



# Health Watch USA<sup>sm</sup> Newsletter

[www.healthwatchusa.org](http://www.healthwatchusa.org) Mar. 6, 2016

Member of the National Quality Forum and a designated "Community Leader" for Value-Driven Healthcare by the U.S. Dept. of Health and Human Services

## REVIEW ARTICLE

OPEN

### A Perspective on the Principles of Integrity in Infectious Disease Research

Kevin T. Kavanaugh, MD, MS,\* Stephen S. Tomez, MD,† and Daniel M. Sawan, DrPH, MPH‡

**Abstract:** The medical literature is prone to overstating results, a condition not thoroughly recognized among policymakers. This article sets forth examples of potential problems with research integrity in the infectious disease literature. We describe articles that may be spun, categories lumped together in hopes of creating a significant effect (and sometimes an insignificant one), changes in metrics, and how trials may fail because of suboptimal interventions. When examined together, the examples show that the problems are widespread and illustrate the difficulty associated with interpreting medical research. The state of the current medical literature makes it of utmost importance that all sections of the manuscript are read, including associated letters to the editors and information on ClinicalTrials.gov before authors' recommendations are accepted.

**Key Words:** research integrity, spinning, data dredging, REDUCE MRSA, STARBUCK, infectious disease, MRSA, surveillance, chlorhexidine, standard of care, HAIs, bacterial resistance, MDRB  
(J Patient Saf 2016;00: 00-00)

#### PERSPECTIVE

##### Introduction

The United States is on the precipice of a devastating infectious disease epidemic, a position it has not been in for well more than 60 years. Multidrug-resistant bacterial infections are becoming all too common with some bacteria threatening to make existing antibiotics obsolete, setting medicine back almost 100 years. Already concerns are being expressed regarding the impact of antibiotic resistance on surgery and cancer chemotherapy.<sup>1</sup> Governments, agencies, and associations are preparing initiatives to confront and reverse this emerging epidemic. Their main weapon is science and research as reported in the peer-reviewed literature. However, nature evolves and adapts, which confounds medicine's advances. The recent Ebola outbreak highlighted the necessity of developing timely, effective, and systematic standards to avert such catastrophes.<sup>2,3</sup>

The current state of the peer-reviewed literature has questionable reliability, making it difficult for our health care system to formulate and implement a reliable course of action. A recent commentary by Horon,<sup>4</sup> the editor of *The Lancet*, stated, "The

case against science is straight forward: much of the scientific literature, perhaps half, may simply be untrue." Self-policing is often lacking, as stated by the Food and Drug Administration:

"When the FDA finds significant departures from good clinical practice, those findings are seldom reflected in the peer-reviewed literature, even when there is evidence of data fabrication or other forms of research misconduct."<sup>5</sup>

Revel of standards of care is also not uncommon. Pineda et al<sup>6</sup> found that of 363 articles that tested standards of care, 40% supported reversing the standard. Most disturbingly, some of the articles in question were published in top medical journals, with the field of infectious diseases being no exception. In a number of articles that had major impacts on infectious disease policy, there have been significant concerns regarding methodology, data analysis, and interpretations. A closer evaluation of the microorganisms in these studies is needed. The objective of this perspective was to identify several contemporary peer-reviewed publications that have had a high impact on infectious disease policy yet also have concerns regarding the publication's research integrity.

Concerns regarding research integrity can be classified as follows:

##### Spinning Results

Spin is an often misunderstood term. It does not mean "lying" or presenting false information, but instead conveying the information in such a way that one may come to an opposite, incorrect conclusion. This is one of the most common integrity issues found in high-profile articles.

