

A Statistical Leadership Journey

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COLLEGE OF SCIENCE
VIRGINIA TECH.

BASS XXVI

26TH ANNUAL BIOPHARMACEUTICAL APPLIED STATISTICS SYMPOSIUM

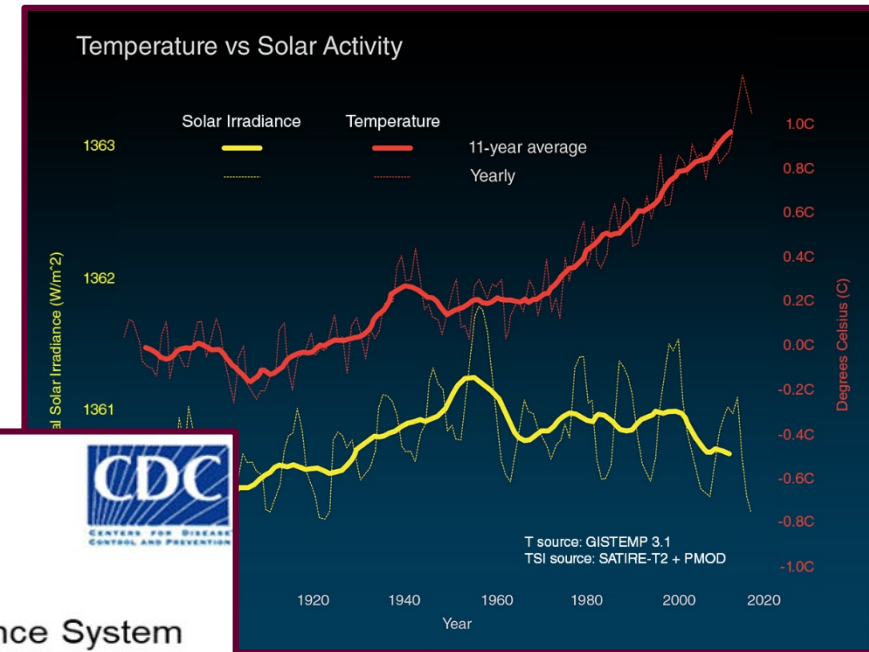
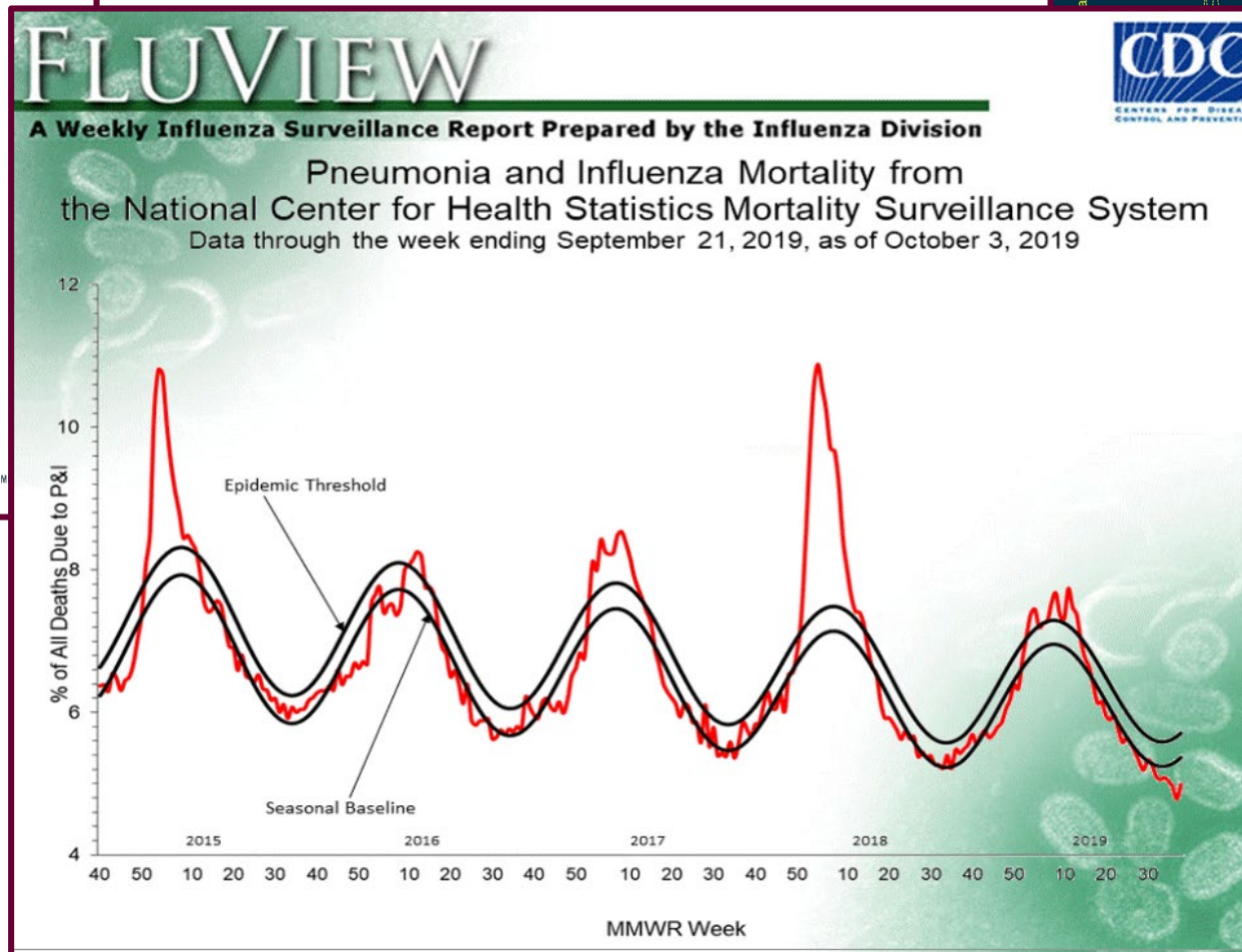
Why You Matter

