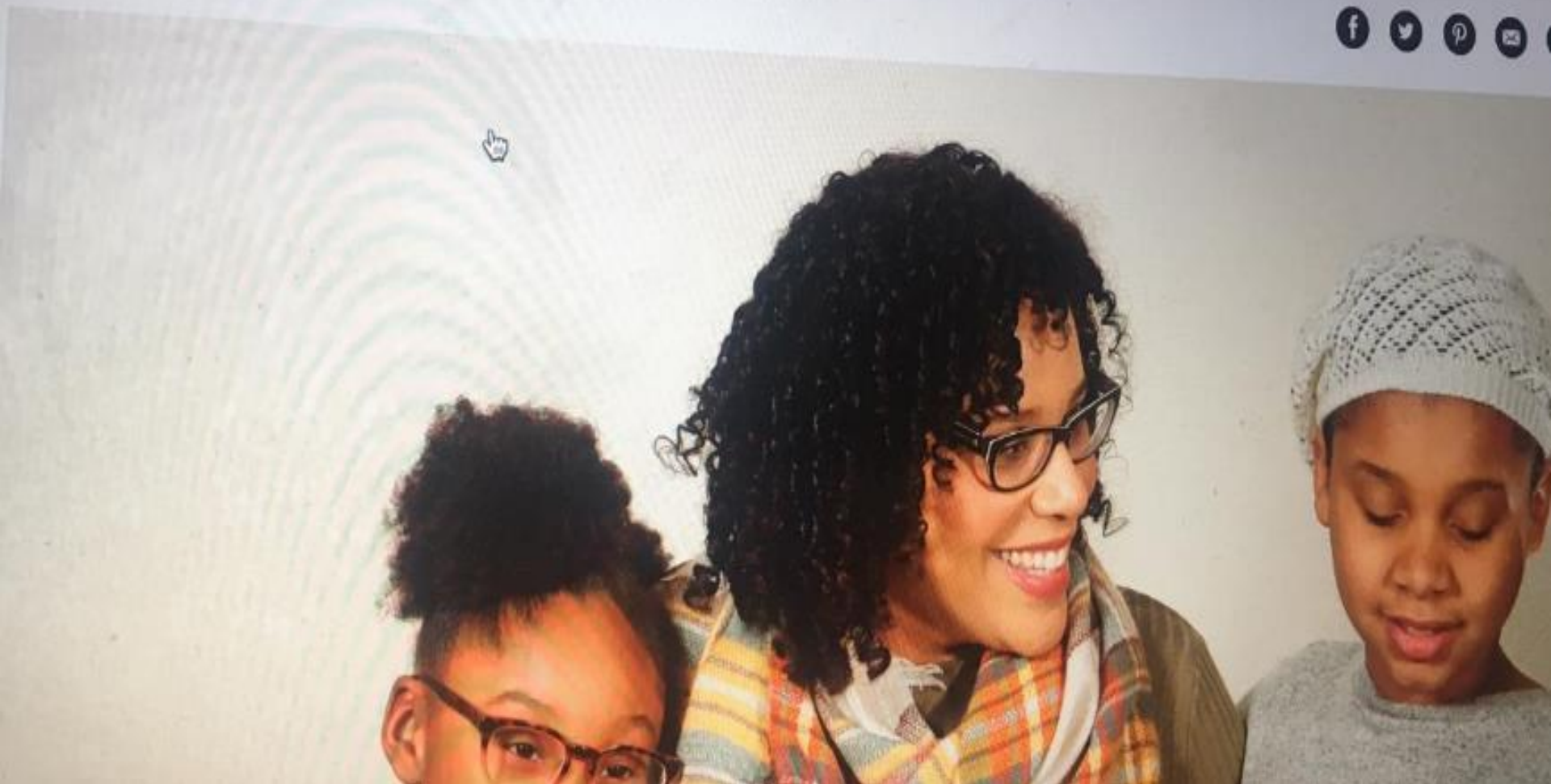
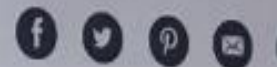
- Her Mother died at age 56 from Ovarian Cancer
- Tested for BRCA1 and BRCA2 mutations at cost of \$3,000 to \$4,000 from Myriad Genetics
- Underwent genetic counseling
- Had double Mastectomy to reduce risk of developing breast cancer
- Underwent breast reconstruction