Readers usually first examine the conclusion sections in the abstract and article. They may be the only sections read. Sometimes, however, salient details are contained in the methods section, which would allow readers to realize that the author's conclusions might be overstated. In articles reporting randomized trials, Bostrom et al<sup>7</sup> detected spin in the abstract's results and conclusion sections in 37.5% (27/72) to 58.3% (42/72), respectively. In addition, spin was identified in the results, discussion, and conclusion sections of the main article in 29%, 43%, and 50% of reports, respectively.<sup>7</sup> Similar findings were observed in wound care research by Lockyer et al,<sup>8</sup> who documented spin in 20 of 28 articles with a statistically nonsignificant result for the primary outcome.

An example of spin can also be found in The Randomized Evaluation of Decolonization versus Universal Clearance to Eliminate methicillin-resistant *Staphylococcus aureus* (REDUCE MRSA) study's abstract, a study that evaluated the efficacy of universal daily chlorhexidine bathing in preventing infections.<sup>9</sup> The abstract stated that MRSA screening and isolation were "implemental" in group 1 and that there was a little reported difference between the intervention and baseline periods in MRSA clinical isolates (3.2 versus 3.4 per 1000 days).<sup>9</sup> This wording may lead one to conclude that screening and isolation were ineffective. However, group 1 was apparently designed for control of overall trends, with screening and isolation being performed in both the intervention and baseline periods. The

From the \*Health Watch USA, Sarasota, Kentucky; †Health Watch USA, WWOA School of Medicine, University of Medicine and Sciences, Annapolis, and Health Watch USA, Eastern Institute of Health, Duluth, Minnesota; ‡Correspondence: Kevin T. Kavanaugh, MD, MS, Health Watch USA, Sarasota, Kentucky, 701 Sun Hill, Sarasota, KY 40505 (kevink@healthwatchusa.com). E.T.K. has had partial conference attendance support (travel, accommodations, or registration) provided by the US Department of Health and Human Services, The National Quality Forum, The Learning Group and Consumer Union. He has served as a national member of the Centers for Medicare and Medicaid's Technical Expert Panel for Hospital Acquired Conditions. The opinions expressed herein are those of the author and do not represent the views of the U.S. Department of Health and Human Services. All rights reserved. This is an open access article distributed under the terms of the Creative Commons Attribution Non-Commercial No Derivatives License 4.0 (CC BY-NC-ND), which is available to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially.

(J Patient Saf • Volume 00, Number 00, Month 2016)

[www.journalpatientsafety.com](http://www.journalpatientsafety.com) | 1

## Healthcare Infections

### Integrity in Infectious Disease Research

"The medical literature is prone to overstating results, a condition not thoroughly recognized among policymakers. This article sets forth examples of potential problems with research integrity in the infectious disease literature. We describe articles that may be spun, categories lumped together in hopes of creating a significant effect (and sometimes an insignificant one), changes in metrics, and how trials may fail because of suboptimal interventions. When examined together, the examples show that the problems are widespread and illustrate the difficulty associated with interpreting medical research. The state of the current medical literature makes it of utmost importance that all sections of the manuscript are read, including associated letters to the editors and information on ClinicalTrials.gov before authors' recommendations are accepted." FREE ACCESS -- Journal of Patient Safety, Mar. 2016. [Download PDF](#)

[http://journals.lww.com/journalpatientsafety/Abstract/publishahead/A\\_Perspective\\_on\\_the\\_Principles\\_of\\_Integrity\\_in.99603.aspx](http://journals.lww.com/journalpatientsafety/Abstract/publishahead/A_Perspective_on_the_Principles_of_Integrity_in.99603.aspx)

## Written Comments Submitted by Health Watch USA to the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, March 30-31, 2016

"One of major approaches which institutions are utilizing to control multi-resistant organisms is universal daily Chlorhexidine Bathing. But there are concerns with the development of resistance. There are also concerns regarding chlorhexidine effectiveness. Much of the research has integrity problems. We would encourage the committee to reexamine the use of surveillance as exemplified by last meeting's VA system's presentation on achieving a dramatic reduction in MRSA infections in a very high risk population. Finally, I again would call upon the members of the CARB Committee to disclose their conflicts of interest." [View Comment](#)



difference. " ".the average brand-name prescribing rate was about 20 percent, compared to about 30 percent for those who received more than \$5,000."