3x

ACCESS TO A GUN
INCREASES THE RISK OF DEATH
BY SUICIDE BY THREE TIMES.



SOURCE: ANGLEMYER A, ET AL. THE ACCESSIBILITY OF FIREARMS AND RISK FOR SUICIDE AND HOMICIDE VICTIMIZATION AMONG HOUSEHOLD MEMBERS: A SYSTEMATIC REVIEW AND META-ANALYSIS. ANN INTERN MED. 2014.



Statistics Is On the Front Page

The Des Moines Register

USDA's plans threaten the integrity and viability of data that farmers need

Katherine Wallman, Guest columnist

Published 1:37 p.m. CT July 3, 2019 | Updated 4:45 p.m. CT July 3, 2019

“Policies built on objective data and credible analyses serve all of us by eliminating political whims from the equation... Government statistics level the playing field by giving everyone — Republican and Democrat, family farmer and agribusiness — the same set of facts.”

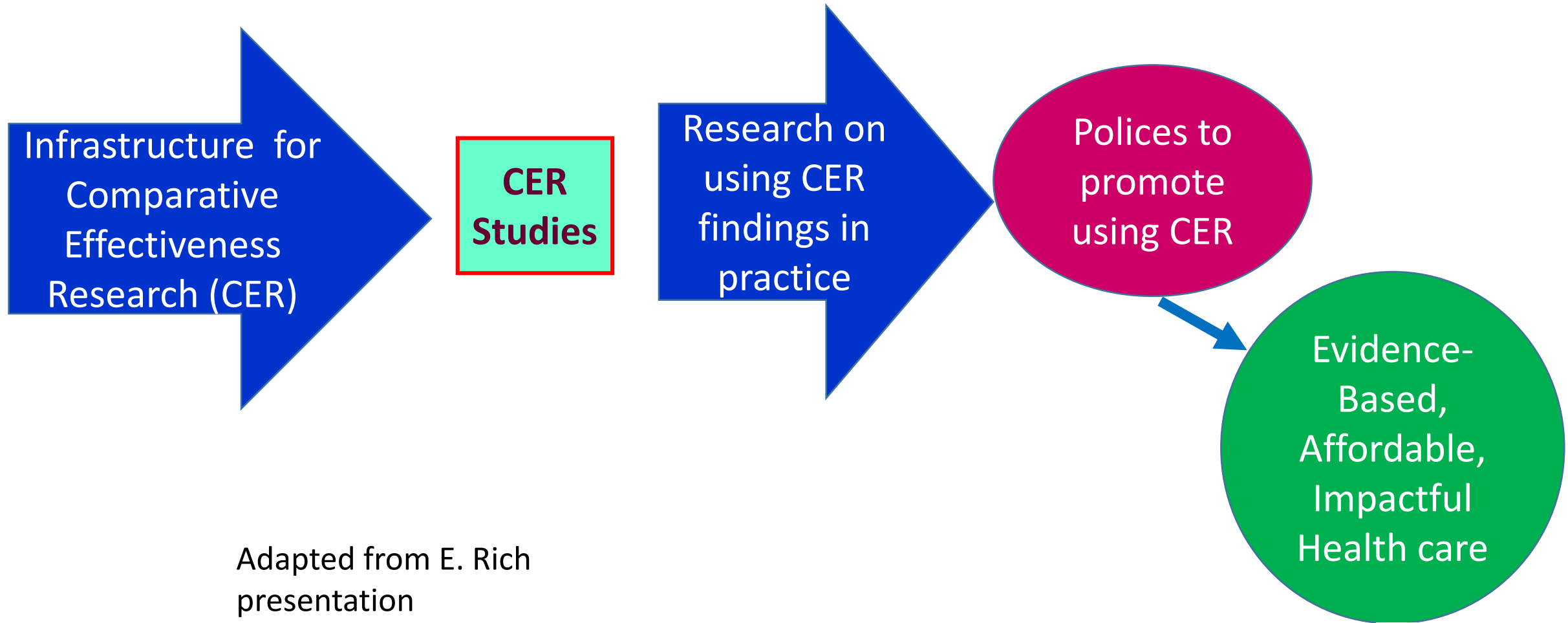
Christopher Coons
Senator, D-CT
Editorial: *Scientists can't be silent*
Science, August 4, 2017



*“Scientists must...reach out
to elected officials to explain
why science matters.”*