The NYT May 14, 2013

# After Mastectomies, an Unexpected Blow: Numb New Breasts

By RONI CARYN RABIN JAN. 29, 2017



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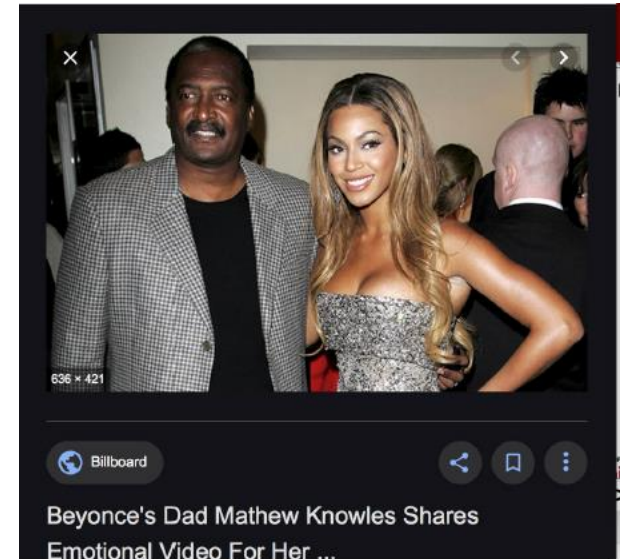
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# Now Beyonce's Father!

- Any laboratory can now test *BRCA1/2*, along with a variety of other cancer-predisposing genes
- Direct to Consumer Marketing expanding demand for **high quality genomic services** focused on the personal needs of healthy individuals



# The Incidentalome

## A Threat to Genomic Medicine

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Isaac S. Kohane, MD, PhD

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Daniel R. Masys, MD

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Russ B. Altman, MD, PhD

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**G**ENOMIC MEDICINE IS POISED TO OFFER A BROAD ARRAY of new genome-scale screening tests. However, these tests may lead to a phenomenon in which multiple abnormal genomic findings are discovered, analogous to the “incidentalomas” that are often discovered in radiological studies. If practitioners pursue these unexpected genomic findings without thought,

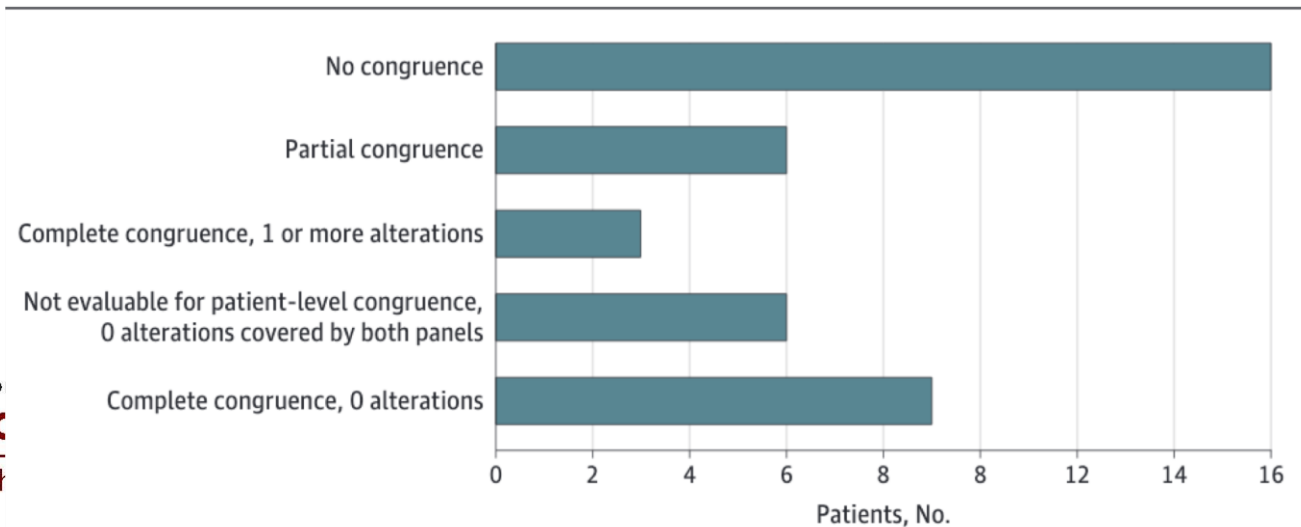
There is a rich literature in radiology on the “incidentaloma,” which is a finding (most commonly a mass) found on computed tomography or magnetic resonance imaging studies ordered for symptoms or concerns totally unrelated to the gland in which the mass is found. The workup of an incidentaloma is complicated by concerns that it may be associated with malignant disease and, at least initially, the lack of good data on the prevalence of malignant disease in the general population. Incidentalomas occur because imaging modes do not only report on the areas of direct clinical concern but, incidentally, report on all organs in the field of view.<sup>1</sup>