<https://www.propublica.org/article/doctors-who-take-company-cash-tend-to-prescribe-more-brand-name-drugs>

## AHRQ Chartbook Shows 17 Percent Decline in Hospital-Acquired Conditions

Download

Chartbook: <http://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrdr/chartbooks/patientsafety/qdr2015-ptschartbook.pdf>

Download PowerPoint

Slides: <http://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrdr/chartbooks/patientsafety/qdr2015-ptschartbook.pptx>

## Cleveland Clinic Queried in U.S. Senate Review of Concurrent Surgeries

[http://www.cleveland.com/healthfit/index.ssf/2016/03/cleveland\\_clinic\\_queried\\_in\\_us.html](http://www.cleveland.com/healthfit/index.ssf/2016/03/cleveland_clinic_queried_in_us.html)

## Healthcare Finances

### Medical Bills are Way Too High - - Here is an Example

In this example the initial charge (asking price) was \$57,640. After the insurance company intervened the charge was reduced over 75% to \$11,284. If a patient does not have insurance, then he/she may have to pay the entire bill. Sometimes the hospital will reduce the amount owed by 25% if all is paid at once. However, this is still much higher than the insurance price. Submitted by Melissa Ann Seibold. [Click on the right hand picture to enlarge.](#)

CLAIM SUMMARY AT A GLANCE		Subscriber ID: 9025
Patient Name: M S		
Patient responsibility: (Amount you paid or owe to provider.)	\$2,821.00	Your claim was re
Amount we paid:	\$11,284.00	We paid MERC
Network savings: (Amount saved by using a network provider.)	\$43,540.00	
Amount billed by Provider:	\$57,645.00	

DETAIL Provider: Participating Provider - No

Service	Type of Service and	Amount	Amount
---------	---------------------	--------	--------

For more information see the Washington Post article on this subject:

Washington Post "50 hospitals charge uninsured more than 10 times cost of care, study finds"

[https://www.washingtonpost.com/national/health-science/why-some-hospitals-can-get-away-with-price-gouging-patients-study-finds/2015/06/08/b7f5118c-0aeb-11e5-9e39-0db921c47b93\\_story.html](https://www.washingtonpost.com/national/health-science/why-some-hospitals-can-get-away-with-price-gouging-patients-study-finds/2015/06/08/b7f5118c-0aeb-11e5-9e39-0db921c47b93_story.html)

## Medical Devices

### Johnson and Johnson Pays Record Verdict in Pinnacle Hip Replacement Court Action

Fox News: "Following a two-month trial, jurors found that the Pinnacle hips were defectively designed, and that the companies failed to warn the public about their risks." "

<http://www.foxnews.com/health/2016/03/17/johnson-johnson-hit-with-500-million-verdict-in-trial-over-hip-implants.html>

---

## Next Health Watch USA Meeting -- April 20th, 2016



Speaker: Deena Sowa McCollum, BSN, RN The Importance of High Quality Nursing Care

In December 2014, Deena's Dad died as a result of 3 delays in care and a misdiagnosis. After his death and almost 10 years in leadership positions, Deena returned to bedside nursing. "I needed to understand why there were so many missed opportunities in my Dad's care. Then educate patients and family members on the importance of their role in being safe." Deena obtained her Bachelor's of Science degree in Nursing from Stephen F. Austin State University in Nacogdoches, Texas. Deena was among Texas Healthcare Association's Top 10 Directors of Nurses for Long Term Care in 2008, 2009. More

recently, Deena has been a contributing writer for Nursecode.com and guest appearances on Surviving Healthcare Today and Advocacy Heals You radio talk shows.

---

To subscribe to Health Watch USA<sup>sm</sup> newsletter go to:

<http://www.hwusa-newsletter.org/lists/?p=subscribe&id=1>



Visit and "Like" HW USA's Facebook Page at:

<https://www.facebook.com/HealthWatchUsa>