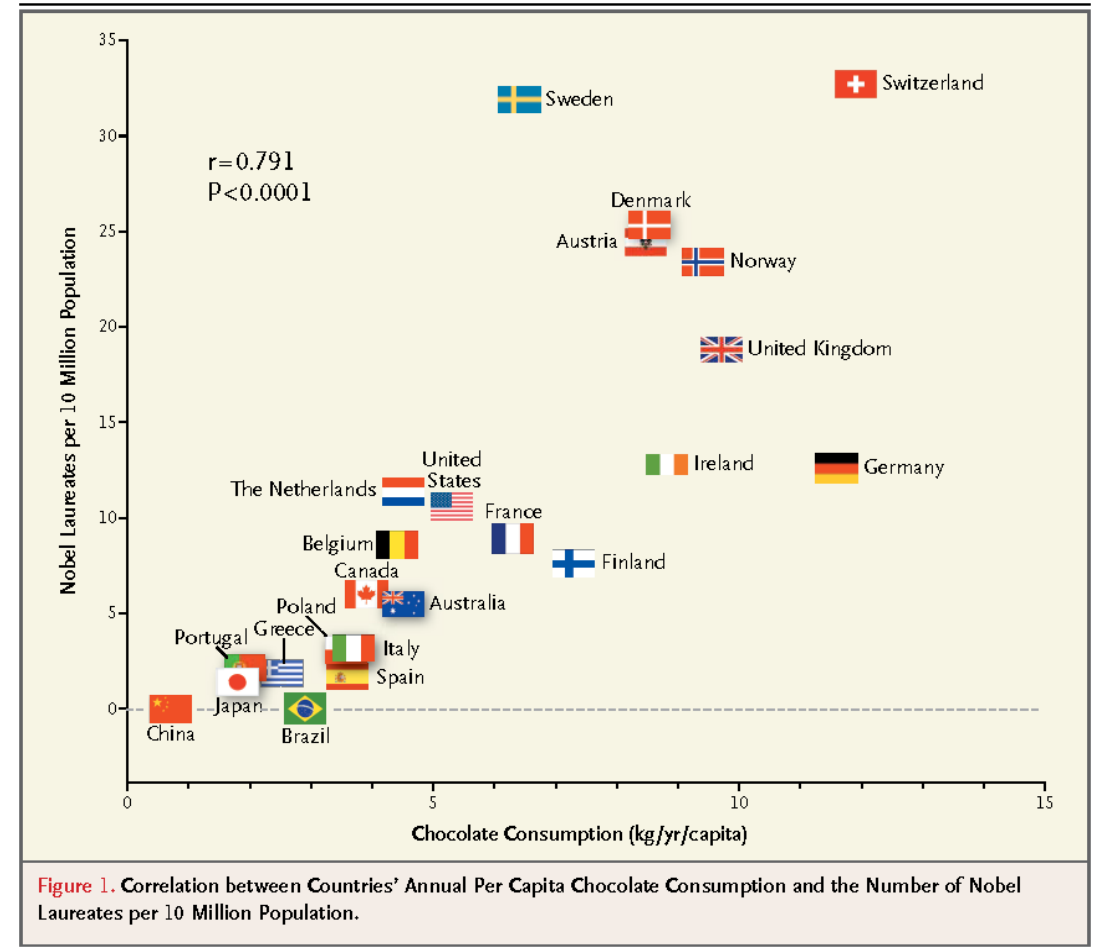
“...don't just publish your
research – publicize it.
Scientists simply can't be silent,
or else science truly will be
silenced.”

If You Want to Have an Impact, Consider the BIG Picture



What You Say and How You Say It Matters

Correlation is not causation ... and sample size never trumps design



Messerli, *NEJM*, 2012

Statistics at a Crossroads: Who is for the Challenge?

“The field of Statistics is at a crossroads: we either flourish by embracing and leading Data Science or we decline and become irrelevant. In the long run, to thrive, we must redefine, broaden, and transform the field of Statistics. ... by reimagining our educational programs, rethinking faculty hiring and promotion, and accelerating the cultural change that is required.”

NSF Workshop, October 2018, Xuming He

Statistics at a Crossroads: Major Findings

The goals of the workshop include

1. Identifying **emerging research topics** that will require new statistical foundations, methodology, and computational thinking;
2. Engaging with important data-driven challenges in different application domain and fostering interdisciplinary collaborations to address important scientific challenges;
3. Creating a vibrant research community, maintaining an appropriate balance between different sub-fields of Statistics including investments in the foundations;

- The central role of practice
- Emphasis on impact
- Research for better practice
- Embracing grand challenges
- Broader metrics of methodology evaluation
- Training in modern skills