**212** JAMA, July 12, 2006—Vol 296, No. 2

**Torga, Gonzalo, and Kenneth J. Pienta. 2018. “Patient-Paired Sample Congruence Between 2 Commercial Liquid Biopsy Tests.” *JAMA Oncology* 4 (6): 868–70.**

40 patients

Guardant360 (Guardant Health, Inc) panel includes 73 genes with complete exon sequencing for 19 cancer genes, PlasmaSELECT (Personal Genome Diagnostics, Inc) consists of a 64-gene panel



Age	Ethnicity	Report Year	Originally Reported Status	Current Status	Indication for Test
46	Unavailable	2005	P		B Clinical Diagnosis of HCM
75	Unavailable	2005	P		B Family History and Clinical Symptoms of HCM
32	Black or African American	2005	P		B Clinical Diagnosis of HCM
34	Black or African American	2005	U		B Clinical Diagnosis and Family History of HCM

Pro82Ser

12	Black or African American	2006
40	Black or African American	2007
45	Black or African American	2007
16	Asian	2008
59	Black or African American	2006
15	Black or African American	2007
16	Black or African American	2007

The NEW ENGLAND JOURNAL of MEDICINE

#### SPECIAL ARTICLE

## Genetic Misdiagnoses and the Potential for Health Disparities

Arjun K. Manrai, Ph.D., Birgit H. Funke, Ph.D., Heidi L. Rehm, Ph.D.,  
Morten S. Olesen, Ph.D., Bradley A. Maron, M.D., Peter Szolovits, Ph.D.,  
David M. Margulies, M.D., Joseph Loscalzo, M.D., Ph.D.,  
and Isaac S. Kohane, M.D., Ph.D.

Gly278Glu



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22	Black or African American	2007	P	B	Clinical Diagnosis and Family History of HCM
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48	Black or African American	2008	U	B	Clinical Diagnosis of
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Fake News Has Its Day in Court

# Newsweek

SPECIAL  
CANCER  
ISSUE:

07.27.08.03.2018

## BLACK GENES MATTER

So why are scientists  
ignoring **African DNA** in  
the search for cures?



THE  
DANGER of  
CELL  
PHONES

NEW  
TRICKS for  
OLD  
DRUGS

SPACE-GROWN  
TREATMENTS

DOES  
EVERYTHING  
CAUSE  
CANCER?