A Nonlinear Career

Head, RAND Statistics Group

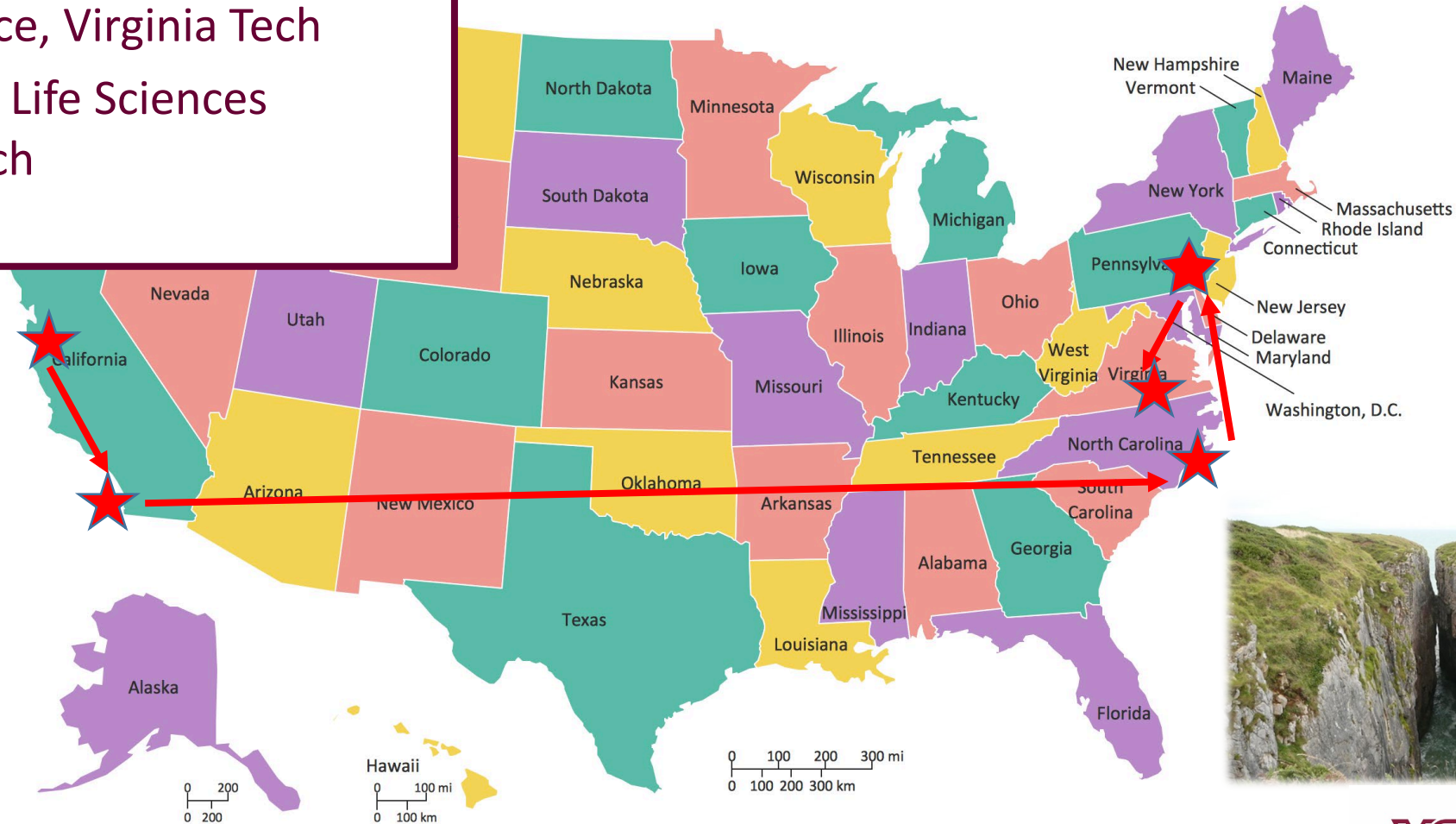
VP, Statistics and Epidemiology, RTI

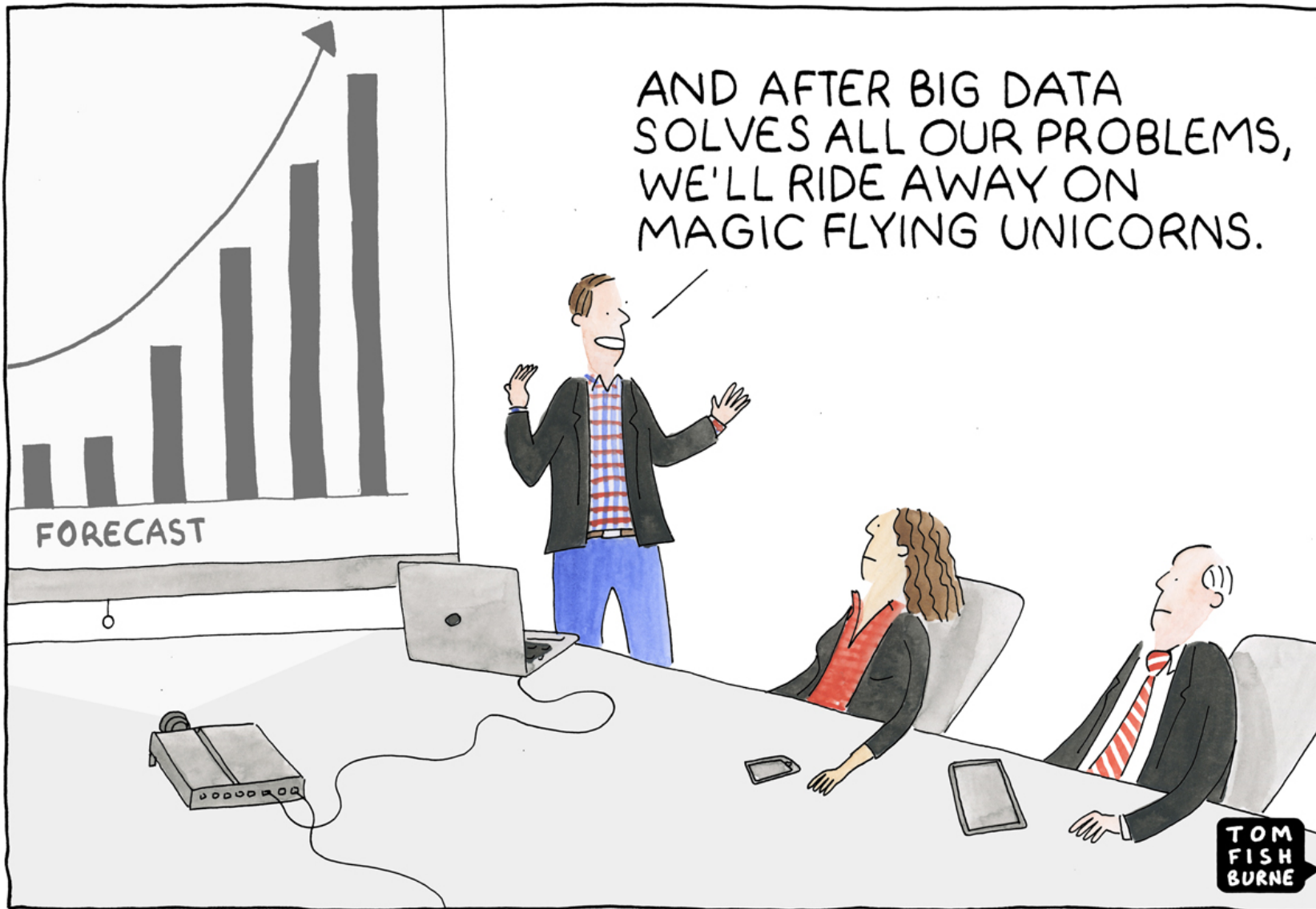
Chair, Biostatistics, University of Pittsburgh

Dean, College of Science, Virginia Tech

Interim Director, Fralin Life Sciences
Institute, Virginia Tech

2009 ASA President





AND AFTER BIG DATA
SOLVES ALL OUR PROBLEMS,
WE'LL RIDE AWAY ON
MAGIC FLYING UNICORNS.

FORECAST

TOM
FISH
BURNE

© marketoonist.com

BIG DATA

The Parable of Google Flu: Traps in Big Data Analysis

David Lazer,^{1,2*} Ryan Kennedy,^{1,3,4} Gary King,³ Alessandro Vespignani^{5,6,3}

Large errors in flu prediction were largely avoidable, which offers lessons for the use of big data.

“Instead of focusing on a “big data revolution,” perhaps it is time we were focused on an “all data revolution,” where we recognize that the critical change in the world has been innovative analytics, using data from all traditional and new sources, and providing a deeper, clearer understanding of our world.”


Statisticians Need to Do “BIG Statistics”

- Get involved early in the process
- Collaborate with scientists
- Communicate with policy-makers
- Acknowledge the politics
- Be a leader and purposefully put yourself at the center of issues, and create value by acting on data and statistical reasoning



Leadership in Statistics: Increasing Our Value and Visibility



Eric W. Gibson 

Biostatistical Sciences and Pharmacometrics, Novartis Pharmaceuticals, One Health Plaza, East Hanover, NJ

ABSTRACT

Scientists in every discipline are generating data more rapidly than ever before, resulting in an increasing need for statistical skills at a time when there is decreasing visibility for the field of statistics. Resolving this paradox requires stronger statistical leadership to guide multidisciplinary teams in the design and planning of scientific research and making decisions based on data. It requires more effective communication to nonstatisticians of the value of statistics in using data to answer questions, predict outcomes, and support decision-making in the face of uncertainty. It also requires a greater appreciation of the unique capabilities of alternative quantitative disciplines such as machine learning, data science, pharmacometrics, and bioinformatics which represent an opportunity for statisticians to achieve greater impact through collaborative partnership. Examples taken from pharmaceutical drug development are used to illustrate the concept of statistical leadership in a collaborative multidisciplinary team environment.

To be world leaders in
transdisciplinary science,
grounded in fundamental disciplines,
fueled by data, focused on discovery,
and directed at decisions.

Science is inherently *Ut Prosim*.

Ephedra: Efficacy and Side Effects



- Baltimore Orioles pitcher Steve Bechler dies on February 17, 2003; ephedra is implicated
- "This was certainly a preventable death; it didn't have to occur, this kind of tragedy," said Broward County's chief medical examiner (CBS News)
- Public Citizen asks Health and Human Services Secretary to ban ephedra



Examine safety using adverse event data from:

- Clinical trials
 - Good internal validity; limited generalizability
 - Limited power
- Case reports, FDA MedWatch and Metabolife databases
 - Observational datasets
 - Poor data quality

Kile's Death Stuns Baseball

Cardinals: St. Louis pitcher, 33, is found in his Chicago hotel room and appears to have died of natural causes. Game against Cubs is canceled.

By ROSS NEWHAN
TIMES STAFF WRITER

Darryl Kile, one of the St. Louis Cardinals' top pitchers and one of the best in baseball, was found dead in his Chicago hotel room Saturday. Police said there were no signs of criminal involvement and that Kile, 33, appeared to have died of natural causes.

"It appears he died in his bed, in his sleep," said Michael Chasen, commanding officer of Chicago's Area Three Homicide unit, adding that medical examiners will conduct an autopsy today.