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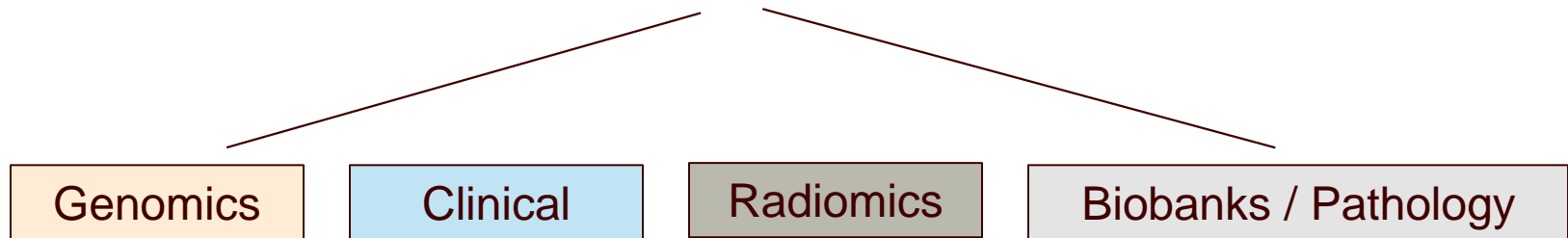
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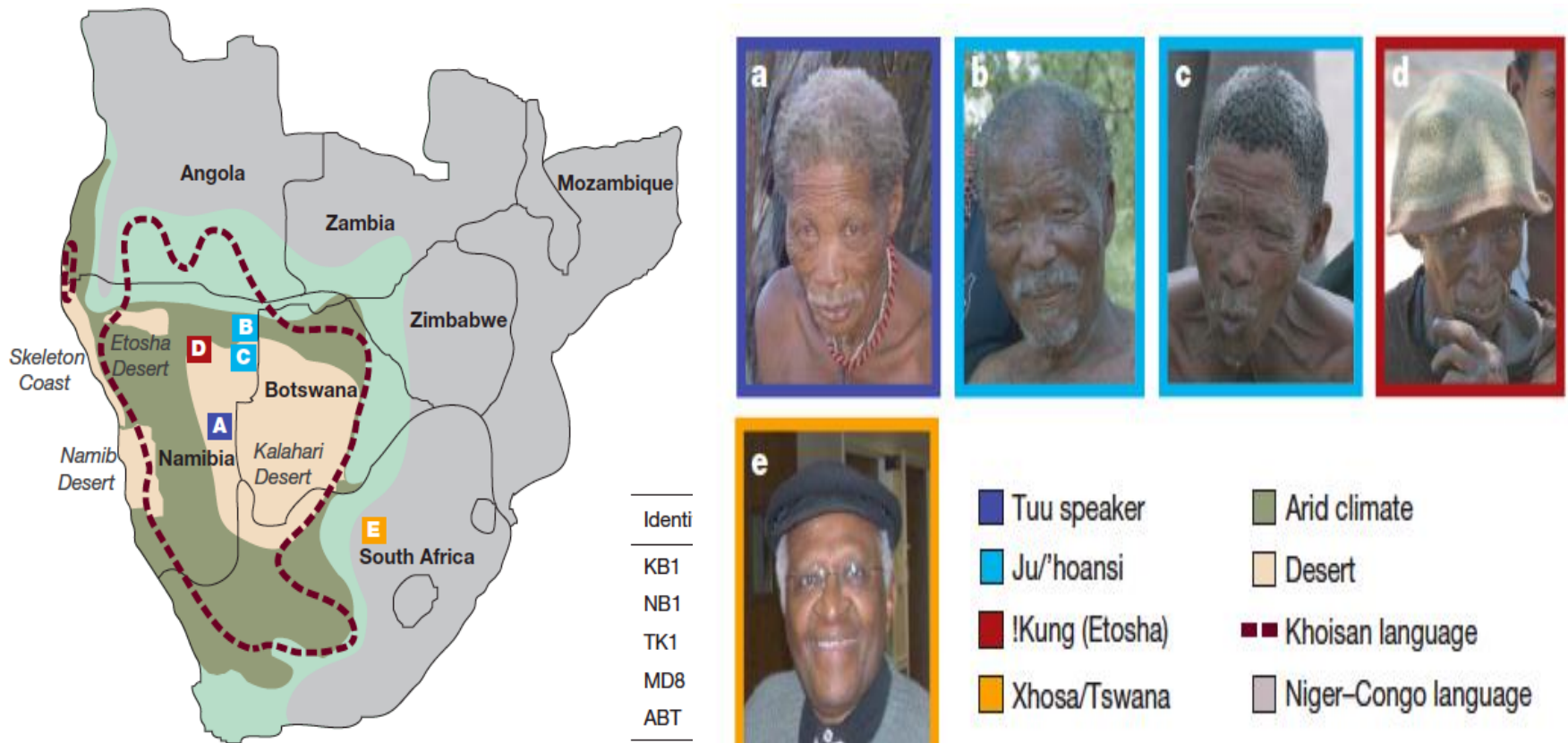
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Newsweek July 18, 2018

# The Ideal Model of Big Data Precision Medicine



# Oldest known lineage of modern human genome sequenced



# The community fought back

- Allege exploitation of vulnerable people
- Request for evidence of documentation of informed consent
- Object to use of insulting and derogatory language in publication
  - Bushmen (uncivilized people)
  - Hunter-gatherer (low social class)
- Lack of sensitivity to the needs of the participants
- Against conclusions made beyond genomic data
- Request retraction of manuscript from Nature



# One patient, one physician, one jurisdiction model

“The ethical approach to experimentation in man has several components; two are more important than the others, the first being informed consent...”

“Secondly, there is the more reliable safeguard provided by the presence of an intelligent, informed, conscientious, compassionate, **responsible investigator**.”

Beecher HK. *NEJM* (1966) 274(24):1354-1360.

# The Worst Offender

James Watson Had a Chance to  
Salvage His Reputation on Race.  
He Made Things Worse.

The Nobel-winning biologist has drawn global criticism with unfounded pronouncements on genetics, race and intelligence. He still thinks he's right, a new documentary finds.



"Decoding Watson," a new film about Dr. James D. Watson, explores the gulf between his scientific brilliance and his views on race. Mark Mannucci/Room 608 Inc.