The shocking development prompted cancellation of Saturday's game between the Cardinals

and Chicago Cubs at Wrigley Field, where Joe Girardi, the Cubs' catcher and player representative, addressed the crowd of about 40,000—unaware at that point of Kile's death—from behind a microphone at home plate and said the game would not be played because of a "tragedy in the Cardinals family" and asked fans to say a prayer for the Cardinal organization and its players.

"Our club is just totally staggered, I mean, devastated," St. Louis Manager Tony La Russa told reporters, wiping away tears. "You guys know what a pro [Darryl] is."

A product of Norco High and Chaffey College who was only a 30th-round draft choice of the

RELATED STORY

JC standout: Kile, deemed too thin for a Division I scholarship, made a move at Chaffey College. **D9**

Houston Astros in 1987, Kile blossomed into a top-of-the-rotation starter with a devastating curveball. He had a 133-119 record in 12 seasons with the Astros, Colorado Rockies and Cardinals, pitching a no-hitter against the New York Mets in 1993 and winning 20 games for the Cardinals in 2000 before going 16-11 last year.

He had pitched the Cardinals into first place in the National League Central with a victory over the Angels on Tuesday night, won three of his last four starts in improving to 5-4 with a 3.72 earned-run average in 14 games and was

Please see **KILE, D9**

Event Classification Criteria

- Documentation of the event
- Documentation that ephedra or ephedrine was consumed within the prior 24 hours (by report or toxicology examination)

Sentinel Event

- Documentation that other potential causes of the adverse event were evaluated and excluded

Possible Sentinel Event

- Other potential causes exist or were not effectively excluded

FDA MedWatch Case Report: Sentinel Event Description

A 22-year-old female collapsed and died... She had a history of asthma that was ... “well-controlled.” She had congenital hydrocephalus with a shunt placed. She was taking Slacker II. Ephedrine was found in the blood. The autopsy report stated that the coronary arteries were free of atherosclerosis... There was no other cause of death. The death certificate listed “cardiac arrhythmia due to ephedrine-containing diet medication.”

FDA MedWatch Case Report: Possible Sentinel Event Description

A 38-year old male collapsed and died after jogging. Prior to jogging, he had had a cup of coffee and Ripped Fuel supplements. At autopsy, he was found to have triple vessel coronary artery disease and mild cardiomegaly...

Metabolife Case Report: Insufficient Information to Assess

HEALTH INFORMATION CALL DOCUMENTATION

Date: 1/19
Name: _____ Age: _____ Sex: _____
Meds: TRANSFERRED TO DAN? 2 MONTHS - OCT. 99 - HER HUSBAND TOOK MET. EVER SINCE THEN HE HAS SUFFERING FROM SEIZURES. NEUROLOGIST SAYS IT MIGHT BE MET. - WK.
Current Dose: _____ Suggested Dose: _____
Race: _____
1/19 2/19

CONFIDENTIAL
CONFIDENTIAL & NON RESPONSIVE REDACTION

MIPER024711

Event	# of events	% insufficient information	# sentinel events	# possible sentinel events
Death	84	80%	5	12
Heart attack	26	58%	5	7
Stroke	56	59%	11	12
Other cardiac	30	90%	0	3
Other neurologic	8	88%	0	1
Seizure	40	73%	4	7

Whose Standards of Evidence?

Herbal supplements, unlike drugs, are

- *Assumed* to be safe, but are not required to be *proven safe*
- Scientific standard used to overturn this assumption of safety is to demonstrate significant or unreasonable risk, not *prove* that an ingredient is unsafe

**DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994
PUBLIC LAW 103-417
103RD CONGRESS**



**U.S. FOOD & DRUG
ADMINISTRATION**

FDA published a final rule prohibiting the sale of dietary supplements containing ephedrine alkaloids:

“Risks are unacceptable in light of any benefits that may result from the use of these products”

Exam Points to Kile's Heart

Baseball: Preliminary autopsy findings reveal “80-to-90% narrowing” of two coronary arteries probably led to death.

By LANCE PUGMIRE
TIMES STAFF WRITER

Communicating With Policymakers (and the Press)

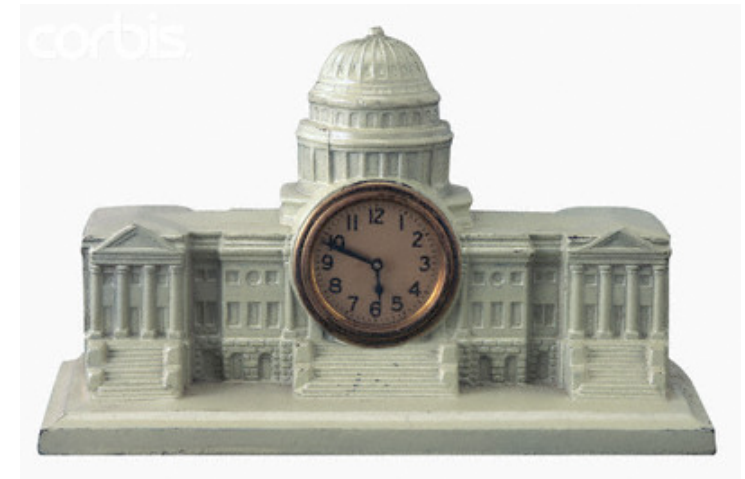
- Focus on a small number of conclusions and support with strong analyses
- Anticipate
 - Who will focus on which conclusions
 - “Spins” by different audiences
- When you speak to journalists, politicians are listening
- *Illustrate* the science

Morton, *Statistical Science*, 2005

The Right Clock Speed

- Statistician and policy-maker clock speeds differ
- Relevancy requires policy clock speed

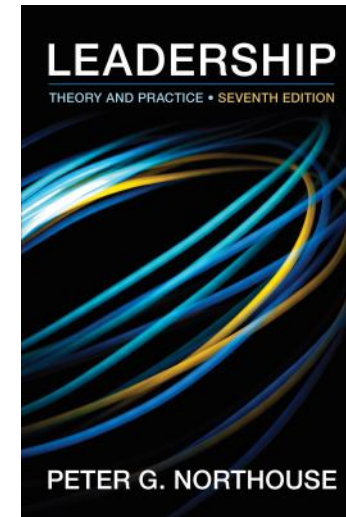
William Thornton



“It’s not what we said, it’s not what they heard,
it’s what they say they heard.”

Barry Nussbaum

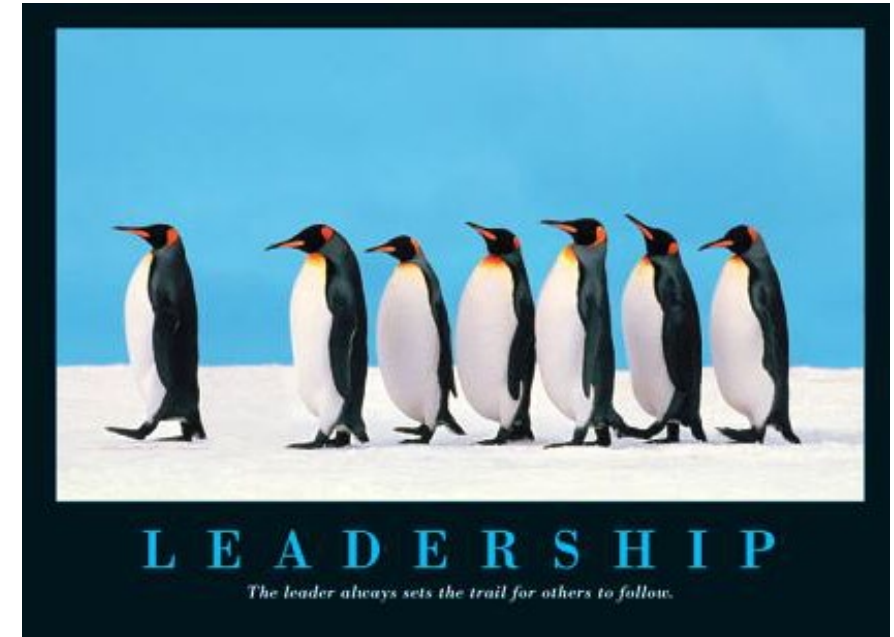
You Don't Have to Be a Dean To be Leader



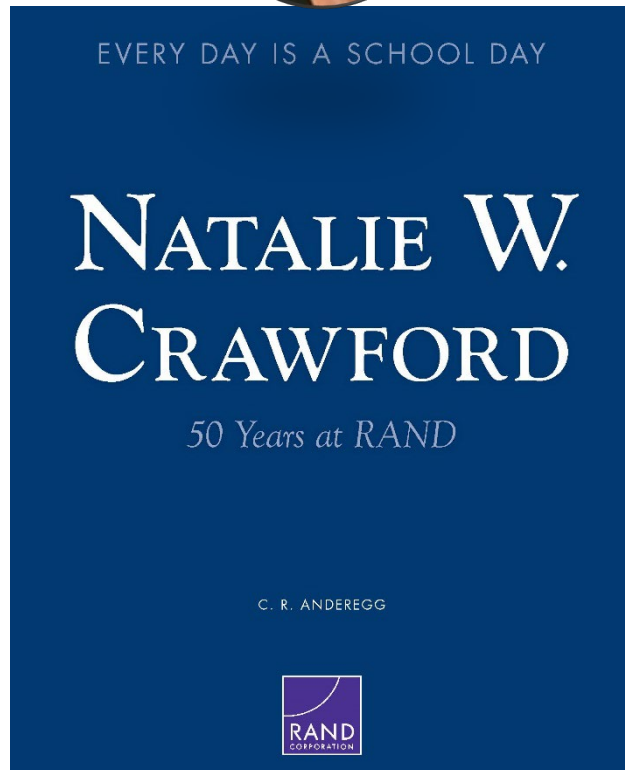
- *Assigned* leadership is based on occupying a position in an organization
- *Emergent* leadership is acquired through other people in the organization who support and accept that individual's behavior... it is not assigned by position; rather it emerges over a period through *communication*

What is Leadership

- The ability to consistently deliver value to an organization or cause by inspiring people to take a specific direction or action when they truly have the freedom or choice to do otherwise.
- Statistical leaders purposefully put themselves at the center of issues that are critical to their organizations. Using their knowledge of the organization, they motivate others to initiate change, develop solutions, and create value by acting on data and statistical reasoning.