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# Op-Ed: My childhood memories of the Holocaust in a world of COVID-19



The Hall of Names at the Yad Vashem Holocaust museum in Jerusalem, which commemorates the 6 million Jews killed by Nazis during World War II. (Uriel Sinai / Getty Images)



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# COVID Pandemic is about Test, Test, Test – It's a Virus Stupid!



f t SHARE

President Donald Trump's failure to respond to the **coronavirus pandemic** didn't begin with the administration's **inability to send out the millions of test kits** and the **protective medical gear for health care workers** that experts say are needed to tackle the crisis. It didn't start with Trump's **bungled messaging** downplaying the crisis even as it's worsened, nor with his mid-March **insistence** that social distancing measures could be lifted by Easter (he later **backpedaled**).

MASA -Make America Smart Again



(Photo by JOSH EDELSON/AFP/Getty Images) AFP/GETTY IMAGES

## Medicare for All!



# Summary

- Uncertainty of risk models – time changes
- Most common diseases are NOT genetic
- Family history is grossly underused
- First rule of clinical care is “*do no harm*”
- *Genetic reductionism is useful distraction from what really ails us.*
- Need to promote Diversity, Inclusion & Equity

# I rest my case!

# Example: The Promise and Problem of Precision medicine

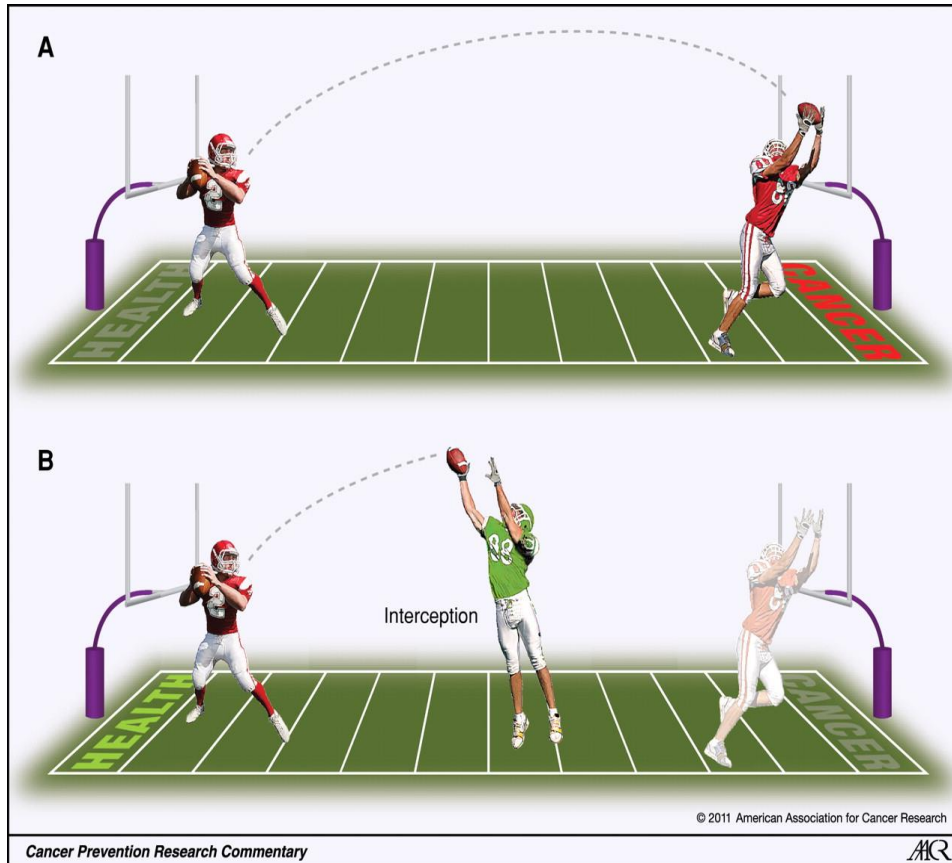
38yo man  
metastatic melanoma  
Rapid progression  
Failed multiple  
treatments

Sequencing of tumor ⇒  
BRAF<sup>V600E</sup>

Targeted  
therapy  
against BRAF  
(vemurafenib)



# Who needs Genetics when you can play football - Cancer Interception.



© The Nobel Foundation. Photo:  
U. Montan

Elizabeth H. Blackburn Cancer Prev Res 2011;4:787-792

# It's all about the Family ---Thank you



## Olopades summit Mount Kilimanjaro