Natalie Crawford's Leadership Advice



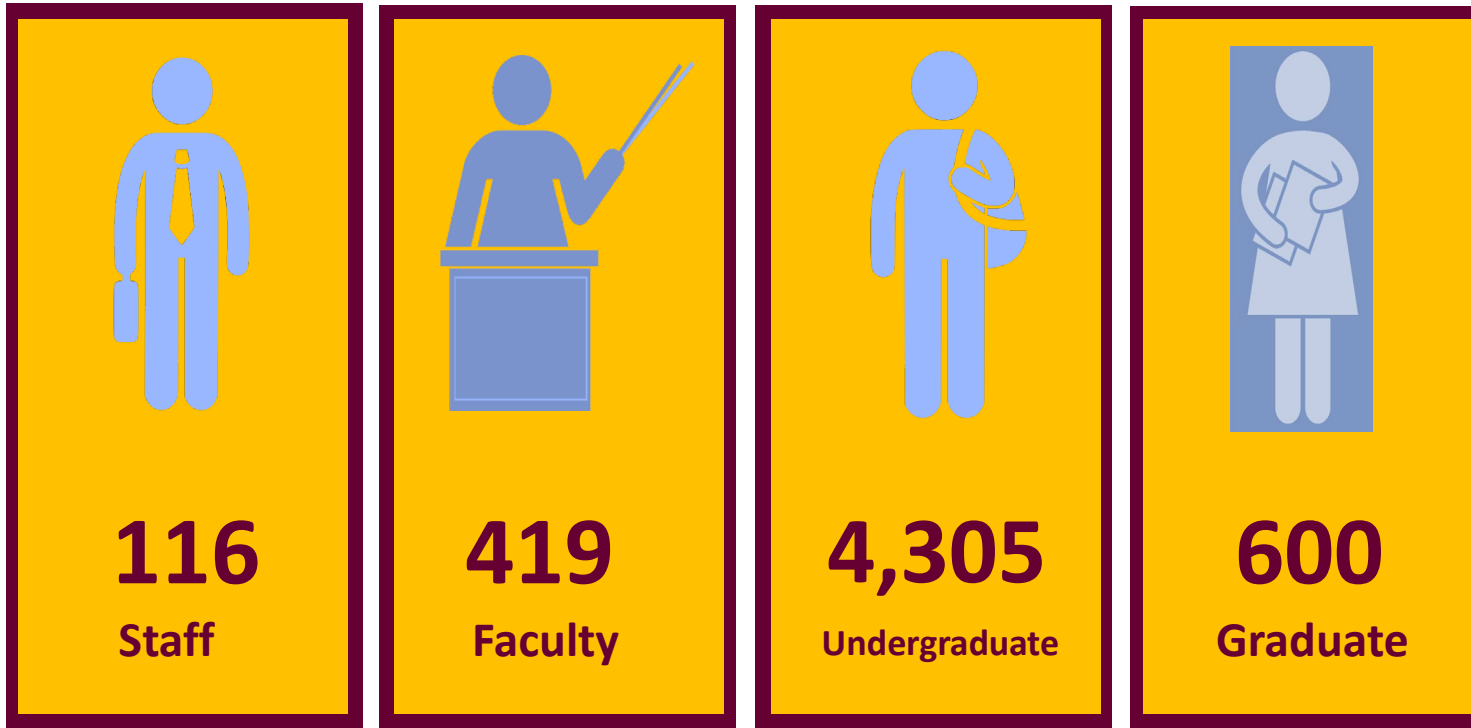
- Always think one level above where you are – what serves Virginia Tech, not what serves the College of Science
- Follow the money – know where it is at all times, understand what you can spend it on, and how you can get more

How to Find Leadership Opportunities

- Volunteer
- Ask for opportunities
- Get a mentor
- Look outside Statistics
- Show your value
- Be self-aware
- Learn and observe formally and informally

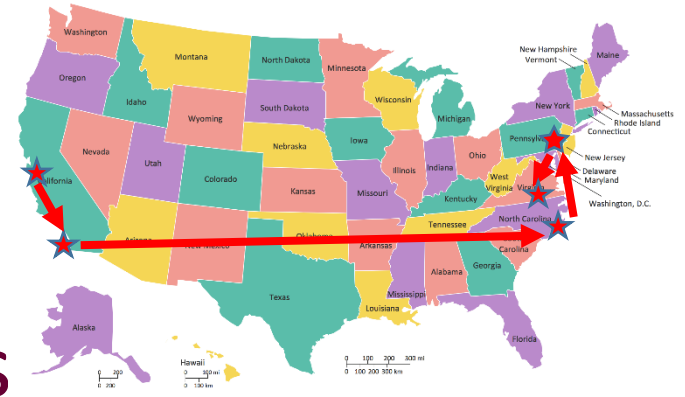


People Are All That Matter



Some Lessons Learned

- Understand the research question
- Thought experiments first
 - What is the optimal *design* and analysis
 - What is the headline
- Understand how and why the data were collected
- Privacy, ethics and your reputation
- Be courageous and ask for help
- Get some shades ... and remember work isn't everything



Why You Matter

We are the music-makers,
And we are the dreamers of dreams;
Wandering by lone sea-breakers,
And sitting by desolate streams;
World-losers and world-forsakers
On whom the pale moon gleams:
Yet we are the movers and shakers
Of the world for ever, it seems.

- O'Shaughnessy

A "Mover and a Shaker" for Women in Statistics
Golbeck, *Significance*, June 2019

Thank You

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